Feasibility Studies Report

Sterile Injectables Manufacturing Plant in Akuse – Quintex Pharma LTD

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Independent Consultancy Services for International Healthcare Projects

Commissioned by

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Executive Summary

Quintex Pharma Limited, a Ghanaian pharmaceutical company, commissioned a comprehensive feasibility study for the development of a biopharmaceutical injectable manufacturing plant in Akuse, Ghana. The facility aims to meet the domestic and regional demand for sterile injectable medicines, targeting both the Ghanaian and wider ECOWAS (West African) markets. This project aligns with Ghana's Ten-Point Industrial Transformation Plan and the Jobs and Economic Transformation (JET) Programme, supported by the UK Foreign and Commonwealth Development Office (FCDO).

The study was conducted by a consortium comprising AMPC International Health Consultants (technical and regulatory guidance), IQVIA (market study and pricing strategy), and PricewaterhouseCoopers (PwC) Ghana (financial modelling). Together, they evaluated the technical, regulatory, economic, financial, and environmental viability of the proposed project.

The key findings were the following:

- **Market Demand & Growth Potential:** Ghana imports around 70% of its pharmaceutical needs. The injectable segment remains underserved, with strong growth opportunities in local production. The project seeks to capitalize on this gap to enhance medicine security.
- **Regulatory & Policy Framework:** Ghana offers supportive policies for pharmaceutical manufacturing. Regulatory pathways for plant and product registration are well-defined, with regional harmonization mechanisms such as the ECOWAS Joint Assessment Procedure (JAP) and WHO Prequalification Programme facilitating broader market access.
- **Technical Viability:** The facility will adopt Good Manufacturing Practices (GMP) and meet international standards. The conceptual design, workflow layout, and equipment planning reflect global benchmarks, ensuring operational efficiency and product quality.
- **Economic Evaluation:** The plant will contribute significantly to local employment, technology transfer, and GDP growth. The economic assessment includes a review of demand drivers, healthcare expenditure trends, and trade policies in Ghana and 15 West African countries.
- **Financial Feasibility:** Financial modelling over a 10-year horizon indicates positive net present value (NPV), internal rate of return (IRR), and debt service coverage ratio (DSCR) under various capital structure scenarios. Sensitivity analyses suggest that optimized CAPEX and reduced O&M costs further enhance project viability.
- **Sustainability Considerations:** The plant will comply with environmental regulations, incorporate waste management systems, and integrate sustainable practices throughout operations.
- **Risk Assessment:** Key risks include supply chain disruptions, regulatory delays, and market competition. Mitigation strategies, including stakeholder engagement and diversified financing, are outlined.
- **Stakeholder Engagement:** The study proposes a stakeholder communication and engagement plan involving regulatory bodies, healthcare institutions, suppliers, and investors to ensure project success.

This comprehensive feasibility study equips Quintex Pharma and its prospective partners with a robust foundation for informed investment decisions and effective project execution. The analysis confirms the financial viability of the initiative, while also underscoring its strategic and economic rationale. Establishing local injectable manufacturing capabilities in Ghana not only aligns with regional development goals but also positions the country as a pivotal entry point into the broader West African pharmaceutical market.

Table of Contents

Feasibility Studies Report| 5

Table of Contents

10 | Feasibility Studies Report

Table of Contents

12 | Feasibility Studies Report

Table of Contents

14 | Feasibility Studies Report

Table of Contents

16 | Feasibility Studies Report

List of Tables

List of Figures

List of Boxes

List of Abbreviations

Abbreviations	Full name
AfCFTA	African Continental Free Trade Area
AfDB	African Development Bank
AMPC	AMPC International Health Consultants
API	Active Pharmaceutical Ingredient
CAPEX	Capital Expenditure
CDC	Centers for Disease Control
CHAG	Christian Health Association of Ghana
CPD	Continuing Professional Development
DFI	Development Finance Institution
DSCR	Debt Service Coverage Ratio
ECOWAS	Economic Community of West African States
EMA	European Medicines Agency
EML	Essential Medicines List
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drugs Authority (Ghana)
FCDO	Foreign and Commonwealth Development Office (UK)
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GRA	Ghana Revenue Authority
GSA	Ghana Standards Authority
GXP	Good (Practice) Guidelines (e.g., GMP, GCP)
HCW	Healthcare Worker
HSE	Health, Safety, and Environment
HRIS	Human Resources Information System
IFC	International Finance Corporation
IQVIA	IQVIA Inc. (market research firm)
IRR	Internal Rate of Return
IT	Information Technology
JAP	Joint Assessment Procedure (ECOWAS)
JET	Jobs and Economic Transformation
KPI	Key Performance Indicator
LMKMA	Lower Manya Krobo Municipal Assembly
MoH	Ministry of Health
MOTI	Ministry of Trade and Industry
NHIS	National Health Insurance Scheme
NPV	Net Present Value

26 | Feasibility Studies Report

O&M	Operations and Maintenance
OTC	Over-the-Counter (medicines)
PwC	PricewaterhouseCoopers
QA	Quality Assurance
QC	Quality Control
ROI	Return on Investment
STG	Standard Treatment Guidelines
UNDP	United Nations Development Programme
WHO	World Health Organization

1 Introduction

1.1 Context and Background

Quintex Pharma Ltd., a recently established private limited liability company based in Ghana, West Africa, is poised to become a leading manufacturer of both generic and branded medications. With a mission to address significant unmet medical needs locally, sub-regionally in West Africa, and internationally, Quintex Pharma plans to launch production operations in Ghana's Eastern Region, positioning itself as a key player in the regional pharmaceutical sector.

In pursuit of this vision, Quintex Pharma engaged three consultancy firms namely IQVIA, AMPC International Health Consultants (AMPC) and (PwC) to develop a comprehensive feasibility study for the construction and operation of a biopharmaceutical injectable plant in Ghana. This project, envisioned as a joint venture with an international partner, seeks to leverage global expertise and resources to establish a sterile injectables facility compliant with international standards, such as Good Manufacturing Practices (GMP) and advanced cleanroom classifications.

The feasibility study, conducted by a consortium of specialized consulting firms, brings together:

- IQVIA – Market study, pricing, and market strategy
- AMPC – Technical infrastructure development and regulatory guidance
- PwC – Financial modelling

This multidisciplinary approach ensures that all critical aspects of the project, from financial viability to regulatory compliance, are thoroughly assessed.

The initiative aligns with the Government of Ghana's broader vision for the pharmaceutical manufacturing sector. Through the Ministry of Trade and Industry's (MOTI) Ten-Point Industrial Transformation Plan, Ghana aims to become Africa's new pharmaceutical manufacturing hub. This strategy, supported by the Jobs and Economic Transformation (JET) Project in partnership with the UK Foreign and Commonwealth Development Office (FCDO), seeks to attract investments into strategic anchor industries, catalyse new growth poles, and significantly boost job creation.

By fostering strategic partnerships between Ghanaian and multinational companies, the Government intends to reduce the country's heavy reliance on imported pharmaceutical products—currently estimated at 70%—and enhance local production capabilities. The partnership between Quintex Pharma and the consultants represents a significant step towards realizing this national vision, strengthening Ghana's pharmaceutical landscape, and contributing to sustainable economic development.

28 | Feasibility Studies Report

Through this assignment, the consultancy firms committed to delivering a detailed, actionable feasibility study that will guide Quintex Pharma in making informed, strategic decisions for the successful development of the biopharmaceutical injectable plant.

1.2 Project Objectives

The primary objective of this feasibility study is to conduct a comprehensive assessment of the economic, technical, and operational viability of establishing a biopharmaceutical injectable manufacturing facility. This facility will be developed under a joint venture partnership with an internationally recognized pharmaceutical firm, leveraging their expertise, technology, and market access. The study will evaluate key factors such as capital investment requirements, production costs, regulatory compliance, supply chain logistics, and projected financial returns to determine the long-term sustainability of the project.

This study serves as a critical foundation for the project's approval and execution, ensuring that all stakeholders—including investors, regulatory bodies, and joint venture partners—have a clear understanding of the risks, opportunities, and strategic benefits involved. The analysis will cover:

- **Market Demand & Commercial Viability** – Assessment of global and regional demand for injectable biopharmaceuticals, competitive landscape, and pricing strategies.
- **Technical & Operational Feasibility** – Evaluation of manufacturing technologies, facility design, production capacity, and compliance with Good Manufacturing Practices (GMP).
- **Financial & Economic Analysis** – Detailed cost-benefit analysis, projected revenue streams, return on investment (ROI), and break-even timelines.
- **Regulatory & Compliance Requirements** – Examination of licensing, quality standards (e.g., FDA, EMA), and local regulatory approvals.
- **Risk Assessment & Mitigation Strategies** – Identification of potential challenges (e.g., supply chain disruptions, market fluctuations) and contingency plans.

1.3 Scope of Works

The consultancy conducted a detailed feasibility study for the establishment of a biopharmaceutical injectable plant in Ghana, with potential expansion considerations for the ECOWAS region. The study focused on a predetermined list of products while allowing for the inclusion of additional biopharmaceutical products in projections. Key components of the study included:

1. **Market Survey & Analysis** – A thorough assessment of market gaps, including addressable demand, competitive landscape, and commercial opportunities, culminating in draft and final reports.
2. **Market Entry Strategy** – Development of a framework and detailed strategy for entering the regional and international pharmaceutical market.
3. **Pricing Strategy** – Creation of a pricing model to ensure competitive and sustainable product positioning.
4. **Technical Feasibility** – Evaluation of plant design, regulatory compliance (e.g., sterile injectables manufacturing), and production capabilities, supported by inception and draft reports.
5. **Regulatory Access** – Analysis of legal and institutional requirements, including gap assessments and compliance reports to meet international standards (e.g., US FDA, EU GMP).
6. **Financial Modelling** – Development of revenue and cost projections, including 10-year financial forecasts (income statements, cash flows, and balance sheets).

1 Introduction

7. **Economic Evaluation** – Assessment of social and economic impacts, with draft and final reports highlighting the project's broader benefits.
8. **Risk Assessment & Mitigation** – Identification of potential risks (e.g., supply chain, regulatory hurdles) and strategies to address them.
9. **Sustainability & Environmental Considerations** – Framework and report on environmental compliance and sustainable practices.
10. **Stakeholder Engagement & Communication** – A structured plan to engage stakeholders and a marketing strategy to support project rollout.
11. **Management Capabilities** – Assessment of organizational structure, staff competencies, and legal requirements for operational readiness.

Disclaimer: This report is a compilation of different reports. For further details and understanding please refer to the individual report.

30 | Feasibility Studies Report

2 Market Survey and Analysis

2.1 Overview of the Ghana pharmaceutical market

Ghana's pharmaceutical market is one of the most attractive in Sub-Saharan Africa, driven by increasing healthcare needs, a growing population, and government initiatives to enhance healthcare access and promote local manufacturing.

Ghana's pharmaceutical market remains largely import-driven, with approximately 70% of pharmaceutical products sourced from international suppliers. The market is dominated by around 20 major importers. Generic medicines account for over 90% of total market share, while patented/originator drugs make up the remainder. Additionally, prescription medicines constitute an estimated 74.8% of market value, with over the counter (OTC) medicines representing 25.2%.

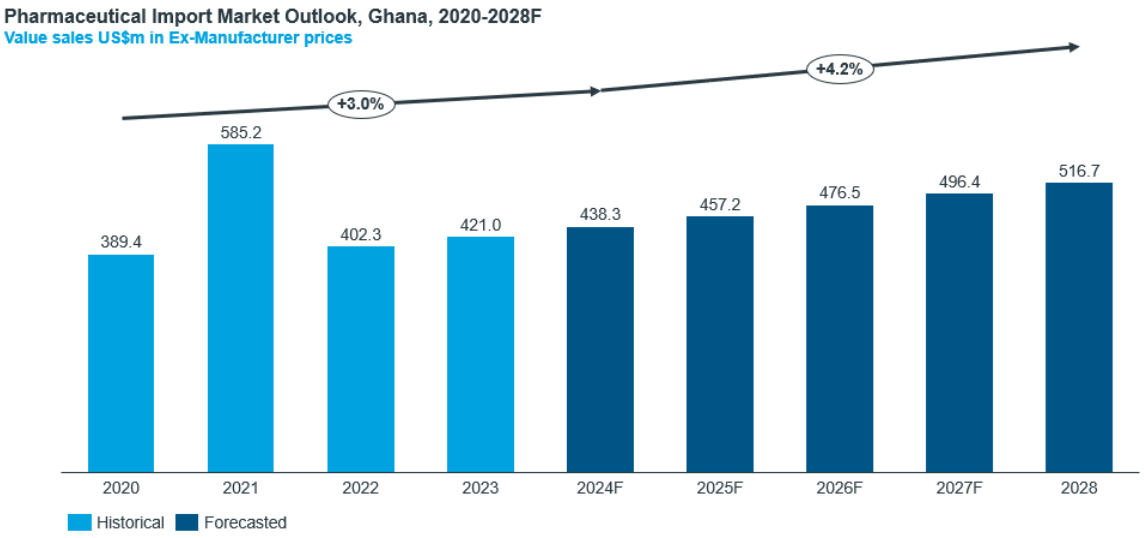
2.1.1 Ghana pharmaceutical import market estimation

Estimating the market size has been challenging due to the lack of published data. Using import data, IQVIA estimates the pharmaceutical Ghana import market at around $438 million in 2024 using good landing prices. This market has been growing with an estimated compound annual growth rate (CAGR) of approximately 3% since 2020.

IQVIA forecast the pharmaceutical import market to rise to $517 million in 2028 with an estimated compound annual growth rate (CAGR) of 4.2%. This healthy growth rate will be driven mainly by increased volume consumption within the generic medicines sub-sector as there are still risks that innovative pharmaceuticals will remain too expensive for majority of the population. The expansion of the universal healthcare coverage across Ghana, and Government investment into the country's healthcare sector will be the main factors leading to the pharmaceutical market growth although cost-containment measures aimed at limiting government expenditure will weigh on growth a little. In addition, domestic generic market is likely to contribute to the market growth in the long term with Governments efforts to boost the sector.

2 Market Survey and Analysis

Figure 2.1 Pharmaceutical import market outlook, Ghana, 2020-2028F



Source: primary research, IQVIA analysis

Based on discussions with local importers/distributors, a mark-up of 25-30% is applied on the landing price to cover their overhead costs, distribution cost and profit. By Applying this average mark-up of 27%, IQVIA estimate the import market at $557 million at distributor prices.

2.1.2 Ghana total pharmaceutical market estimation

Considering that import market account for around 70% of the total market, IQVIA estimate the overall pharmaceutical market in Ghana at $795 million in 2024.

IQVIA estimates seems to be aligned with the various reports that have attempted to size the Ghana pharmaceutical market. According to the 2022 Healthcare Sector Report by the Ghana Investment Promotion Center (GIPC), the market was valued at $590 million in 2018 but declined to $440 million in 2021, with a projected recovery to $490 million by 2024. Similarly, the 2024 Ghana Pharmaceuticals Report by Fitch BMI valued the market at $595 million as of 2023. Meanwhile, an internal estimate from the Pharmaceutical Importers and Wholesalers Association (PIWA) placed the market at $760 million in 2023. According to Fitch BMI, it is expected that sales would reach a compound annual growth rate (CAGR) of 10.0% by 2028. This growth in medicine sales is expected to be driven mainly by increased volume consumption within the generic medicines sub-sector.

2.1.3 Market governance and key stakeholders

The pharmaceutical sector consists of key stakeholders, including local manufacturers, multinational pharmaceutical companies, importers, regulatory bodies, research and development institutions, distributors, wholesalers, and retailers.

Governance of the pharmaceutical sector in Ghana is structured around policies, regulations, and institutions that oversee the development, manufacturing, importation, distribution, and use of

medicines. Key regulatory and oversight bodies include the Ministry of Health (MOH), the Food and Drugs Authority (FDA), the Pharmacy Council, the Ghana Standards Authority, and the Health Facilities Regulatory Agency (HeFRA). These institutions play a critical role in ensuring the quality, safety, and accessibility of pharmaceutical products in the country.

The pharmaceutical associations and professional bodies also play a crucial role in shaping the pharmaceutical industry by ensuring compliance, professional development, advocacy and industry growth. Key associations and bodies include Pharmaceutical Society of Ghana (PSGH), Ghana National Chamber of Pharmacy (GNCoP), Pharmaceutical Importers and Wholesalers Association (PIWA), Pharmaceutical Manufacturers Association of Ghana (PMAG), Small-scale Pharmaceutical Manufacturers Association of Ghana (SSPMAG), Association of Representatives of Ethical Industry (AREPI), Community Practice Pharmacists Association (CPPA), Government Hospital Pharmacists Association (GHOSPA), Pharmacists in Regulatory Affairs, Sales and Marketing Association (PRASMA), Lady Pharmacists Association of Ghana and Over the Counter Medicine Sellers (OTCMS)

2.2 Local manufacturing industry in Ghana

Ghana has an established local pharmaceutical manufacturing industry that plays a crucial role in the country's healthcare system and economy by producing essential medicines, creating jobs, improving access affordable healthcare as well as reducing dependence on imports.

The local manufacturers account for 30% of the total pharmaceutical market share. While local manufacturers produce both OTCs and prescription medications, it is estimated that OTCs account for about 70% of their total sales, while 30% accounts for prescription medications.

The local manufacturing companies are categorized into three (3); small-scale, medium and large-scale companies. Currently, Ghana has about 19 licensed medium to large local pharmaceutical manufacturers registered with FDA. There are also about 100-150 small scale manufacturing companies in the country.

2.2.1 Key players and products in the local manufacturing industry

Some of the key players in the local manufacturing industry include Ernest Chemist ltd, Kinapharma ltd, Danadams, M&G Pharmaceuticals, DAS Pharma, LaGray Chemical company, Entrance Pharmaceuticals, Pharmanova and Letap pharmaceuticals ltd. Most of the local pharmaceutical manufacturing companies especially the medium and large-scale companies are primarily located in the urban centers and industrial zones, with a significant concentration in the Greater Accra region of Ghana, particularly in and around the capital city Accra. Other regions such as Ashanti, Eastern and Western region also host pharmaceutical manufacturing facilities.

The key products manufactured by the local manufacturing companies include antimalarials, antibiotics, antifungals, analgesics and anti-inflammatory, antihypertensives, antacids, cough and cold preparations, hematinics, multivitamins and topical medications. Furthermore, the main product categories produced include syrups, suspensions, capsules, tablets, large volume infusion, small volume infusion, eyedrops, eardrops.

2 Market Survey and Analysis

2.2.2 Business operating models

Local pharmaceutical companies in Ghana operate under several distinct business models depending on their scale, market strategy and regulatory compliance. The various models include:

1. **Contract Manufacturing**: Where companies produce pharmaceutical products on behalf of other firms. This helps smaller manufacturers to optimize their production capacity without investing heavily in Research and Development (R&D) and marketing. Some examples of companies employing this model include Ernest Chemist and LaGray Chemical Company ltd.
2. **Full manufacturing**: where companies manufacture their own branded generic medicines. They usually handle the full cycle from production to distribution.
   Examples of such companies include Entrance pharmaceuticals, Ernest Chemist and Pharmanova.
3. **Importation and repackaging**: where companies import semi-finished products and repackage them for the local market. This model has a lower capital investment compared to full manufacturing. Some examples of companies include Kinapharma, Letap pharmaceuticals ltd.
4. **Public-Private partnerships**: where companies partner with government agencies or donors to produce essential medicines for public health programs. These partnerships help ensure availability and affordability of medicines.
5. **Specialty Manufacturing**: where companies focus their production on specific therapeutic areas like antimalarials, herbal medicine.
   Some examples include: Taabea Company Ltd, Phytotec Ltd

2.2.3 Funding mechanisms utilized by local pharmaceutical manufacturers.

Securing sufficient funding is crucial for the growth and sustainability of local pharmaceutical manufacturing in Ghana. Funding supports key areas such as infrastructure development, raw material procurement, research and development, regulatory compliance, and workforce training. Local pharmaceutical manufacturers in Ghana obtain capital from various sources, including:

- **Internal revenue and retained earnings**: most of the established pharmaceutical manufacturing companies reinvest their profits into business expansion and infrastructure improvements. It is worth noting that some of the local pharmaceutical manufacturing companies in Ghana started as importers and distributors and were able to leverage on that capital in addition to other sources to go into local manufacturing.
- **Bank loans and credit facilities**: companies secure loans from commercial banks and development finance institutions. However, these loans usually have high interest rates and require collateral.
- **Government support and funding programs**: the government provides various forms of support and funding to strengthen the local pharmaceutical manufacturing industry including funding programs and policy frameworks aimed at boosting domestic production.
- **Private equity and venture capital**: Some local pharmaceutical manufacturing companies have attracted investment from private equity firms and venture capitalists, particularly the manufacturing companies with innovative business models or export potential.
- **Public-private partnership (PPP)**: The government has entered into PPPs with local pharmaceutical manufacturing companies to produce essential medicines for public health

programs. These partnerships usually include funding from international development partners.

2.2.4 Policy provisions and incentives enabling local manufacturing.

The government has implemented some key policies to support the local pharmaceutical manufacturing industry, aiming at enhancing capacity, ensuring self-sufficiency and improving access to affordable medicines. These key policy provisions include:

- **Import restrictions**: Local manufacturers benefit from a regulation that bans the import of certain generic essential medicines that can be manufactured in sufficient quantities in Ghana. This policy restricts the importation of specific finished products, allowing only the import of raw materials for local manufacturing. The ban covers 142 products.
- **Tax exemptions**: The government has introduced tax exemptions to reduce production costs for local manufacturers. Notably raw materials used in local pharmaceutical manufacturing are exempt from Value Added Tax (VAT) as per LI 2255 (2017)
- **Framework contracting (FC)**: Framework contracting is in use for procurement by the Ministry of Health; this system allows the bulk procurement of selected medicines – via a competitive tendering process – at a controlled price from local manufacturers.
- **Public procurement preferences**: This policy is designed to promote local participation in public procurement. It is embedded within the Public Procurement Act, 2003 (Act 663) as amended with Act 914 (2016). Some key features of this policy include:
    - Preferential treatment for local companies especially SMEs in procurement opportunities
    - In competitive bidding, local suppliers and manufacturers may receive a margin of preference (up to 15% price advantage on goods and services) over foreign bidders – meaning that when evaluating bids, a local company can offer a price that is up to 15% higher than that of a foreign competitor and still be considered for the contract award

2.2.5 Factors impacting demand for locally manufactured products

The demand for locally manufactured pharmaceutical products in Ghana is influenced by several factors, including:

- **Price and affordability**: Many consumers opt for cheaper generic drugs especially for over-the-counter medications. Lower prices for local products drive higher demand especially among low and middle-income consumers. Locally manufactured products are more often affordable than imported alternatives due to lower production and transportation costs.
- **Quality and Efficacy**: Perception of quality tends to influence consumer choices especially when it comes to prescription products. Local products are more often perceived to have lower quality than their imported counterparts.
- **Government local content policies**: Government policies that promote the use of locally manufactured products, such as preferential procurement for public health institutions, can increase demand.
- **Consumer Preferences and Trust**: Established local brands with a strong reputation for quality and reliability usually enjoy relatively higher demand. Furthermore, some consumers may prefer locally made products due to a sense of national pride or trust in local industries.

2 Market Survey and Analysis

2.2.6 Key Trends in the pharmaceutical industry

The pharmaceutical sector in Ghana is evolving rapidly, driven by regulatory reforms, local manufacturing growth, and digital health innovations. Some key trends include:

2.2.6.1 Pharmaceutical Industry as a strategic sector

The government has recognized the sector as a key focus for industrial development and is consistently providing targeted support. Some key examples include:

- Development of a pharmaceutical manufacturing policy
  - The vision of this policy is to establish Ghana as the pharmaceutical manufacturing hub within West Africa. The specific objectives include:
  - Production of a sustainable supply of affordable, quality essential medicines and biological products (including vaccines)
  - Diversification of the pharmaceutical sector by promoting high end pharmaceutical products manufacturing and enhance the production of plant medicines, herbal preparations and nutraceuticals.
  - To promote investment in industries that manufacture critical inputs for pharmaceutical manufacturing such as Active Pharmaceutical Ingredients (API), raw material packaging materials etc.
  - Attract foreign investment into the pharmaceutical value chain.
- A specialized Pharma Unit has been established at the Ministry of Trade and Industry to address issues pertaining to the industry.
- A feasibility study is being facilitated regarding local production of Active Pharmaceutical Ingredients (API)

2.2.6.2 Regulatory strengthening and WHO compliance

Ghana has one of the most robust regulatory systems on the continent, with a continued commitment to strengthening the FDA to meet the evolving regulatory demands and innovations in the biopharmaceutical and healthcare sectors. Some of these efforts include:

- Developing and implementing regulatory documents to facilitate effective regulation of local vaccine manufacturing in the areas of Research (Clinical Trials) and Manufacturing (Regulatory Inspection (GMP), Lab testing (QC),
  Registration or Marketing Authorization (MA), Lot Release (LR) and Post Market Surveillance (MC and VL). The EU has provided €5 M towards to support the strengthening of the FDA.
- WHO maturity level 3 regulator (MoU with other African ML 3 regulators, signed recently to promote regulatory harmonization) – key benefit for local manufacturers seeking to export within the region. Efforts are underway to attain Maturity Level 4 (ML4), the highest WHO classification for regulatory authorities
- 30-60 test parameters accredited under one roof, making it the largest lab in Africa that has been pre-qualified by WHO.

2.2.6.3 Vaccine manufacturing

Ghana has made significant strides in vaccine manufacturing in response to the COVID-19 pandemic and the broader need for vaccine self-sufficiency.

- A 10-year road map with strategies for the development of vaccine manufacturing plants, strengthening of R&D and the FDA have been developed.
- A National Vaccine Institute has been set up with a mandate to coordinate and facilitate the local manufacturing ecosystem across the entire value chain.
- PharmaVax Ghana programme is being implemented by GIZ Ghana in collaboration with the pharma industry to strengthen the ecosystem for the local manufacturing of vaccines and medicines. There is a provision of €33 million, co-financed by the EU and Germany/BMZ.

2.2.6.4 African Continental Free Trade Area (AfCFTA) Opportunities

AfCFTA is a continental agreement aimed at creating a single market for goods and services across 54 African countries. It aims to boost intra-African trade by reducing tariffs, eliminating trade barriers, and harmonizing trade policies. One of the four priority sectors of AfCFTA is pharmaceuticals.

- Ghana was one of the first countries to ratify the agreement and hosts the AfCFTA Secretariat in Accra, giving it a strategic advantage.
- Additionally, AfCFTA launched its Guided Trade Initiative (GTI) in 2022, for which Ghana was part of the eight countries (Cameroon, Egypt, Ghana, Kenya, Mauritius, Rwanda, Tanzania and Tunisia) selected to provisionally start trading goods under AfCFTA on pilot basis to fine-tune the operational, institutional, legal and trade policy aspects of AfCFTA. Following the success of the pilot, AfCFTA announced in 2024 that an additional 24 countries will be covered by the GTI and start preferential trade under AfCFTA

2.2.6.5 Public-Private Partnerships (PPP)

Public-private partnerships (PPPs) are playing a significant role in advancing Ghana's pharmaceutical sector, enhancing healthcare delivery, and improving access to quality medicines. These collaborations between government entities and private organizations have addressed various challenges, from local drug production to combating counterfeit medications.

2.2.6.6 Pharma-park initiative

Ghana is actively pursuing the establishment of a pharmaceutical manufacturing hub, commonly referred to as the "Pharma Park," to bolster local drug production and reduce reliance on imports. This initiative aims to position Ghana as a leading pharmaceutical producer in Sub-Saharan Africa

2.2.6.7 National Electronic Pharmacy Platform (NEPP)

Launched in 2023, the National Electronic Pharmacy Platform (NEPP) implemented by the Pharmacy Council sets standards for e-pharmacy services. Currently, pharmacies can choose to enrol voluntarily, but from 2025, participation will become mandatory for both public and private sector facilities. Once fully implemented, NEPP is expected to enhance the availability of accurate data on medicine consumption.

2.3 Biopharmaceutical Injectable market

2.3.1 Market overview

Based on import data analysis, discussion with local importers/distributors and benchmark countries analysis, IQVIA estimate the injectable market in Ghana to account for about 15% to 20% of the total

2 Market Survey and Analysis

pharmaceutical market ($119 to $159 million in 2024). The market historical growth is estimated at around 10% CAGR and is expected to grow at around 10-15% CAGR in the next 5 years.
It is estimated that 70% of injectable pharmaceuticals is imported and 30% locally manufactured. Large volume parenteral accounts for 90% to 95% of the locally manufactured products while small volume parenteral represent the remaining 5% to 10%.
Major injectable categories imported in Ghana are antibiotics, anticoagulants, contraceptives, antiparasitics, oncologics and vaccines accounting all together for almost 70% of the injectable imported market.

Table 2.1 Top 10 therapy areas in injectable import market by value

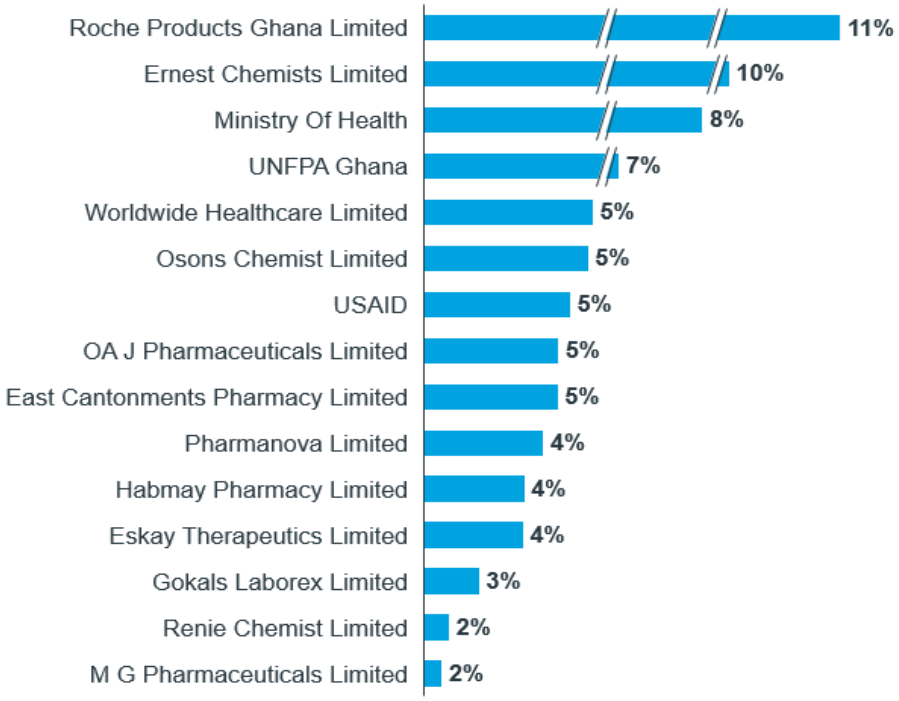
Therapy area	Value
Vaccines	55%
Systemic Antibacterials	11%
Contraceptives	7%
Anti-Parasitics Incl. Anti-Malarials	5%
Oncologics	4%
Anti-Coagulants	4%
Anti-Ulcerants	3%
Non-Narcotic Analgesics	3%
Insulins & Analogs	1%
Narcotic Analgesics	1%

Source: Primary research, IQVIA analysis

2.3.2 Key importers of biopharmaceutical injectables

Fifteen (15) importers account for 80% of injectable pharmaceutical imports in value in Ghana. Roche dominate the injectable import market mainly driven by its high-priced oncology portfolio. Ministry of Health is the 3rd importer. Private importers are dominated by Ernest Chemist followed by Worldwide Healthcare and Osons Chemist.

Figure 2.2 Top 15 importers of injectable pharmaceuticals in Ghana by value

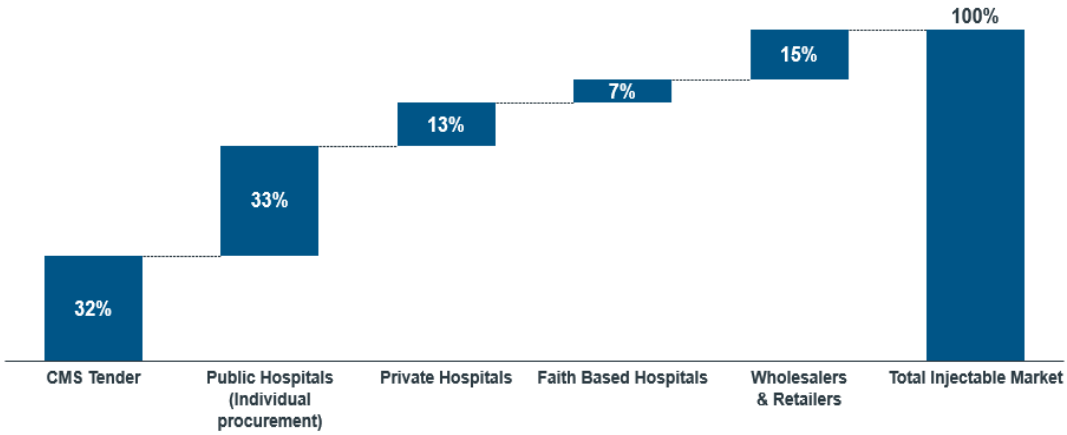


Source: Primary research, IQVIA analysis

2.3.3 Market split of biopharmaceutical injectables by sector

Based on discussion with local importers/distributors, the public sector contributes up to 65% of the injectable market sales while private sector account for the remaining 35% market share.

Figure 2.3 Biopharmaceutical injectable market split by sector



Source: Primary research, IQVIA analysis

2 Market Survey and Analysis

Free on board (FOB) prices of injectable pharmaceutical have been stable in the last 5 years however distributors prices have been increasing mainly due to the depreciation of the currency. Price increases have reached up to 20% for some molecules as per local importers/distributors.

2.4 Local injectable manufacturing in Ghana

Based on the list of licensed local pharmaceutical manufacturing facilities published by the Ghana FDA and discussion with local market experts, there are 4 players who manufacture injectables in Ghana: Atlantic Lifesciences Limited, Sanbao (GH) Pharmaceuticals Limited, Intravenous Infusions PLC and Prolife Infusions Limited. While Sanbao Pharmaceuticals Limited, Intravenous Infusions PLC and Prolife Infusions Limited have only large volume parenteral manufacturing capabilities, Atlantic Lifesciences Limited has both large and small volume parenteral manufacturing lines.

Current small volume parenteral molecules registered by Atlantic Lifesciences Limited in Ghana include:

- Morphine Sulfate
- Furosemide
- Pethidine Hydrochloride
- Adrenaline
- Gentamicin
- Hyoscine Butylbromide
- Fentanyl
- Oxytocin
- Tramadol

The manufacturing unit of the Korle-Bu Teaching Hospital manufactures quite small amounts of small volume and large volume injectables mostly for management of their patients.

- Potassium chloride injection
- Caffeine citrate injection
- Sodium bicarbonate injection
- 3% Hypertonic saline infusion
- 1/5 normal saline infusion

3 Regulatory Landscape

3.1 Introduction

There are multiple government agencies involved in the regulation of different aspects of the pharmaceutical sector. These agencies include the Ministry of Health, Food and Drugs Authority (FDA), Pharmacy Council, Ghana Standards Authority, Environmental Protection Authority and Ghana Revenue Authority. However, the primary body responsible for defining and implementing drug policies and monitoring the pharmaceutical sector performance parameters is the Food and Drugs Authority (FDA). The FDA is responsible for ensuring the safety, quality, and efficacy of medicines, medical devices, and other health products.

As medicines regulator, the FDA plays a critical role in ensuring the safety, quality, and efficacy of pharmaceuticals. It oversees the licensing of local manufacturers and warehouses, the registration of medicines for distribution, the issuance of import and export permits, the regulation of clinical trials, and the approval of marketing materials for both prescription and over-the-counter (OTC) medicines. Additionally, it enforces compliance with Good Manufacturing Practices (GMP) and conducts rigorous post-market surveillance and pharmacovigilance.

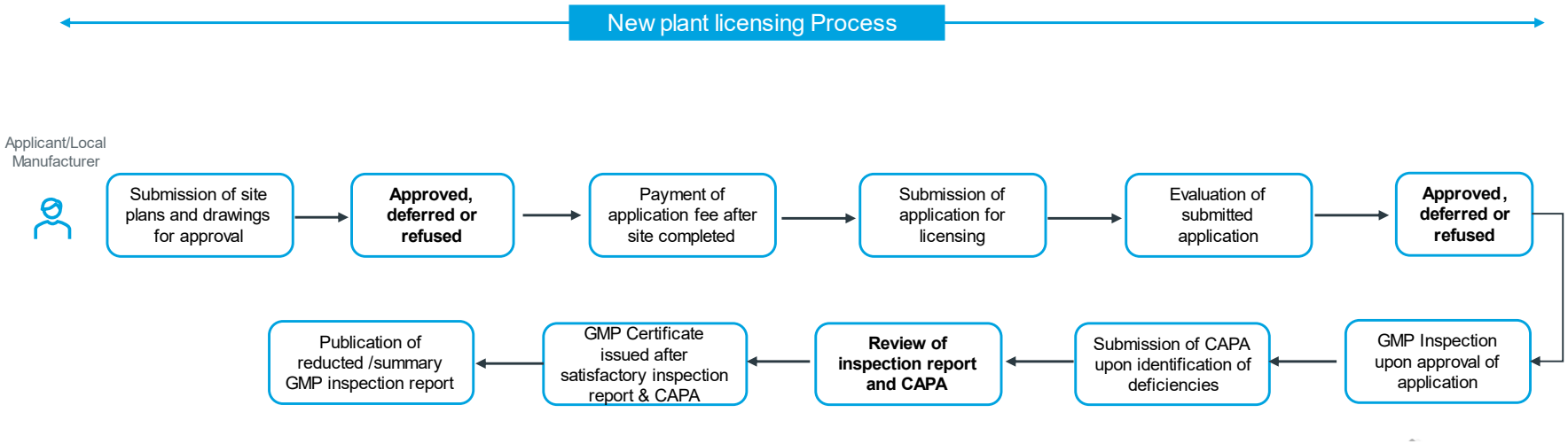
Ghana boasts one of the most robust and efficient regulatory systems in Africa. In 2020, the Ghana FDA became the second African National Regulatory Authority (NRA) to be recognized by the WHO as operating at Maturity Level (ML) 3 under the Global Benchmarking Tool—both for medicines and non-producing vaccines. This designation signifies a “stable, well-functioning, and integrated regulatory system.” Building on this achievement, the Ghana FDA is actively working towards obtaining ML3 status for vaccine manufacturing, a crucial step in supporting companies looking to produce vaccines in Ghana. Furthermore, efforts are underway to attain Maturity Level 4 (ML4), the highest WHO classification for regulatory authorities. The FDA benefits from support from the European Union and has a collaboration agreement with South Korea’s medicines regulatory agency, which has already achieved ML4 status.

3.2 Process for registering a new plant.

Registering a new pharmaceutical manufacturing plant in Ghana involves several steps and compliance with regulations set by key regulatory bodies, including the FDA and other relevant agencies. The diagram below illustrates the various processes per the FDA guidelines.

3 Regulatory Landscape

Figure 3.1 Licencing process for a new plant



Source: Ghana Food and Drugs Authority (FDA)

Box 3.1 Key insights

- Key bodies involved in the entire licensing process of a pharmaceutical manufacturing plant includes, Food and Drug Authority (FDA), Environmental Protection Agency (EPA), Ghana Revenue Authority, Registrar General's department.
- Site plans and drawings need to be submitted and approved by FDA before commencing the building of the manufacturing plant
- Key documents to be submitted as part of the initial application for a license includes; application letter, application form, proof of business name registered, credentials of pharmacist, site master file, EPA permit (where applicable), location plan and proof of payment
- Application fee for registering a new plant is Gh₵5,000.00,
- Entire process of licensing a pharmaceutical manufacturing plant takes at least between 1 and 2 years.

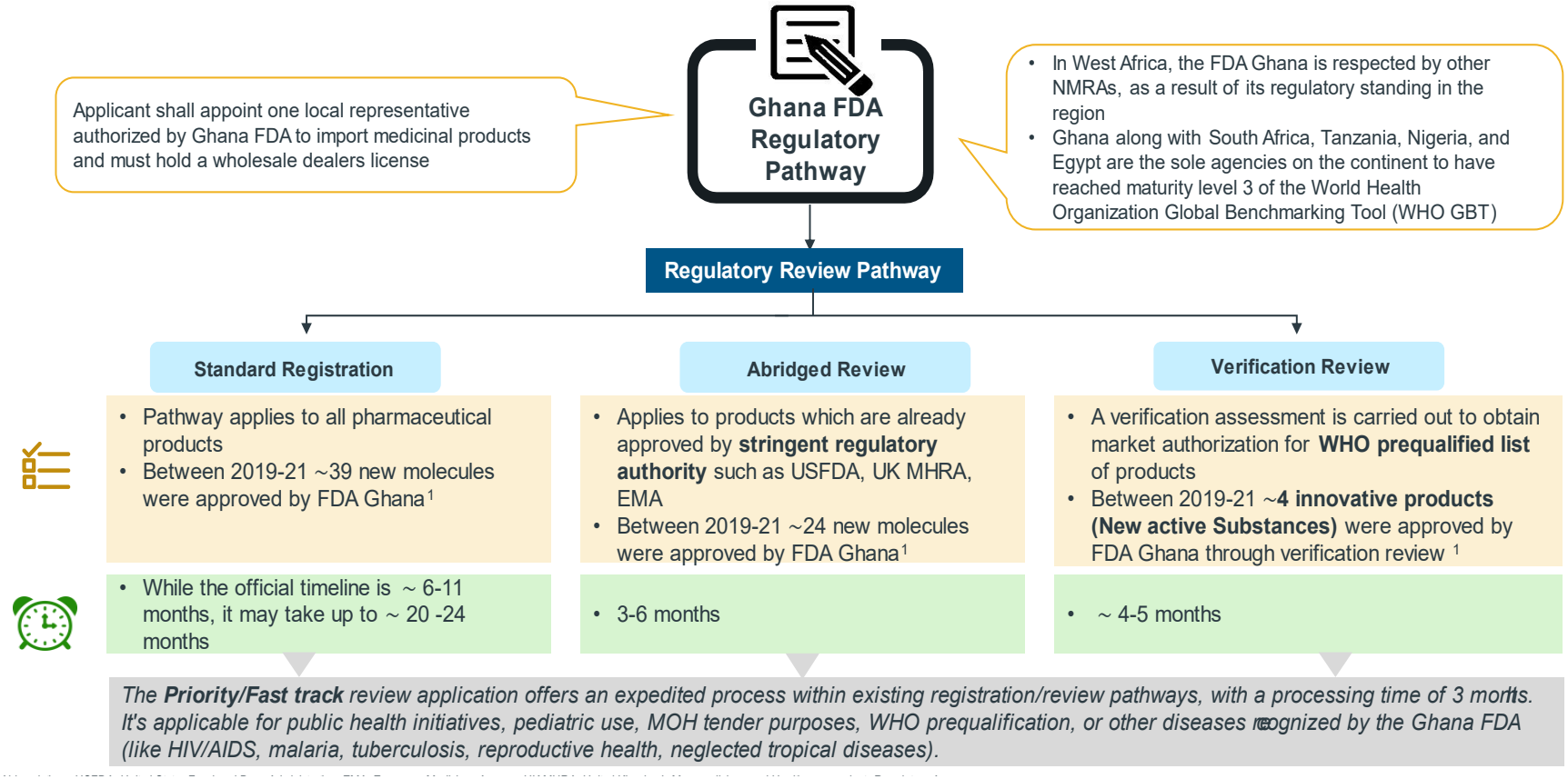
Source: IQVIA

42 | Feasibility Studies Report

3 Regulatory Landscape

3.3 Regulatory review pathway for registration of products

Figure 3.2 Regulatory review pathway



Source: Ghana Food and Drugs Authority (FDA)

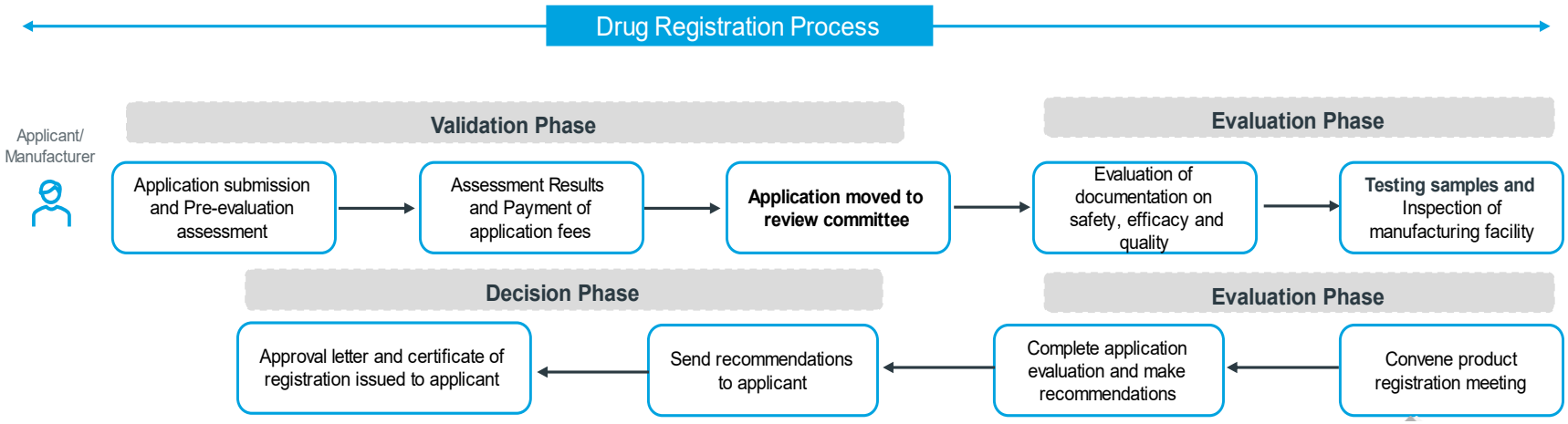
Feasibility Studies Report| 43

3 Regulatory Landscape

3.4 Process for registering pharmaceutical products

The registration of pharmaceutical products in Ghana is a critical regulatory process overseen by the FDA. It ensures that all medicines—whether locally manufactured or imported meet safety, quality, and efficacy standards before made available to the public.

Figure 3.3 Registration process for pharmaceutical products



Source: Ghana Food and Drugs Authority (FDA)

Box 3.2 Key insights

- FDA follows an agile registration process in the country; the products required for public health program receive priority in the approval process.
- Validation Phase: Applicant shall submit a common technical document (CTD), the application is served on first come first basis unless the product meets the classification criteria for expedited review process.

44 | Feasibility Studies Report

- Evaluation Phase: The site inspection is carried out by Inspection Committee while the scientific assessment is responsibility of technical staff (26 reviewers comprising 25 pharmacists and 1 scientist) and Drug Registration Committee who are assigned to review the quality, safety, and clinical documentation.
- Decision Phase: The approval is dependent on sample analysis and inspection of the manufacturing facility, which is conducted in parallel with the scientific review to provide faster approvals and market authorization. Once FDA provides the approval the certificate of registration is provided to applicant.

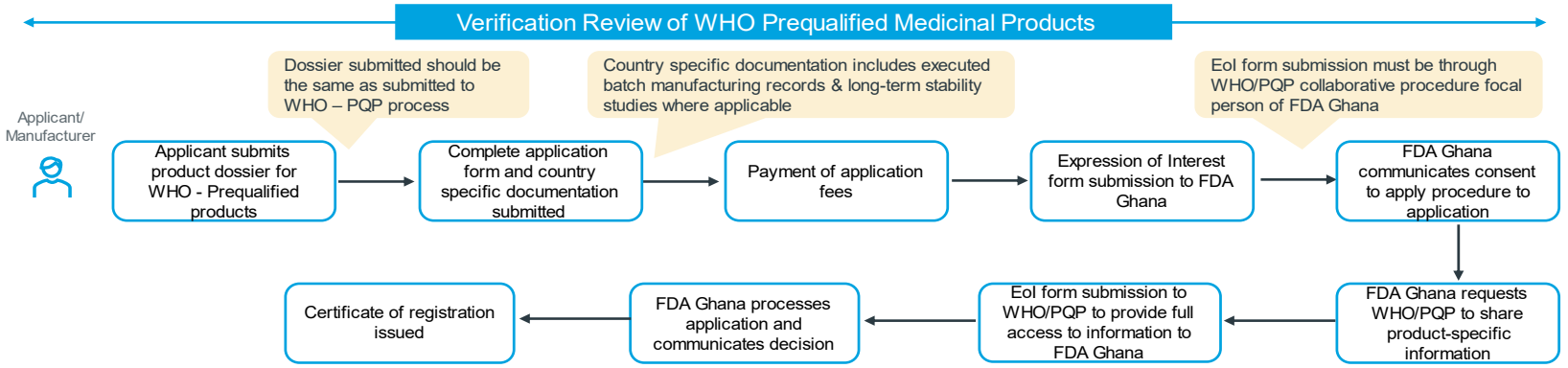
Source: IQVIA

3.5 WHO prequalification Medicines Programme

WHO prequalification of medicines is a service provided by WHO to assess the quality, safety and efficacy of medicinal products. It ensures that medicines supplied by procurement agencies meet global standards for quality, safety, and efficacy. It allows local manufacturers to compete for international tenders from UN agencies like UNICEF, UNFPA, as well as the Global Fund. Prequalification helps manufacturers access global markets and ensures their products meet WHO Good Manufacturing Practices (GMP).

3 Regulatory Landscape

Figure 3.4 Process for verification review of WHO prequalified medicinal products.



Examples of WHO prequalified products registered in Ghana (innovative and generics 2013 -2023)

Anti-Malarial Drugs	Amodiaquine, Artemether, Pyrimethamine, Sulfadoxine , Artesunate, Lumefantrine
Antibiotics	Isoniazid, Cycloserine, Levofloxacin, Sulfamethoxazole, Trimethoprim, Rifampicin, Ethambutol
Anti Retroviral Therapy	Nevirapine, Tenofovir, Efavirenz, Dolutegravir, Lamivudine, Emtricitabine, Zidovudine, Abacavir, Lopinavir, Ritonavir, Atazanavir
Oral Contraceptives	Levonorgestrel, Mifepristone
Injectable contraceptives	Medroxyprogesterone acetate

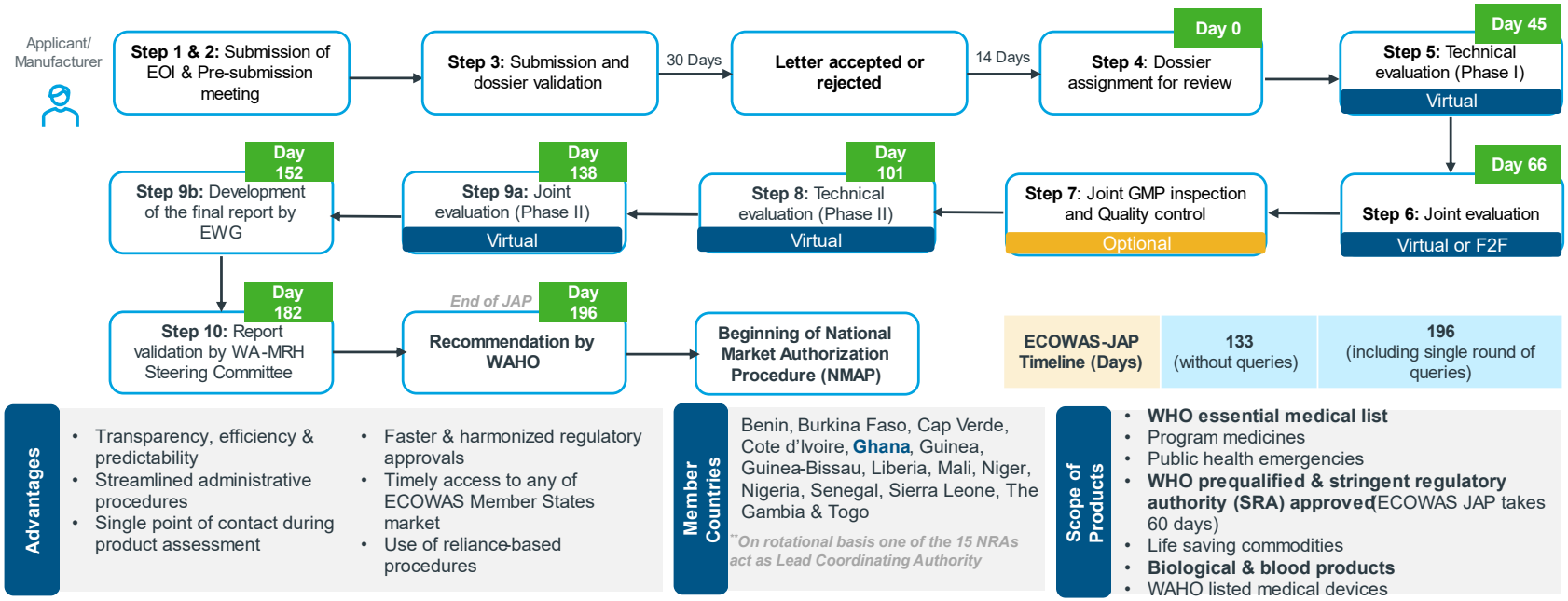
Source: Ghana Food and Drugs Authority (FDA), World Health Organization (WHO)

3.6 Ecowas joint assessment procedure (JAP)

ECOWAS JAP is a collaborative initiative among 15 National regulatory agencies (NRAs) in West Africa
Upon approval notification by the WAHO, applicant has 2 years to apply to 15 ECOWAS Member states that will grant MA within max 60 days.

46 | Feasibility Studies Report

Figure 3.5 ECOWAS joint assessment procedure.



Source: West African Health Organization

4 Pricing and market access landscape

4 Pricing and market access landscape

4.1 Pricing mechanism in the market

Ghana is a free pricing market; the country has potentially one of the highest prices in the region. The cost of medicine and their mark-ups across the distribution system are not regulated. On average, certain retail drug prices in Ghana are four to five times more than international reference prices, and they have been going up over the past decade, which is costly to the system. The total price build-up of medicine can be summarized as follows: manufacturer's selling price, freight, taxes, tariffs and markups across the distribution chain.

Profit margins are kept high. The typical profit margins for manufacturers are in the range of 10–40 percent; wholesalers add another 10–20 percent; and average retail margins are 20–50 percent. Data suggests that in Ghana, taxes and tariffs contribute between 30% to 40% of the end-user cost with markups representing anywhere between 50% and 200%. This means the manufacturing cost for medicines is less than 10% of the actual price to the patient. Taxes and tariffs are calculated on the dollar estimation of the imported pharmaceutical and converted into Cedis at an exchange rate that is reviewed weekly. Additionally, the importer mark-ups factor any inflationary pressures which may affect his business. This further increases the product price at entry.

Table 4.1 Price mark-ups across supply chain

Channel	Distributor	Wholesaler	Hospital/Retailer
Public	10-35%	10-15%	30-40%
Private			35-40%

Source: primary research, IQVIA

4.2 Government mechanism to control pricing

In 2018, the Government of Ghana made efforts to improve medicine pricing and access to essential medicines by implementing policies related to VAT exemptions for selected imported pharmaceutical products and a framework contracting (FC) which is a centralized procurement process for bulk purchase and negotiated reduced prices of high-demand essential medicines.

48 | Feasibility Studies Report

A National Medicine Price Committee was established in 2019, with the mandate to supervise the execution and monitoring of medicine prices in the country.

In 2022, the Ministry of Health (MOH) further launched a national pricing strategy for pharmaceuticals and other technologies, with the aim of optimizing medicine prices as well as ensuring a thriving private sector and sustainable National Health Insurance Scheme (NHIS). The strategy defines several mechanisms for lowering medicine prices in different market segment.

The strategy suggests a range of direct and indirect tools to influence prices in a market that has been largely unregulated, except for the indirect effect of NHIS reimbursement prices. It recommends external reference pricing to set ceiling prices for patented and innovative medicines, while leaving room for negotiated agreements below these ceilings. Another recommendation is to regulate mark-ups along the supply chain. The goal of this regulation is to lower prices in the middle of the market, where there is strong competition among various generic versions of the same molecules. The strategy also recommends reviewing and strengthening the public procurement process, at central and regional level, as delays in procurement and contract management create costs for suppliers that they need to consider when bidding. The only elements already implemented are framework contracts for generic medicines and VAT exemptions to support the local manufacturing industry.

4.3 Reimbursement

The reimbursement landscape in Ghana primarily revolves around the National Health Insurance Scheme, private health insurance and employer-based schemes.

4.3.1 National Health Insurance Scheme

The main public source of funding for medicines is the NHIS, which is financed through a National Health Insurance Levy of 2.5% on goods and services, collected under the Value Added Tax (VAT). NHIS also gets a share 2.5 percentage points of the Social Security and National Insurance Trust (SSNIT) contributions from the formal sector. Additional funding comes from subscription and renewal fees, premiums paid by informal sector subscribers and investment returns from National Health Insurance Fund (NHIF).

Inclusion in the NHIS medicine list is mandatory for drug reimbursement in Ghana. NHIS covers 100% of the reimbursement price with no annual cap. However, with medicines prices not being regulated, actual average price of medicines in the market are significantly higher than the reimbursement price and patient has to pay the difference out-of-pocket (OOP) causing affordability as well as availability issues in Ghana.

4.3.2 NHIS Medicines List

The NHIS Medicines List defines which medicines can be prescribed by which level of facilities and how much NHIS reimburses for each medicine. It is developed by a multidisciplinary committee comprising of medical doctors, pharmacists and a midwife which review the evidence for the management of the health problems commonly seen at health facilities in Ghana. Medicines to be included in the list are selected based on their efficacy, safety and cost-effectiveness assessment.

4 Pricing and market access landscape

This list is updated each year and latest one (2023) includes 548 formulations. Additionally, in almost all cases, medicines would have to be on the Essential Medicines List to be considered for reimbursements. Medicines are listed in their Generic or INN names and include the dosage form and strength covered. NHIS list defines the reimbursement price for each molecule as well as the level of prescribing (the lowest level of health care delivery at which a specific medicine can be prescribed).

4.3.3 Essential Medicines List (EML)

The EML is an official document that outlines the medicines considered essential for meeting the healthcare needs of the population in Ghana. It serves as a guideline for procurement, supply, and prescription of medicines within Ghana's healthcare system.

Selection of medicines are based on efficacy and safety evaluations obtained in controlled clinical trials and epidemiological studies, and on the performance in general use in a variety of medical settings. Furthermore, medicines considered are those indicated for the treatment of health problems in the Standard Treatment Guidelines.

Not all medicines on the EML are reimbursed under the NHIS, however, almost every single drug reimbursed is on the EML.

When several drugs are available for the same indication, only the drug and the pharmaceutical firm that provides the more convenient benefit/risk ratio is selected. Additionally, when two or more drugs are therapeutically equivalent, the selection is based on: level of evidence, most favourable pharmacokinetic properties, lowest cost, economically convenient manufacturing if available in the country, health workers experience, better stability at the available storage conditions.

The EML is to be updated every 2 years per policy, however the latest edition was published in 2017. There are current ongoing efforts to update the EML.

4.3.4 Standard Treatment Guidelines

Standard Treatment Guidelines (STGs) are systematically developed statements that assist healthcare providers in deciding on appropriate treatments for specific clinical problems. They usually reflect the consensus on the optimal treatment options within a health system and aim at beneficially influencing prescribing behaviour at all levels of care. STGs provide the tool for health care providers to give quality standardized care at affordable cost. They are applicable to both public and private facilities. Both STGs and EML are currently undergoing an update – the latest versions are from 2017.

50 | Feasibility Studies Report

4 Pricing and market access landscape

4.3.5 Considerations for inclusion in the STG, EML and NHIS list

Figure 4.1 Inclusion into STG, EML and NHIS List

Inclusion in EML & STG

Submit inclusion request to **National Medicines Selection Committee of Experts within the GNDP** (Ghana National Drugs Programme - MOH)

Request should include the below information:

- Name of medication with formulation, strength and indication
- Target population
- Disease prevalence (for STG inclusion)
- How should the medication be listed in the EML (class, healthcare facilities to be used in and type of prescribers)
- Reasons and justification for the recommended inclusion supported by solid evidence:
  - Comparative Efficacy, Effectiveness and Clinical Benefits
  - Comparative Cost and Cost -Effectiveness
  - Comparative Safety and Quality
  - Supply Chain and Storage Issues
  - Use (dosing) and Administration
- Organizations and or any policies in favour of the application e.g. A Health Policy, a WHO recommendation etc.
- Availability in Ghana (Manufacturers, country of manufacturing, suppliers, registration status in Ghana)

The submission will go through **reviews by the National Selection Committee of Experts** along with local health experts including **National Health insurance authority, The teaching hospitals, the patient groups, the NGOs, the civil society organizations, The Chamber of Pharmacy and local manufacturers**

Inclusion in NHIS list

Product included in EML does not guarantee the product enlistment in NHIS list

To be included in the NHIS, a request need to be submitted to the Ghana HTA comprises of a steering committee, a technical working group and secretariat with members appointed by the minister of health

Request should include the following:

- *Benefit of having the product reimbursed by NHIS from the payer perspective*
- *Budget impact analysis to assess the financial implication of covering the drug over 5 years period including projectedpatients number, adoption rates and potential cost saving for NHIS*
- *Assumptions used for direct and indirect cost calculations*
- *Calculation model to be shared with the HTA body*

The HTA will review the evidence provided from an economic perspective by assessing the cost effectiveness and the potential cost saving and will make their recommendation to the NHIS. This process can be lengthy

> To accelerate the process, you may consider collaborative effort with the government to address specific needs, such as Roche's sponsorship for Burkitt lymphoma and Herceptin. These projects often receive faster commitment from health insurance.
>
> **~ Market expert**

Source: primary research, IQVIA

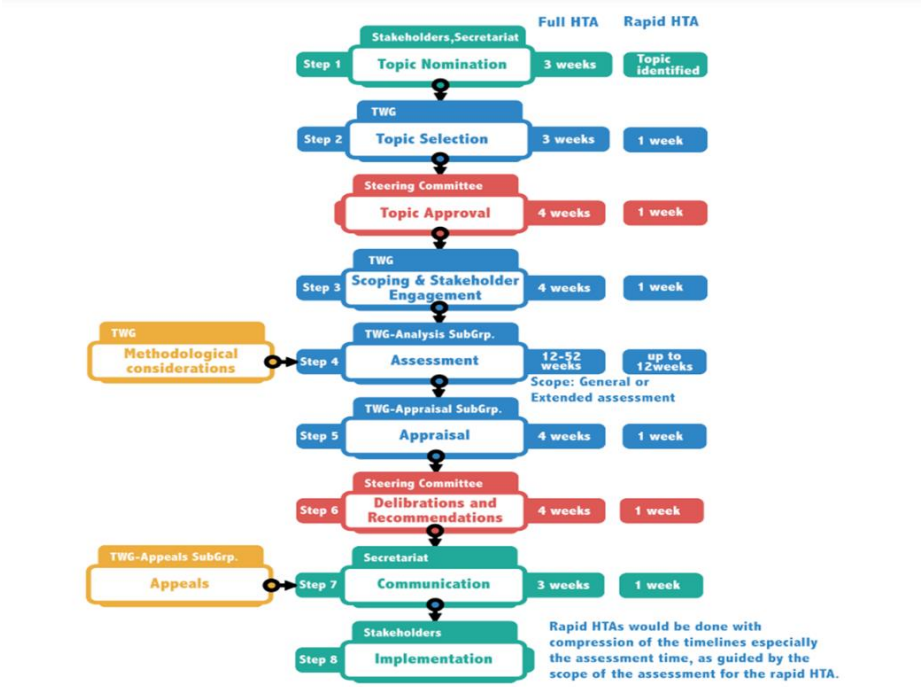
Feasibility Studies Report| 51

4 Pricing and market access landscape

4.3.6 Health Technology Assessment

Ghana is among the early adopters of Health Technology Assessment (HTA) in Sub-Saharan Africa. The HTA Steering Committee was established in 2019, with support from WHO and the Norwegian Institute of Public Health. HTA is currently being used as a technique to generate evidence, determine the country's priorities and define benefit packages and medicines on the reimbursed list - the HTA pathway allows for pharma to make submissions.

Figure 4.2 Ghana HTA process



Source: The first edition of Process Guidelines for Health Technology Assessment (HTA) in Ghana

Box 4.1 Key insights

The HTA process in Ghana is a step-wise mechanism, which details actions to be taken, the entities responsible for these actions and the estimated timelines

- Step 1 - Topic nomination: Stakeholders submit potential topics to the secretariat
- Step 2 - Topic selection and Topic approval: The Technical Working Group (TWG) assesses proposed topics based on topic selection criteria, thereafter the Steering Committee prioritizes and approves topics for assessment
- Step 3 - Scoping and stakeholder engagement: The TWG defines the objectives and research questions of the HTA based on the approved topic and conducts a stakeholder engagement
- Step 4 - Assessment: The TWG analysis sub-group assembles the evidence base on which the health technology is evaluated. TWG conducts analysis of the health technology
- Step 5 - Appraisal: The TWG appraisal sub-group critically evaluates the evidence collected analysed and presented

52 | Feasibility Studies Report

- Step 6 - Deliberation and recommendation: The Steering Committee makes critical judgements on the evidence presented and takes decisions
- Step 7 - Communication & Appeals The Secretariat communicates the decision, they also review any appeals from stakeholder

Step 8 - Implementation: Secretariat may conduct implementation research

Source: IQVIA

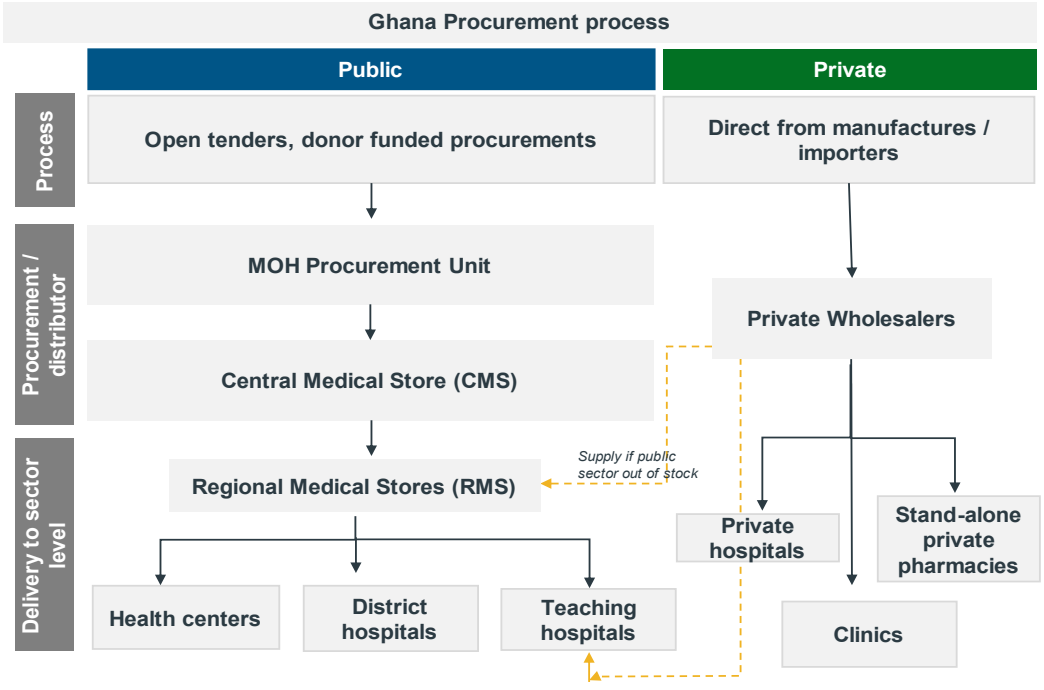
5 Procurement and distribution landscape

5 Procurement and distribution landscape

5.1 Procurement process in the pharmaceutical sector

The procurement process in Ghana varies between the public and private sectors, with the public sector being more regulated and structured. The procurement of medicines in the public sector is regulated by the Public Procurement Act, 2003 (Act 663), as amended by the Public Procurement (Amendment) Act, 2016 (Act 914). The Ministry of Health (MoH) oversees the centralized procurement system.

Figure 5.1 Procurement process in the public and private sectors.



Source: Secondary research, IQVIA analysis

54 | Feasibility Studies Report

Box 5.1 Key findings

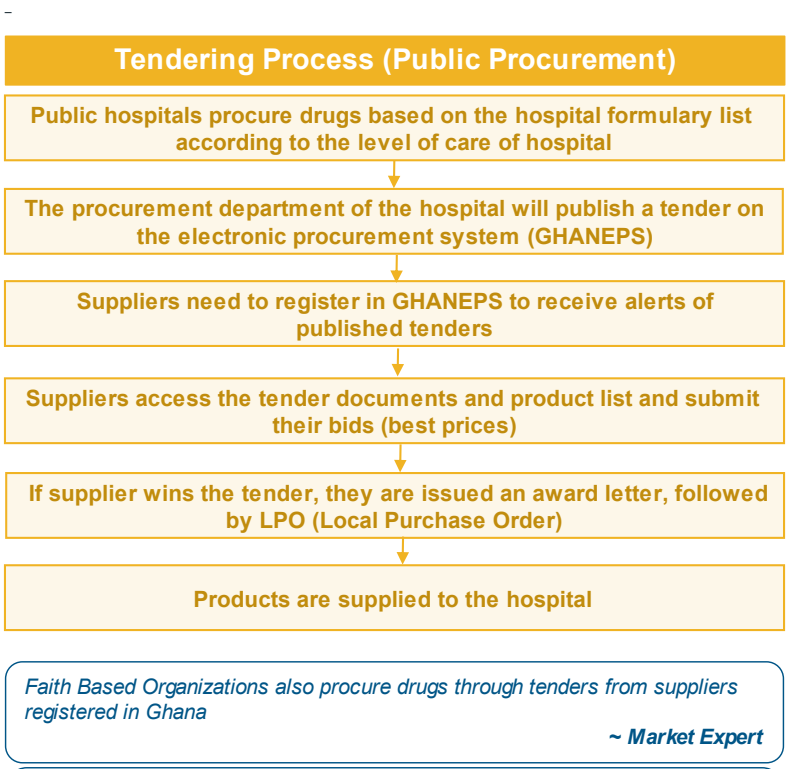
- MOH/Ghana Health Service introduced the Medicines Procurement Framework Agreement in 2017 aimed at ensuring the constant availability of essential medicines in all public health facilities across the country for quality healthcare delivery. However due to limited stakeholder engagement, it is not fully implemented
- MOH Procurement Unit procures drugs for Central Medical Store (CMS) (public sector)
- Regional Medical Stores (RMS) can purchase drugs from private sector only if the CMS is out of stock for requested product which seem to be quite common
- A platform called GHANEPS was developed to facilitate public procurement
- Private Wholesalers procure directly from manufacturers and distribute to registered pharmacies, private clinics & hospitals
- Christian Health Association of Ghana (CHAG) runs a central warehouse in Accra, the Catholic Distribution Centre (CDC) for the distribution of drugs

Source: IQVIA

5.1.1 Tender process for public procurement of pharmaceutical products

The medicine tender process follows a structured and competitive framework aimed at promoting transparency, fairness, and cost-effectiveness in pharmaceutical procurement. This process is typically managed by public health institutions, including the Ministry of Health (MoH), the Ghana Health Service (GHS), and other relevant government agencies. Below is an overview of Ghana's medicine tender process.

Figure 5.2 Public sector tendering process



Source: Primary research

5 Procurement and distribution landscape

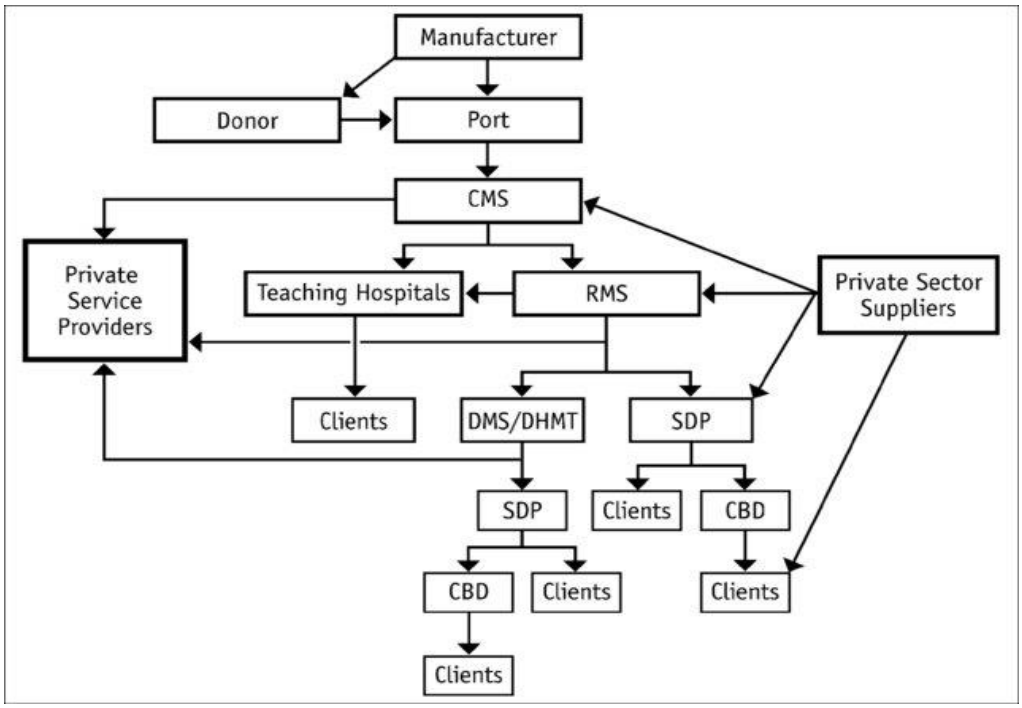
5.2 Distribution Landscape

5.2.1 Public sector distribution

The public sector supply chain in Ghana is managed through a collaborative effort between the Ministry of Health (MOH) Directorates of Pharmacy, Procurement, and Supply Chain, along with the Ghana Health Service (GHS).

The diagram below illustrates the health commodity delivery system in the public sector of Ghana.

Figure 5.3 Health commodity delivery system (public sector)



Source: Ghana: Estimating the Cost of Logistics in the Ministry of Health Supply System (Maggie Huff-Rousselle et al)

Box 5.2 Key Insights

- Commodities are purchased by Central Medical Stores (CMS) through both competitive international procurement and local private sector procurement. There are two central medical stores that supply the public sector; Temporal Central Medical stores (TCMS) and the Imperial Health Services (IHS). The disease programs (National Malaria Elimination Program (NMEP), National Tuberculosis Control Program (NTP), National AIDS control Program (NACP) commodities from development partners like The Global Fund are supplied through the IHS, while other medicines procured are supplied through the TCMS.
- The regional medical stores (RMS) and tertiary/teaching hospitals procure commodities from the central medical stores (CMS)
- In the case of stockouts or limited access to medicines at the tertiary facilities, regional medical stores or service delivery points (SDP), they are permitted to purchase products directly from the private sector

Source: IQVIA

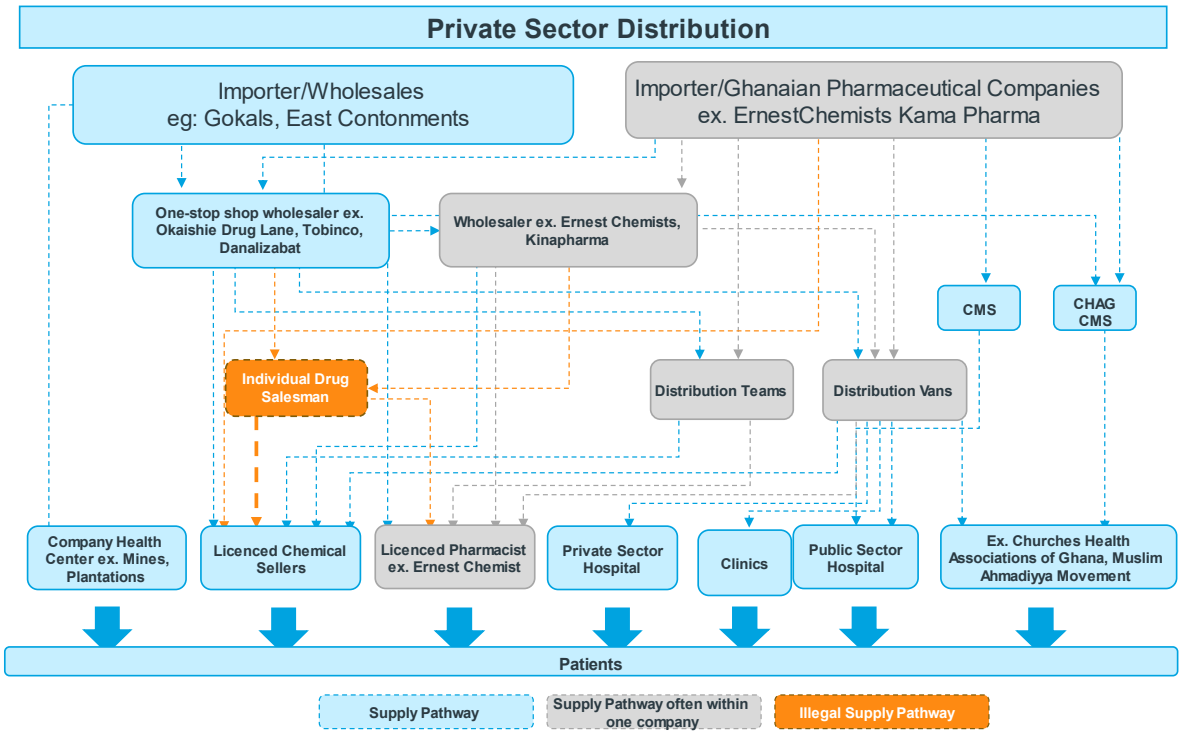
56 | Feasibility Studies Report

5 Procurement and distribution landscape

5.2.2 Private sector distribution

The supply and distribution network in Ghana is chaotic and fragmented, leading to little visibility and multiple mark-ups along the distribution chain. Below is an illustration of the private sector distribution.

Figure 5.4 Distribution of pharmaceutical products in the private sector



Source: World bank; Asokoinsight

Box 5.3 Key Insights

- 60 importers/wholesalers that import and sell to one-stop-shop wholesalers and about 166 national wholesalers.
- ~80% of the medicines supplied through public sector are procured from local private distributors/wholesalers.

Products also move from the private sector into the informal sector as small wholesalers use their import licenses to supply illegal drug sellers

Source: IQVIA

Feasibility Studies Report| 57

5 Procurement and distribution landscape

5.2.3 Key distributors in the pharmaceutical sector

While Ghana has multiple distributors, some of the leading players in the market are Ernest chemist, Osons chemist, Gokals Laborex and ECPL. The diagram below shows details of these leading distributors.

Figure 5.5 Some leading distributors in the pharmaceutical sector in Ghana.

Distributer	Founded	Org. size	Partners	Services offered
ERNEST CHEMISTS LIMITED	1986	501-1,000 employees	NOVARTIS, AstraZeneca, Roche, gsk, MSD, Johnson&Johnson	
OSON'S CHEMIST LTD	1990	100+ employees	Roche, Alcon, ipca A dose of life, gsk, NOVARTIS, Johnson&Johnson	
ecpl LTD East Cantonments Pharmacy Ltd	1992	200+ employees	AstraZeneca, sanofi, BAYER, Johnson&Johnson, MSD	
GOKALS-LABOREX LTD	1987	201-500 employees	NOVARTIS, sanofi, Roche, Pfizer, MSD, novo nordisk	

Contract manufacturing | Marketing and sales | Distribution | Regulatory

Source: Ghana FDA Importers List, Company Website

58 | Feasibility Studies Report

5.3 SWOT Analysis

The table below provides the SWOT analysis for the pharmaceutical sector in Ghana

Table 5.1 SWOT Analysis

Strengths	Weaknesses
• Established Local Manufacturing Industry: Ghana has about 19 licensed medium to large pharmaceutical manufacturers and about 100-150 small-scale companies, contributing 30% of the market • Government Support and Incentives: Policies such as import restrictions on essential medicines, tax exemptions on raw materials, and a 15% price preference for local manufacturers in public procurement • Regulatory Strength: Ghana FDA operates at WHO Maturity Level 3 and is working towards Level 4, making it one of the strongest regulatory agencies in Africa • Growing Market Demand: Driven by increasing healthcare needs, population growth, and a focus on universal health coverage • Potential for Regional Export: The African Continental Free Trade Area (AfCFTA) and ECOWAS trade agreements present export opportunities for local manufacturers. Ghana hosts the AfCFTA Secretariat in Accra, giving it a strategic advantage	• Limited R&D and Innovation: The sector lacks significant investment in research and development, restricting innovation and high-value pharmaceutical production • Financing Constraints: High interest rates on bank loans and limited access to venture capital hinder expansion and technological upgrades for manufacturer • Pricing Challenges: High medicine prices due to supply chain inefficiencies, high mark-ups (50%-200%), and the impact of currency depreciation • Dominance of foreign branded generics: Pharmaceutical market that is dominated by high-priced branded generics from India • Counterfeit Medicines and Parallel imports: The presence of illegal and substandard drugs in the market poses a undermines legitimate businesses
Opportunities	**Threats**
• Vaccine Manufacturing Initiatives: The establishment of the National Vaccine Institute and partnerships with GIZ and EU funding (€33M) for vaccine production • Growing Investment Interest: Opportunities for private equity and foreign direct investment (FDI) due to government incentives and Ghana's strategic position in West Africa • Increased Health Coverage & NHIS Expansion: Strengthening the National Health Insurance Scheme (NHIS) could drive demand for essential medicines • Possibility for WHO qualification and GMP certification • Technology transfer and licensing partnerships	• The economy of Ghana has been unstable owing to external shocks and pre-existing vulnerabilities; recovery prospects are modest – This could impact disposable income and consequently purchasing power for medicines • The recent suspension of US foreign aid could pose public procurement risk – potential delays in payment from government contracts Financial sustainability will continue to limit the success of Ghana's National Health Insurance Scheme, the main public payer for medicines

Source: Secondary research, IQVIA analysis

6 Pricing Strategy

6.1 Forecast of 20 molecules in Ghana

6.1.1 Objective

The objective of this section is to provide a comprehensive assessment of the molecules of interest for Quintex Pharma in order to shortlist the top 20 molecules based on their attractiveness in benchmark countries and prioritize top 10 molecules based on their potential in Ghana.

6.1.2 Forecast Methodology

IQVIA forecasting is driven by 3 key elements: estimation of total molecule volumes in standard units, volume share of Quintex Pharma product and product pricing.

1. **Estimation of total molecule volume in standard units:** The 2025 total molecule size in Ghana was estimated using SU/Capita data from benchmark countries. The total molecule volume has been projected using historical growth trend of each molecule in benchmark countries. The projection was then adjusted considering stabilization of volume in Ghana market in the longer term.
2. **Estimation of the achievable peak Market Share by molecule:** IQVIA developed Quintex Pharma peak share assumptions taking into account availability of local manufacturer in Ghana impacting the potential order of entry. To develop realistic assumptions of the peak share, IQVIA used benchmark countries analysis looking at local manufacturer uptake for target molecules in Egypt, Tunisia, and Algeria (analysis from benchmark countries showed that local manufacturers dominate the market with over 80% share) as well as local distributors willingness to source from local manufacturers when available, collected during discussion with local distributors in Ghana. Additionally, IQVIA applied an uptake curve to reach the estimated peak share. This uptake curve was derived from the analysis of the uptake of several new products in multiple countries.
3. **Estimation of Quintex Pharma price for each molecule:** Quintex Pharma price was estimated based on average molecule distributor price reduced by 25% as distributor markup factor based on PMR inputs. An additional discount of 5% to 10% was applied to provide Quintex Pharma products a price advantage versus imported molecules

The revenue that Quintex Pharma can achieve from each molecule was then calculated using price & volume assumptions.
IQVIA created a base case scenario as well as an optimistic scenario assuming lesser competition from local manufacturer and expected higher market share for Quintex Pharma.

60 | Feasibility Studies Report

6.1.3 Forecast Assumptions & Outputs by Molecule (First Top 10 Molecules)

6.1.3.1 Enoxaparin Forecast

Table 6.1 Forecast assumptions – Enoxaparin

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031 In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market
Uptake curve	Moderate 3 years	
SU Price	$4.42	10% price discount vs imported molecules to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	2	Benchmark countries (average)
Strength Split	2000IU: 9% 4000IU: 66% 6000IU: 18% 8000IU: 7% 10000IU: 0.04%	Benchmark countries (average)

Source: IQVIA

6 Pricing Strategy

Table 6.2 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Enoxaparin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.3	1.4	1.6	1.7	1.9	2.1	2.2	2.4
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.3	0.6	0.8	0.9	0.9	1.0	1.0	1.1	1.1	1.2	1.2	1.2
	Estimated Sales ($Mn)				0.9	2.3	3.4	3.9	4.5	5.1	5.7	6.3	6.8	7.4	7.8	8.1
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.3	0.6	0.8	0.9	1.0	1.1	1.3	1.4	1.5	1.6	1.8	1.9
	Estimated Sales ($Mn)				0.9	2.3	3.4	4.1	4.9	5.8	6.8	7.9	9.1	10.4	11.7	13.0

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

62 | Feasibility Studies Report

Table 6.3 Net Sales (Quintex Pharma) Forecasts - Enoxaparin

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.8	2.0	2.9	3.4	3.9	4.5	5.0	5.5	6.0	6.5	6.9	7.1
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.8	2.0	2.9	3.6	4.3	5.1	6.0	7.0	8.0	9.1	10.3	11.4

Source: IQVIA

Table 6.4 Quintex Pharma Volume Forecast by Strength – Enoxaparin

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	2000 IU (SU, Mn)				0.02	0.05	0.07	0.08	0.08	0.09	0.09	0.10	0.10	0.11	0.11	0.11
	4000 IU (SU, Mn)				0.2	0.4	0.5	0.6	0.6	0.7	0.7	0.7	0.8	0.8	0.8	0.8
	6000 IU (SU, Mn)				0.0	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
	8000 IU (SU, Mn)				0.02	0.04	0.05	0.06	0.06	0.07	0.07	0.08	0.08	0.08	0.08	0.08
	10000 IU (SU, Mn)				0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	2000 IU (SU, Mn)				0.02	0.05	0.07	0.08	0.09	0.10	0.11	0.13	0.14	0.15	0.16	0.17
	4000 IU (SU, Mn)				0.2	0.4	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.1	1.2	1.3
	6000 IU (SU, Mn)				0.0	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3
	8000 IU (SU, Mn)				0.02	0.04	0.05	0.06	0.07	0.08	0.09	0.10	0.10	0.11	0.12	0.13

6 Pricing Strategy

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	10000 IU (SU, Mn)				0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Source: IQVIA

6.1.3.2 Furosemide Forecast

Table 6.5 Forecast Assumptions – Furosemide

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 30% Optimistic case: 40%	In Base case, assumed 30% peak MS as Quintex Pharma will be the 2nd local player In Optimistic case, assumed 40% peak share with equal market split between the 2 local manufacturers
No. of local players (including Quintex Pharma)	2 (Base & Optimistic case)	Quintex Pharma will be the 2nd local player as Atlantic Lifesciences is already locally manufacturing Furosemide
Uptake curve	Moderate 5 years	Considering that Quintex Pharma will be the 2nd to market
SU Price	$ 0.04	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	10	Benchmark countries (average)
Strength Split	10mg: 0.3% 20mg: 88% 40mg: 10% 250mg: 1%	Benchmark countries (average)

Source: IQVIA

64 | Feasibility Studies Report

Table 6.6 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts – Furosemide

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		3.7	4.3	5.1	5.9	6.9	8.0	9.3	10.6	12.0	13.6	15.2	16.9	18.6	20.3	22.1
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.5	1.1	1.9	2.6	3.2	3.6	4.1	4.6	5.1	5.6	6.1	6.6
	Estimated Sales ($Mn)				0.0	0.0	0.1	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.4	0.4
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.6	1.4	2.5	3.5	4.2	4.8	5.4	6.1	6.7	7.4	8.1	8.8
	Estimated Sales ($Mn)				0.0	0.1	0.1	0.2	0.2	0.2	0.3	0.3	0.4	0.5	0.5	0.6

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

6 Pricing Strategy

Table 6.7 Net Sales (Quintex Pharma) Forecasts – Furosemide

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.01	0.04	0.07	0.10	0.13	0.16	0.19	0.22	0.26	0.30	0.35	0.39
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.02	0.05	0.09	0.14	0.18	0.21	0.25	0.30	0.35	0.40	0.46	0.52

Source: IQVIA

Table 6.8 Quintex Pharma Volume Forecast by Strength - Furosemide

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	10mg (SU, Mn)				0.00	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.02	0.02
	20mg (SU, Mn)				0.4	0.9	1.7	2.3	2.8	3.2	3.6	4.0	4.5	4.9	5.4	5.9
	40mg (SU, Mn)				0.0	0.1	0.2	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.7
	250mg (SU, Mn)				0.00	0.01	0.02	0.02	0.03	0.03	0.04	0.04	0.04	0.05	0.05	0.06
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	10mg (SU, Mn)				0.00	0.00	0.01	0.01	0.01	0.01	0.02	0.02	0.02	0.02	0.02	0.03
	20mg (SU, Mn)				0.6	1.3	2.2	3.1	3.7	4.3	4.8	5.4	6.0	6.6	7.2	7.8

66 | Feasibility Studies Report

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	40mg (SU, Mn)				0.1	0.1	0.3	0.4	0.4	0.5	0.6	0.6	0.7	0.8	0.8	0.9
	250mg (SU, Mn)				0.01	0.01	0.02	0.03	0.04	0.04	0.05	0.05	0.06	0.06	0.07	0.08

Source: IQVIA

6.1.3.3 Oxytocin Forecast

Table 6.9 Forecast Assumptions – Oxytocin

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 50% Optimistic case: 80%	In Base case, assumed 50% peak MS. Even though, Quintex Pharma will be the 2nd local player (currently, Atlantic Lifesciences is facing regulatory challenge and not able to supply the market – this is assumed to continue) In Optimistic case, assumed 80% peak share with Atlantic Lifesciences withdrawing their product from the market
No. of local players (including Quintex Pharma)	2 (Base & Optimistic case)	Quintex Pharma will be the 2nd local player as Atlantic Lifesciences is already locally manufacturing Oxytocin but facing regulatory challenges
Uptake curve	Moderate 5 years	Considering that Quintex Pharma will be the 2nd to market
SU Price	$ 0.56	Assumed a 25% markup factor and a 5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period

6 Pricing Strategy

Parameter	Assumption	Comments
SU factor	1	Benchmark countries (average)
Strength Split	5IU: 35% 10IU: 65%	Benchmark countries (average)

Source: IQVIA

Table 6.10 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts – Oxytocin

Key \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		6.1	6.5	6.9	7.3	7.7	8.2	8.6	9.1	9.6	10.0	10.4	10.9	11.3	11.6	12.0
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				1.0	2.0	3.2	4.1	4.6	4.8	5.0	5.2	5.4	5.6	5.8	6.0
	Estimated Sales ($Mn)				0.5	1.1	1.9	2.5	3.0	3.4	3.7	4.1	4.5	4.9	5.3	5.6
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				1.5	3.2	5.1	6.5	7.3	7.6	8.0	8.3	8.7	9.0	9.3	9.6
	Estimated Sales ($Mn)				0.8	1.7	3.0	4.0	4.8	5.4	6.0	6.6	7.2	7.8	8.4	9.0

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

68 | Feasibility Studies Report

Table 6.11 Net Sales (Quintex Pharma) Forecasts - Oxytocin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.4	0.9	1.6	2.2	2.6	3.0	3.3	3.6	3.9	4.3	4.6	5.0
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.7	1.5	2.6	3.6	4.2	4.7	5.2	5.8	6.3	6.9	7.4	7.9

Source: IQVIA

Table 6.12 Quintex Pharma Volume Forecast by Strength - Oxytocin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	5 IU (SU, Mn)				0.3	0.7	1.1	1.4	1.6	1.7	1.7	1.8	1.9	2.0	2.0	2.1
	10 IU (SU, Mn)				0.6	1.3	2.1	2.7	3.0	3.1	3.3	3.4	3.5	3.7	3.8	3.9
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	5 IU (SU, Mn)				0.5	1.1	1.8	2.3	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.3
	10 IU (SU, Mn)				1.0	2.1	3.4	4.3	4.7	5.0	5.2	5.4	5.7	5.9	6.1	6.2

Source: IQVIA

6 Pricing Strategy

6.1.3.4 Omeprazole Forecast

Table 6.13 Forecast Assumptions: Omeprazole Forecast Assumptions: Omeprazole

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031 In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first to market
Uptake curve	Moderate 3 years	
SU Price	$0.56	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	1	Benchmark countries (average)
Strength Split	40mg: 100%	Benchmark countries (average)

Source: IQVIA

Table 6.14 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Omeprazole

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.5	0.7	0.9	1.2	1.6	2.1	2.7	3.4	4.2	5.2	6.2	7.3	8.4	9.4	10.4
Potential Opportunity	Estimated Volume (SU Mn)				0.4	1.1	1.7	2.1	2.5	3.0	3.5	3.9	4.4	4.8	5.0	5.2

70 | Feasibility Studies Report

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Estimated Sales ($Mn)				0.20	0.6	1.0	1.3	1.6	2.1	2.6	3.1	3.6	4.1	4.5	4.9
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.4	1.1	1.7	2.1	2.7	3.4	4.2	5.0	5.8	6.7	7.5	8.3
	Estimated Sales ($Mn)				0.20	0.6	1.0	1.3	1.8	2.4	3.1	3.9	4.8	5.8	6.8	7.8

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

Table 6.15 Net Sales (Quintex Pharma) Forecasts - Omeprazole

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.2	0.5	0.8	1.1	1.5	1.8	2.3	2.7	3.2	3.6	4.0	4.3
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.2	0.5	0.8	1.2	1.6	2.1	2.7	3.4	4.2	5.1	6.0	6.9

Source: IQVIA

6 Pricing Strategy

6.1.3.5 Tranexamic Acid Forecast

Table 6.16 Forecast Assumptions – Tranexamic Acid

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031 In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be 1st to market
Uptake curve	Moderate 3 years	
SU Price	$ 0.48	10% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	5	Benchmark countries (average)
Strength Split	100mg: 2% 500mg: 98%	Benchmark countries (average)

Source: IQVIA

Table 6.17 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts – Tranexamic Acid

Time Period / Key Components	2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)	1.4	1.6	1.7	1.9	2.0	2.2	2.4	2.6	2.8	3.0	3.2	3.4	3.6	3.8	3.9

72 | Feasibility Studies Report

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.4	1.3	1.8	1.9	1.9	2.0	2.0	2.0	2.0	2.0	2.0	2.0
	Estimated Sales ($Mn)				0.1	0.6	0.8	0.9	1.0	1.1	1.2	1.3	1.3	1.4	1.4	1.5
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.6	1.4	1.8	1.9	2.1	2.2	2.4	2.6	2.7	2.9	3.0	3.1
	Estimated Sales ($Mn)				0.2	0.6	0.8	0.9	1.1	1.2	1.4	1.6	1.8	2.0	2.2	2.3

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.
Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

Table 6.18 Net Sales (Quintex Pharma) Forecasts – Tranexamic Acid

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.1	0.5	0.7	0.8	0.9	1.0	1.0	1.1	1.2	1.2	1.3	1.3

6 Pricing Strategy

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.2	0.5	0.7	0.8	1.0	1.1	1.2	1.4	1.6	1.7	1.9	2.1

Source: IQVIA

Table 6.19 Quintex Pharma Volume Forecast by Strength – Tranexamic Acid

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	100mg (SU, Mn)				0.01	0.02	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
	500mg (SU, Mn)				0.3	1.3	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.0	2.0	1.9
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	100mg (SU, Mn)				0.01	0.02	0.03	0.03	0.03	0.04	0.04	0.04	0.04	0.05	0.05	0.05
	500mg (SU, Mn)				0.6	1.4	1.8	1.9	2.1	2.2	2.4	2.5	2.7	2.8	3.0	3.1

Source: IQVIA

74 | Feasibility Studies Report

6.1.3.6 Diclofenac Forecast

Table 6.20 Forecast Assumptions: Diclofenac

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031 In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first to market
Uptake curve	Moderate 3 years	
SU Price	$ 0.04	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	10	Benchmark countries (average)
Strength Split	75mg: 100%	Benchmark countries (average)

Source: IQVIA

Table 6.21 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Diclofenac

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		1.7	1.8	2.0	2.2	2.5	2.7	2.9	3.2	3.4	3.7	3.9	4.2	4.5	4.7	4.9
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.4	1.6	2.1	2.2	2.3	2.4	2.5	2.5	2.5	2.5	2.5	2.5
	Estimated Sales ($Mn)				0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2

6 Pricing Strategy

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.7	1.7	2.1	2.3	2.5	2.7	3.0	3.2	3.4	3.6	3.8	3.9
	Estimated Sales ($Mn)				0.0	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.3	0.3

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.
Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

Table 6.22 Net Sales (Quintex Pharma) Forecasts - Diclofenac

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.01	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.02	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2

Source: IQVIA

76 | Feasibility Studies Report

6.1.3.7 Dexamethasone Forecast

Table 6.23 Forecast Assumptions: Dexamethasone

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031 In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first to market
Uptake curve	Moderate 3 years	
SU Price	$ 0.04	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	10	Benchmark countries (average)
Strength Split	4mg: 6.3% 5mg: 0.4% 8mg: 93.2%	Benchmark countries (average)

Source: IQVIA

Table 6.24 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Dexamethasone

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		6.0	6.3	6.7	7.1	7.5	8.0	8.4	8.9	9.3	9.8	10.2	10.6	11.0	11.3	11.7
Potential Opportunity for Quintex Pharma	Estimated Volume (SU Mn)				2.4	5.1	6.4	6.5	6.5	6.5	6.5	6.4	6.4	6.2	6.1	5.8

6 Pricing Strategy

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Estimated Sales ($Mn)				0.1	0.2	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.4
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				2.4	5.1	6.4	6.7	7.1	7.5	7.8	8.1	8.5	8.8	9.1	9.3
	Estimated Sales ($Mn)				0.1	0.2	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.6	0.6	0.7

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.
Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

Table 6.25 Net Sales (Quintex Pharma) Forecasts - Dexamethasone

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.1	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4

78 | Feasibility Studies Report

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.1	0.2	0.2	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.6	0.6

Source: IQVIA

Table 6.26 Quintex Pharma Volume Forecast by Strength - Dexamethasone

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	4mg (SU, Mn)				0.15	0.33	0.40	0.41	0.41	0.41	0.41	0.41	0.40	0.39	0.38	0.37
	5mg (SU, Mn)				0.01	0.02	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.02
	8mg (SU, Mn)				2.21	4.78	5.95	6.03	6.07	6.09	6.07	6.01	5.92	5.80	5.64	5.45
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	4mg (SU, Mn)				0.15	0.33	0.40	0.43	0.45	0.47	0.50	0.52	0.54	0.56	0.58	0.59
	5mg (SU, Mn)				0.01	0.02	0.03	0.03	0.03	0.03	0.03	0.03	0.04	0.04	0.04	0.04
	8mg (SU, Mn)				2.21	4.78	5.95	6.29	6.62	6.96	7.28	7.60	7.90	8.19	8.46	8.72

Source: IQVIA

6.1.3.8 Midazolam Forecast

Table 6.27 Forecast Assumptions: Midazolam

Parameter	Assumption	Comments
Product launch year	2028	

6 Pricing Strategy

Parameter	Assumption	Comments
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031 In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first to market
Uptake curve	Moderate 3 years	
SU Price	$ 1.19	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	10	Benchmark countries (average)
Strength Split	5mg: 91.2% 15mg: 6.3% 25mg: 0.2% 50mg: 2.3%	Benchmark countries (average)

Source: IQVIA

80 | Feasibility Studies Report

Table 6.28 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Midazolam

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.7	0.7	0.8	0.8	0.9	1.0	1.0	1.1
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.2	0.3	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Estimated Sales ($Mn)				0.1	0.3	0.5	0.6	0.6	0.7	0.8	0.8	0.9	0.9	1.0	1.0
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.2	0.3	0.4	0.5	0.5	0.6	0.6	0.7	0.7	0.8	0.8	0.9
	Estimated Sales ($Mn)				0.1	0.3	0.5	0.6	0.7	0.8	0.9	1.0	1.2	1.3	1.4	1.6

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

Table 6.29 Net Sales (Quintex Pharma) Forecasts - Midazolam

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.1	0.3	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.8	0.8	0.9

6 Pricing Strategy

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.1	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.3	1.4

Source: IQVIA

Table 6.30 Quintex Pharma Volume Forecast by Strength - Midazolam

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	5mg (SU, Mn)				0.14	0.30	0.39	0.43	0.47	0.52	0.56	0.61	0.65	0.70	0.74	0.78
	15mg (SU, Mn)				0.01	0.02	0.03	0.03	0.03	0.04	0.04	0.04	0.05	0.05	0.05	0.05
	25mg (SU, Mn)				0.0002	0.0005	0.0007	0.0007	0.0007	0.0008	0.0008	0.0008	0.0008	0.0008	0.0008	0.0008
	50mg (SU, Mn)				0.0035	0.0076	0.0099	0.0105	0.0110	0.0114	0.0118	0.0121	0.0123	0.0124	0.0124	0.0123
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	5mg (SU, Mn)				0.01	0.02	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
	15mg (SU, Mn)				0.01	0.02	0.03	0.03	0.03	0.04	0.04	0.04	0.05	0.05	0.05	0.05
	25mg (SU, Mn)				0.0002	0.0005	0.0007	0.0007	0.0008	0.0009	0.0010	0.0010	0.0011	0.0012	0.0013	0.0013
	50mg (SU, Mn)				0.0035	0.0076	0.0099	0.0109	0.0120	0.0131	0.0142	0.0153	0.0165	0.0176	0.0186	0.0197

Source: IQVIA

82 | Feasibility Studies Report

6.1.3.9 Phytomenadione Forecast

Table 6.31 Forecast Assumptions: Phytomenadione

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031 In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first to market
Uptake curve	Moderate 3 years	
SU Price	$0.15	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	10	Benchmark countries (average)
Strength Split	2mg: 82.8% 10mg: 0.1% 20mg: 17.1%	Benchmark countries (average)

Source: IQVIA

Table 6.32 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Phytomenadione

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.6	0.7	0.8	0.9	1.0	1.1	1.3	1.5	1.7	1.9	2.2	2.4	2.7	2.9	3.2
Potential Opportunity	Estimated Volume (SU Mn)				0.3	0.7	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.5	1.6	1.6

6 Pricing Strategy

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Estimated Sales ($Mn)				0.04	0.1	0.1	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.3	0.7	0.9	1.0	1.2	1.4	1.5	1.7	1.9	2.1	2.3	2.5
	Estimated Sales ($Mn)				0.04	0.1	0.1	0.2	0.2	0.3	0.3	0.4	0.4	0.5	0.6	0.6

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

Table 6.33 Net Sales (Quintex Pharma) Forecasts - Phytomenadione

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.03	0.1	0.1	0.1	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.4
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.03	0.1	0.1	0.2	0.2	0.2	0.3	0.3	0.4	0.4	0.5	0.6

Source: IQVIA

84 | Feasibility Studies Report

Table 6.34 Quintex Pharma Volume Forecast by Strength - Phytomenadione

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	2mg (SU, Mn)				0.05	0.11	0.15	0.17	0.19	0.21	0.22	0.24	0.25	0.26	0.27	0.27
	10mg (SU, Mn)				0.24	0.54	0.74	0.83	0.91	0.99	1.07	1.14	1.20	1.25	1.29	1.31
	20mg (SU, Mn)				0.000	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	2mg (SU, Mn)				0.05	0.11	0.15	0.18	0.21	0.23	0.27	0.30	0.33	0.37	0.40	0.43
	10mg (SU, Mn)				0.24	0.54	0.74	0.86	0.99	1.13	1.28	1.44	1.60	1.77	1.94	2.10
	20mg (SU, Mn)				0.000	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.002	0.002	0.002	0.002

Source: IQVIA

6.1.3.10 Propofol Forecast

Table 6.35 Forecast Assumptions: Propofol

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 30% Optimistic case: 40%	In Base case, assumed 30% peak MS as Quintex Pharma will be the 2nd local player In Optimistic case, assumed 40% peak share with equal market split between the 2 local manufacturers
No. of local players (including Quintex Pharma)	2 (Base & Optimistic case)	Quintex Pharma will be the second local player, as there is already a local manufacturer producing Propofol
Uptake curve	Moderate 5 years	Considering that Quintex Pharma will be the 2nd to market
SU Price	$1.26	5% price discount to remain competitive

6 Pricing Strategy

Parameter	Assumption	Comments
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	1	Benchmark countries (average)
Strength Split	10mg: 52.1% 200mg: 47.5% 500mg: 0.4%	Benchmark countries (average)

Source: IQVIA

Table 6.36 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Propofol

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.4	0.4
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09	0.10	0.11	0.12
	Estimated Sales ($Mn)				0.01	0.02	0.04	0.06	0.07	0.09	0.11	0.13	0.16	0.19	0.21	0.24
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.01	0.02	0.04	0.06	0.07	0.08	0.10	0.11	0.12	0.14	0.15	0.17
	Estimated Sales ($Mn)				0.01	0.03	0.05	0.08	0.10	0.12	0.15	0.18	0.21	0.25	0.29	0.33

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

86 | Feasibility Studies Report

Table 6.37 Net Sales (Quintex Pharma) Forecasts - Propofol

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.01	0.02	0.03	0.05	0.07	0.08	0.10	0.12	0.14	0.16	0.19	0.21
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.01	0.02	0.04	0.07	0.09	0.11	0.13	0.16	0.19	0.22	0.25	0.29

Source: IQVIA

Table 6.38 Quintex Pharma Volume Forecast by Strength - Propofol

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	10mg (SU, Mn)				0.0038	0.0089	0.0161	0.0229	0.0283	0.0327	0.0376	0.0427	0.0481	0.0537	0.0594	0.0650
	200mg (SU, Mn)				0.0035	0.0081	0.0147	0.0209	0.0258	0.0299	0.0343	0.0390	0.0439	0.0490	0.0542	0.0593
	500mg (SU, Mn)				0.0000	0.0001	0.0001	0.0002	0.0002	0.0002	0.0003	0.0003	0.0003	0.0004	0.0004	0.0005
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	10mg (SU, Mn)				0.0051	0.0118	0.0215	0.0305	0.0377	0.0436	0.0501	0.0570	0.0642	0.0716	0.0792	0.0867
	200mg (SU, Mn)				0.0046	0.0108	0.0196	0.0278	0.0344	0.0398	0.0457	0.0520	0.0586	0.0654	0.0723	0.0791
	500mg (SU, Mn)				0.0000	0.0001	0.0002	0.0002	0.0003	0.0003	0.0004	0.0004	0.0004	0.0005	0.0006	0.0006

Source: IQVIA

6 Pricing Strategy

6.1.4 Forecast Revenues Top 10 Molecules

Table 6.39 Gross Revenue Forecast: Base Case for Top 10 Molecules ($, Mn)

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 10 Molecules Revenue for Quintex Pharma (Base case, $Mn)	Enoxaparin				0.93	2.33	3.35	3.90	4.48	5.08	5.68	6.28	6.84	7.35	7.79	8.12
	Omeprazole				0.20	0.57	0.95	1.27	1.65	2.09	2.58	3.10	3.62	4.12	4.55	4.88
	Furosemide				0.02	0.04	0.08	0.12	0.15	0.18	0.22	0.25	0.30	0.34	0.39	0.44
	Oxytocin				0.48	1.06	1.85	2.52	3.00	3.35	3.72	4.10	4.49	4.87	5.26	5.63
	Tranexamic Acid				0.14	0.56	0.81	0.91	1.00	1.09	1.18	1.26	1.33	1.39	1.44	1.46
	Diclofenac				0.02	0.06	0.09	0.11	0.12	0.13	0.14	0.15	0.16	0.17	0.17	0.18
	Dexamethasone				0.09	0.21	0.28	0.30	0.33	0.35	0.37	0.39	0.40	0.41	0.42	0.42
	Midazolam				0.15	0.35	0.49	0.55	0.62	0.68	0.75	0.81	0.87	0.92	0.96	0.98
	Phytomenadione				0.04	0.09	0.14	0.17	0.20	0.23	0.26	0.29	0.32	0.35	0.38	0.40
	Propofol				0.01	0.02	0.04	0.06	0.07	0.09	0.11	0.13	0.16	0.19	0.21	0.24
	Total				2.1	5.3	8.1	9.9	11.6	13.3	15.0	16.8	18.5	20.1	21.6	22.8

Source: IQVIA

Table 6.40 Net Revenue Forecast: Base Case for Top 10 Molecules ($, Mn)

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 10 Molecules Revenue	Enoxaparin				0.82	2.05	2.95	3.43	3.94	4.47	5.00	5.53	6.02	6.47	6.85	7.15
	Omeprazole				0.17	0.50	0.84	1.12	1.45	1.84	2.27	2.72	3.19	3.62	4.00	4.29

88 | Feasibility Studies Report

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Furosemide				0.01	0.04	0.07	0.10	0.13	0.16	0.19	0.22	0.26	0.30	0.35	0.39
	Oxytocin				0.42	0.94	1.63	2.22	2.64	2.95	3.28	3.61	3.95	4.29	4.63	4.96
	Tranexamic Acid				0.12	0.49	0.72	0.80	0.88	0.96	1.04	1.11	1.17	1.22	1.26	1.29
	Diclofenac				0.01	0.06	0.08	0.09	0.10	0.11	0.12	0.13	0.14	0.15	0.15	0.16
	Dexamethasone				0.08	0.18	0.25	0.27	0.29	0.31	0.32	0.34	0.35	0.36	0.37	0.37
	Midazolam				0.13	0.30	0.43	0.48	0.54	0.60	0.66	0.71	0.76	0.81	0.84	0.87
	Phytomenadione				0.03	0.08	0.12	0.15	0.17	0.20	0.23	0.26	0.28	0.31	0.33	0.35
	Propofol				0.01	0.02	0.03	0.05	0.07	0.08	0.10	0.12	0.14	0.16	0.19	0.21
	Total				1.8	4.7	7.1	8.7	10.2	11.7	13.2	14.8	16.3	17.7	19.0	20.0

Source: IQVIA

Table 6.41 Gross Revenue Forecast: Optimistic Case for Top 10 Molecules ($, Mn

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 10 Molecules Revenue for Quintex Pharma (Optimistic case, $Mn)	Enoxaparin				0.93	2.33	3.35	4.07	4.88	5.80	6.82	7.93	9.12	10.3	11.6	13.0
	Omeprazole				0.20	0.57	0.95	1.33	1.80	2.39	3.09	3.91	4.83	5.81	6.82	7.80
	Furosemide				0.02	0.05	0.10	0.15	0.20	0.24	0.29	0.34	0.40	0.46	0.52	0.59
	Oxytocin				0.76	1.70	2.97	4.04	4.80	5.37	5.96	6.56	7.18	7.80	8.41	9.01
	Tranexamic Acid				0.25	0.59	0.81	0.95	1.09	1.25	1.42	1.59	1.78	1.96	2.15	2.34
	Diclofenac				0.03	0.07	0.09	0.11	0.13	0.15	0.17	0.19	0.21	0.24	0.26	0.28
	Dexamethasone				0.09	0.21	0.28	0.32	0.36	0.40	0.44	0.49	0.53	0.58	0.63	0.67

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Midazolam				0.15	0.35	0.49	0.57	0.67	0.78	0.90	1.03	1.16	1.30	1.44	1.58
	Phytomenadione				0.04	0.09	0.14	0.17	0.21	0.26	0.31	0.37	0.43	0.50	0.57	0.64
	Propofol				0.01	0.03	0.05	0.08	0.10	0.12	0.15	0.18	0.21	0.25	0.29	0.33
	Total				2.5	6.0	9.2	11.8	14.2	16.8	19.5	22.6	25.8	29.3	32.8	36.2

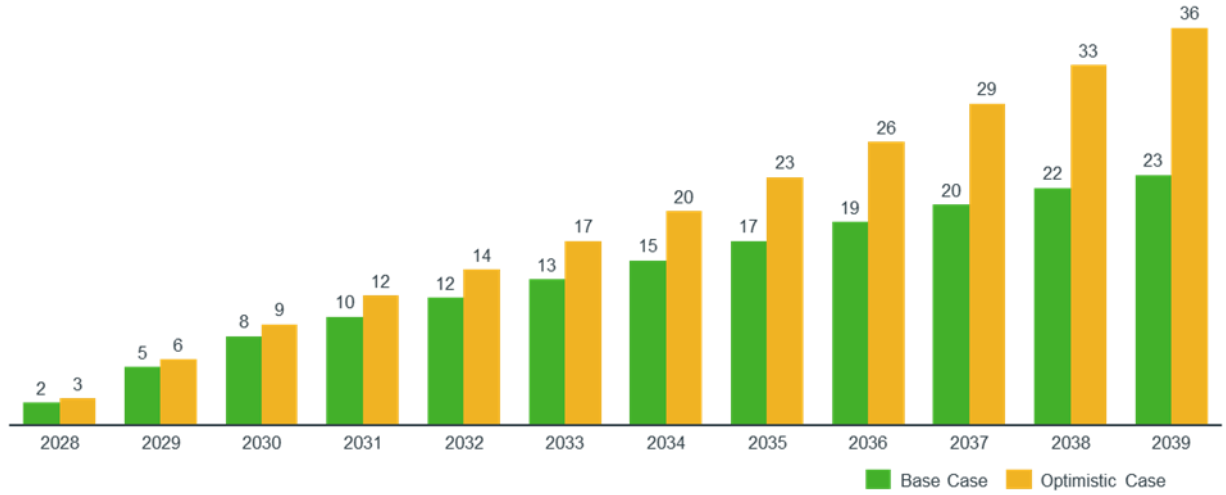
Source: IQVIA

Table 6.42 Net Revenue Forecast: Optimistic Case for Top 10 Molecules ($, Mn)

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 10 Molecules Revenue for Quintex Pharma (Optimistic case, $Mn)	Enoxaparin				0.82	2.05	2.95	3.58	4.30	5.11	6.00	6.98	8.03	9.13	10.2	11.4
	Omeprazole				0.17	0.50	0.84	1.17	1.58	2.10	2.72	3.44	4.25	5.11	6.00	6.87
	Furosemide				0.02	0.05	0.09	0.14	0.18	0.21	0.25	0.30	0.35	0.40	0.46	0.52
	Oxytocin				0.67	1.50	2.61	3.55	4.23	4.72	5.24	5.77	6.32	6.86	7.40	7.93
	Tranexamic Acid				0.22	0.52	0.72	0.83	0.96	1.10	1.25	1.40	1.56	1.73	1.90	2.06
	Diclofenac				0.02	0.06	0.08	0.10	0.11	0.13	0.15	0.17	0.19	0.21	0.23	0.25
	Dexamethasone				0.08	0.18	0.25	0.28	0.31	0.35	0.39	0.43	0.47	0.51	0.55	0.59
	Midazolam				0.13	0.30	0.43	0.51	0.59	0.69	0.79	0.90	1.02	1.14	1.26	1.39
	Phytomenadione				0.03	0.08	0.12	0.15	0.19	0.23	0.27	0.32	0.38	0.44	0.50	0.57
	Propofol				0.01	0.02	0.04	0.07	0.09	0.11	0.13	0.16	0.19	0.22	0.25	0.29
	Total				2.2	5.3	8.1	10.4	12.5	14.7	17.2	19.9	22.7	25.8	28.8	31.9

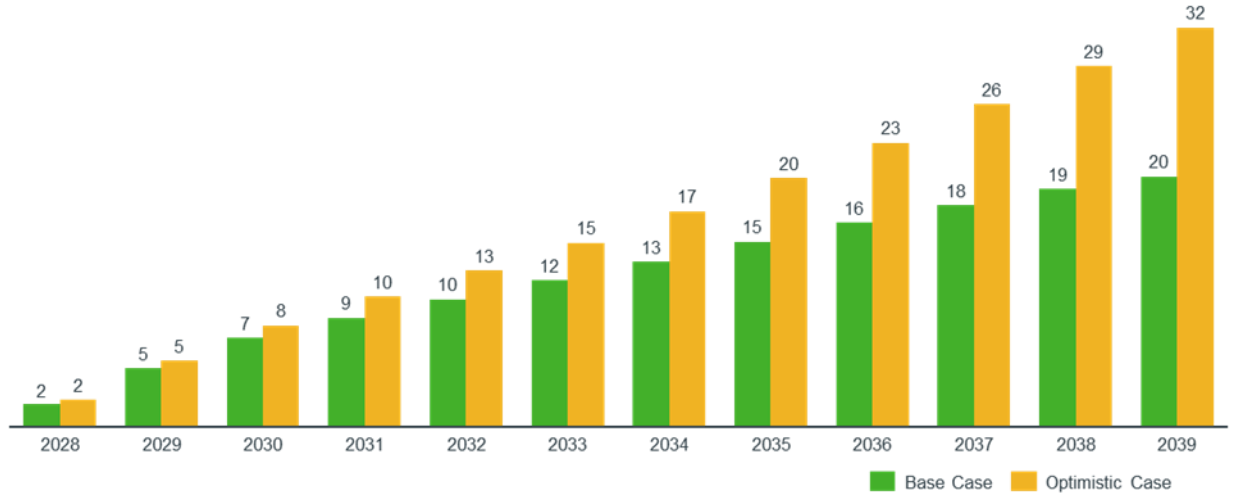
Source: IQVIA

Figure 6.1 Top 10 Molecules Gross Revenue Forecast in $Mns



Source: IQVIA

Figure 6.2 Top 10 Molecules Net Revenue Forecast in $Mns



Source: IQVIA

6 Pricing Strategy

6.1.5 Forecast Assumptions & Outputs by Molecule (Next 11-20 Molecules)

6.1.5.1 Diazepam Forecast

Table 6.43 Forecast Assumptions: Diazepam

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market
Uptake curve	Moderate 3 years	
SU Price	$ 0.36	5% price discount to remain competitive
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market

Source: IQVIA

92 | Feasibility Studies Report

Table 6.44 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Diazepam

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.2	0.2	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6	0.7
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.05	0.20	0.28	0.29	0.31	0.32	0.33	0.33	0.34	0.34	0.34	0.34
	Estimated Sales ($Mn)				0.02	0.09	0.14	0.16	0.18	0.19	0.21	0.23	0.24	0.26	0.27	0.27
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.10	0.22	0.28	0.31	0.33	0.36	0.39	0.42	0.45	0.48	0.51	0.54
	Estimated Sales ($Mn)				0.04	0.10	0.14	0.16	0.19	0.22	0.25	0.29	0.32	0.36	0.40	0.44

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.
Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

6 Pricing Strategy

Table 6.45 Net Sales (Quintex Pharma) Forecasts - Diazepam

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.02	0.08	0.12	0.14	0.15	0.17	0.19	0.20	0.21	0.23	0.23	0.24
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.04	0.09	0.12	0.14	0.17	0.19	0.22	0.25	0.28	0.32	0.35	0.39

Source: IQVIA

6.1.5.2 Hydrocortisone Forecast

Table 6.46 Forecast Assumptions: Hydrocortisone

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market
Uptake curve	Moderate 3 years	
SU Price	$0.37	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until

94 | Feasibility Studies Report

Parameter	Assumption	Comments
		2030, and then reduce to 4% until the end of the forecast period
SU factor	50	Benchmark countries (average)
Strength Split	100mg: 100%	Benchmark countries (average)

Source: IQVIA

Table 6.47 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Hydrocortisone

Key \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		1.16	1.22	1.28	1.34	1.41	1.47	1.53	1.60	1.66	1.72	1.78	1.83	1.89	1.94	1.99
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.45	0.96	1.18	1.18	1.17	1.16	1.15	1.13	1.10	1.07	1.03	0.99
	Estimated Sales ($Mn)				0.20	0.46	0.60	0.65	0.69	0.73	0.76	0.79	0.81	0.83	0.83	0.83
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.45	0.96	1.18	1.23	1.28	1.33	1.37	1.42	1.47	1.51	1.55	1.59
	Estimated Sales ($Mn)				0.20	0.46	0.60	0.68	0.75	0.83	0.91	1.00	1.08	1.17	1.25	1.34

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

6 Pricing Strategy

Table 6.48 Net Sales (Quintex Pharma) Forecasts - Hydrocortisone

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.17	0.40	0.53	0.57	0.61	0.64	0.67	0.69	0.71	0.73	0.73	0.73
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.17	0.40	0.53	0.60	0.66	0.73	0.80	0.88	0.95	1.03	1.10	1.17

Source: IQVIA

6.1.5.3 Metoclopramide Forecast

Table 6.49 Forecast Assumptions: Metoclopramide

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market
Uptake curve	Moderate 3 years	
SU Price	$0.24	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until

96 | Feasibility Studies Report

Parameter	Assumption	Comments
		2030, and then reduce to 4% until the end of the forecast period
SU factor	10	Benchmark countries (average)
Strength Split	10mg: 100%	Benchmark countries (average)

Source: IQVIA

Table 6.50 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Metoclopramide

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.37	0.42	0.47	0.53	0.60	0.67	0.75	0.83	0.91	0.99	1.08	1.17	1.26	1.35	1.44
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.10	0.38	0.54	0.57	0.61	0.64	0.66	0.69	0.70	0.72	0.72	0.72
	Estimated Sales ($Mn)				0.03	0.12	0.18	0.20	0.23	0.26	0.29	0.31	0.34	0.36	0.38	0.39
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.10	0.38	0.54	0.60	0.66	0.73	0.80	0.87	0.94	1.01	1.08	1.15
	Estimated Sales ($Mn)				0.03	0.12	0.18	0.21	0.25	0.30	0.34	0.39	0.45	0.51	0.57	0.63

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

6 Pricing Strategy

Table 6.51 Net Sales (Quintex Pharma) Forecasts - Metoclopramide

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.03	0.10	0.16	0.18	0.20	0.23	0.25	0.27	0.30	0.32	0.33	0.35
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.03	0.10	0.16	0.19	0.22	0.26	0.30	0.35	0.40	0.45	0.50	0.55

Source: IQVIA

6.1.5.4 Pethidine Forecast

Table 6.52 Forecast Assumptions: Pethidine

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 30% Optimistic case: 40%	In Base case, assumed 30% peak MS as Quintex Pharma will be the 2nd local player In Optimistic case, assumed 40% peak share with equal market split between the 2 local manufacturers
No. of local players (including Quintex Pharma)	2 (Base & Optimistic case)	Quintex Pharma will be the second local player, as there is already a local manufacturer producing Pethidine
Uptake curve	Moderate 5 years	Considering that Quintex Pharma will be the 2nd to market
SU Price	$1.49	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period

98 | Feasibility Studies Report

Parameter	Assumption	Comments
SU factor	10	Benchmark countries (average)
Strength Split	50mg: 35% 100mg: 65%	Benchmark countries (average)

Source: IQVIA

Table 6.53 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Pethidine

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.40	0.41	0.42	0.43	0.43	0.44	0.45	0.46	0.46	0.47	0.48	0.48	0.49	0.49	0.50
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.03	0.07	0.10	0.13	0.14	0.14	0.14	0.14	0.15	0.15	0.15	0.15
	Estimated Sales ($Mn)				0.06	0.13	0.22	0.28	0.33	0.35	0.38	0.40	0.43	0.46	0.48	0.51
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.04	0.09	0.14	0.17	0.18	0.19	0.19	0.19	0.19	0.20	0.20	0.20
	Estimated Sales ($Mn)				0.08	0.17	0.29	0.38	0.43	0.47	0.50	0.54	0.57	0.61	0.64	0.68

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

6 Pricing Strategy

Table 6.54 Net Sales (Quintex Pharma) Forecasts - Pethidine

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.05	0.11	0.19	0.25	0.29	0.31	0.33	0.36	0.38	0.40	0.42	0.45
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.07	0.15	0.25	0.33	0.38	0.41	0.44	0.47	0.51	0.54	0.57	0.59

Source: IQVIA

Table 6.55 Quintex Pharma Volume Forecast by Strength - Pethidine

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	50mg (SU, Mn)				0.012	0.023	0.037	0.045	0.048	0.049	0.049	0.050	0.051	0.051	0.052	0.052
	100mg (SU, Mn)				0.022	0.044	0.068	0.083	0.089	0.091	0.092	0.093	0.094	0.095	0.096	0.097
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	50mg (SU, Mn)				0.016	0.031	0.049	0.059	0.064	0.065	0.066	0.067	0.068	0.068	0.069	0.070
	100mg (SU, Mn)				0.029	0.058	0.091	0.111	0.119	0.121	0.122	0.124	0.126	0.127	0.129	0.130

Source: IQVIA

100 | Feasibility Studies Report

6.1.5.5 Ketamine Forecast

Table 6.56 Forecast Assumptions: Ketamine

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market
Uptake curve	Moderate 3 years	
SU Price	$2.58	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	1	Benchmark countries (average)
Strength Split	50mg: 21.5% 250mg: 0.2% 500mg: 78.3%	Benchmark countries (average)

Source: IQVIA

Table 6.57 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Ketamine

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.02	0.02	0.03	0.03	0.03	0.03	0.04	0.04	0.04	0.04	0.05	0.05	0.05	0.05	0.06
Potential Opportunity	Estimated Volume (SU Mn)				0.004	0.01	0.01	0.02	0.02	0.02	0.02	0.02	0.02	0.03	0.03	0.03

6 Pricing Strategy

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Estimated Sales ($Mn)				0.01	0.03	0.05	0.07	0.08	0.09	0.10	0.11	0.13	0.14	0.15	0.17
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.01	0.01	0.02	0.03	0.03	0.03	0.04	0.04	0.04	0.04	0.04	0.05
	Estimated Sales ($Mn)				0.02	0.04	0.08	0.10	0.13	0.14	0.16	0.18	0.20	0.22	0.25	0.27

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

Table 6.58 Net Sales (Quintex Pharma) Forecasts - Ketamine

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.01	0.02	0.04	0.06	0.07	0.08	0.09	0.10	0.11	0.12	0.14	0.15

102 | Feasibility Studies Report

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.02	0.04	0.07	0.09	0.11	0.13	0.14	0.16	0.18	0.20	0.22	0.24

Source: IQVIA

Table 6.59 Quintex Pharma Volume Forecast by Strength - Ketamine

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	50mg (SU, Mn)				0.001	0.002	0.003	0.004	0.004	0.004	0.005	0.005	0.005	0.006	0.006	0.006
	250mg (SU, Mn)				0.000 001	0.000 002	0.000 002	0.000 003	0.000 004	0.000 004	0.000 004	0.000 004	0.000 005	0.000 005	0.000 005	0.000 005
	500mg (SU, Mn)				0.003	0.006	0.010	0.013	0.015	0.016	0.017	0.018	0.019	0.020	0.021	0.022
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	50mg (SU, Mn)				0.001	0.003	0.005	0.006	0.007	0.007	0.008	0.008	0.009	0.009	0.009	0.010
	250mg (SU, Mn)				0.000 001	0.000 002	0.000 004	0.000 005	0.000 006	0.000 006	0.000 007	0.000 007	0.000 008	0.000 008	0.000 008	0.000 009
	500mg (SU, Mn)				0.005	0.010	0.016	0.021	0.024	0.026	0.028	0.029	0.031	0.033	0.034	0.036

Source: IQVIA

6 Pricing Strategy

6.1.5.6 Phenytoin Forecast:

Table 6.60 Forecast Assumptions: Phenytoin

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market
Uptake curve	Moderate 3 years	
SU Price	$1.50	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	5	Benchmark countries (average)
Strength Split	50mg: 1.6% 100mg: 8% 250mg: 90.4%	Benchmark countries (average)

Source: IQVIA

Table 6.61 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Phenytoin

Key Components \ Time Period	2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)	0.13	0.15	0.17	0.19	0.21	0.23	0.26	0.28	0.31	0.33	0.36	0.39	0.42	0.44	0.47
Potential Opportunity – Estimated Volume (SU Mn)				0.04	0.13	0.19	0.20	0.21	0.22	0.22	0.23	0.23	0.24	0.24	0.24

104 | Feasibility Studies Report

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Estimated Sales ($Mn)				0.06	0.26	0.39	0.44	0.49	0.55	0.60	0.65	0.70	0.74	0.77	0.80
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.06	0.14	0.19	0.20	0.22	0.25	0.27	0.29	0.31	0.33	0.36	0.38
	Estimated Sales ($Mn)				0.11	0.28	0.39	0.46	0.54	0.62	0.72	0.82	0.93	1.05	1.16	1.28

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.
Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

Table 6.62 Net Sales (Quintex Pharma) Forecasts - Phenytoin

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.06	0.23	0.34	0.39	0.43	0.48	0.53	0.57	0.61	0.65	0.68	0.70
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.10	0.24	0.34	0.40	0.47	0.55	0.63	0.72	0.82	0.92	1.02	1.13

Source: IQVIA

6 Pricing Strategy

Table 6.63 Quintex Pharma Volume Forecast by Strength - Phenytoin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	50mg (SU, Mn)				0.001	0.002	0.003	0.003	0.003	0.003	0.004	0.004	0.004	0.004	0.004	0.004
	100mg (SU, Mn)				0.003	0.011	0.015	0.016	0.016	0.017	0.018	0.018	0.018	0.019	0.019	0.019
	250mg (SU, Mn)				0.032	0.121	0.168	0.178	0.187	0.195	0.201	0.207	0.211	0.214	0.214	0.213
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	50mg (SU, Mn)				0.001	0.002	0.003	0.003	0.004	0.004	0.004	0.005	0.005	0.005	0.006	0.006
	100mg (SU, Mn)				0.005	0.011	0.015	0.016	0.018	0.019	0.021	0.023	0.025	0.026	0.028	0.030
	250mg (SU, Mn)				0.057	0.129	0.168	0.185	0.203	0.222	0.242	0.262	0.282	0.301	0.321	0.340

Source: IQVIA

6.1.5.7 Vancomycin Forecast

Table 6.64 Forecast Assumptions: Vancomycin

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market

106 | Feasibility Studies Report

Parameter	Assumption	Comments
Uptake curve	Moderate 3 years	
SU Price	$4.87	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	1	Benchmark countries (average)
Strength Split	500mg: 71% 1000mg: 29%	Benchmark countries (average)

Source: IQVIA

Table 6.65 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Vancomycin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.25	0.30	0.36	0.42	0.50	0.59	0.68	0.79	0.90	1.03	1.16	1.30	1.45	1.60	1.75
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.08	0.32	0.47	0.52	0.58	0.63	0.69	0.74	0.78	0.82	0.85	0.88
	Estimated Sales ($Mn)				0.46	2.02	3.18	3.80	4.48	5.22	6.00	6.80	7.59	8.36	9.07	9.68
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.14	0.34	0.47	0.55	0.63	0.72	0.82	0.93	1.04	1.16	1.28	1.40
	Estimated Sales ($Mn)				0.82	2.14	3.18	3.96	4.89	5.97	7.20	8.59	10.1	11.8	13.6	15.5

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

6 Pricing Strategy

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

Table 6.66 Net Sales (Quintex Pharma) Forecasts - Vancomycin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	500mg (SU, Mn)				0.06	0.23	0.33	0.37	0.41	0.45	0.49	0.52	0.55	0.58	0.61	0.62
	1000mg (SU, Mn)				0.02	0.09	0.14	0.15	0.17	0.18	0.20	0.21	0.23	0.24	0.25	0.25
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	500mg (SU, Mn)				0.10	0.24	0.33	0.39	0.45	0.51	0.58	0.66	0.74	0.82	0.91	0.99
	1000mg (SU, Mn)				0.04	0.10	0.14	0.16	0.18	0.21	0.24	0.27	0.30	0.34	0.37	0.41

Source: IQVIA

6.1.5.8 Carbetocin Forecast

Table 6.67 Forecast Assumptions: Carbetocin

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market
Uptake curve	Moderate 3 years	
SU Price	$11.61	5% price discount to remain competitive

108 | Feasibility Studies Report

Parameter	Assumption	Comments
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	5	Benchmark countries (average)
Strength Split	100mcg: 100%	Benchmark countries (average)

Source: IQVIA

Table 6.68 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Carbetocin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.01	0.02	0.02	0.03	0.03	0.04	0.05	0.06	0.07	0.08	0.09	0.11	0.12	0.14	0.15
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.005	0.022	0.033	0.038	0.043	0.048	0.054	0.059	0.064	0.069	0.073	0.076
	Estimated Sales ($Mn)				0.073	0.327	0.531	0.654	0.794	0.950	1.119	1.299	1.484	1.668	1.845	2.006
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.005	0.022	0.033	0.039	0.047	0.055	0.064	0.075	0.085	0.097	0.109	0.122
	Estimated Sales ($Mn)				0.073	0.327	0.531	0.683	0.866	1.085	1.343	1.641	1.978	2.355	2.767	3.209

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

6 Pricing Strategy

Table 6.69 Net Sales (Quintex Pharma) Forecasts - Carbetocin

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.06	0.29	0.47	0.58	0.70	0.84	0.98	1.14	1.31	1.47	1.62	1.76
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.06	0.29	0.47	0.60	0.76	0.96	1.18	1.44	1.74	2.07	2.44	2.82

Source: IQVIA

6.1.5.9 Heparin Forecast

Table 6.70 Forecast Assumptions: Heparin

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market
Uptake curve	Moderate 3 years	
SU Price	$4.70	5% price discount to remain competitive
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until

110 | Feasibility Studies Report

Parameter	Assumption	Comments
		2030, and then reduce to 4% until the end of the forecast period
SU factor	1	Benchmark countries (average)
Strength Split	100mg: 100%	Benchmark countries (average)

Source: IQVIA

Table 6.71 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Heparin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.09	0.10	0.10	0.11	0.11	0.12	0.12	0.13	0.13	0.14	0.14	0.15	0.15	0.16	0.16
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.04	0.08	0.10	0.10	0.10	0.09	0.09	0.09	0.09	0.09	0.08	0.08
	Estimated Sales ($Mn)				0.21	0.47	0.63	0.67	0.71	0.75	0.79	0.82	0.84	0.85	0.86	0.86
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.04	0.08	0.10	0.10	0.10	0.11	0.11	0.12	0.12	0.12	0.13	0.13
	Estimated Sales ($Mn)				0.21	0.47	0.63	0.70	0.78	0.86	0.94	1.03	1.12	1.21	1.29	1.38

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.
Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices

6 Pricing Strategy

Table 6.72 Net Sales (Quintex Pharma) Forecasts - Heparin

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.18	0.42	0.55	0.59	0.63	0.66	0.69	0.72	0.74	0.75	0.76	0.76
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.18	0.42	0.55	0.62	0.68	0.76	0.83	0.91	0.98	1.06	1.14	1.21

Source: IQVIA

6.1.5.10 Ceftriaxone Forecast

Table 6.73 Forecast Assumptions: Ceftriaxone

Parameter	Assumption	Comments
Product launch year	2028	
Market share % (MS)	Base case: 80% (2030)-50% (2039) Optimistic case: 80%	In Base case, assumed 80% MS by 2030 with reduction to 50% share following the entry of an additional local manufacturer in 2031. In Optimistic case, assumed 80% peak share with no new local manufacturer entry in the market
No. of local players (including Quintex Pharma)	2 (Base case) 1 (Optimistic case)	No local manufacturer available currently. Quintex Pharma is expected to be first local player in the market
Uptake curve	Moderate 3 years	
SU Price	$0.44	5% price discount to remain competitive

112 | Feasibility Studies Report

Parameter	Assumption	Comments
Price growth	8%	The price growth is assumed to align with the inflation rate, i.e., 8% until 2030, and then reduce to 4% until the end of the forecast period
SU factor	1	Benchmark countries (average)
Strength Split	250mg: 1% 500mg: 8% 1000mg: 88% 2000mg: 3%	Benchmark countries (average)

Source: IQVIA

Table 6.74 Volume (Total Market & Quintex Pharma) and Gross Sales (Quintex Pharma) Forecasts - Ceftriaxone

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		1.45	1.64	1.85	2.09	2.35	2.63	2.93	3.24	3.56	3.90	4.25	4.60	4.95	5.30	5.65
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU Mn)				0.70	1.60	2.11	2.24	2.37	2.49	2.60	2.69	2.76	2.81	2.83	2.82
	Estimated Sales ($Mn)				0.36	0.90	1.27	1.46	1.65	1.84	2.03	2.22	2.40	2.55	2.69	2.79
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU Mn)				0.39	1.51	2.11	2.34	2.59	2.85	3.12	3.40	3.68	3.96	4.24	4.52
	Estimated Sales ($Mn)				0.20	0.85	1.27	1.52	1.80	2.10	2.44	2.80	3.19	3.61	4.03	4.46

Source: IQVIA

Note: Public hospital tender market represents 33% of the total Ghana market, with drug prices approximately 15% lower than those in the private market. The Tender CMS market makes up 32% of the total Ghana market, offering drugs at prices around 30% lower than the private market. The remaining 35% of the market is the private sector.

Overall, the average weighted price of drugs across all three markets is about 12% lower than private market prices.

6 Pricing Strategy

Table 6.75 Net Sales (Quintex Pharma) Forecasts - Ceftriaxone

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case)	Estimated Net Sales ($Mn)				0.78	1.86	3.42	4.90	6.12	7.17	8.32	9.56	10.9	12.3	13.7	15.2
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Net Sales ($Mn)				0.98	2.32	4.28	6.13	7.66	8.96	10.4	12.0	13.6	15.4	17.2	19.0

Source: IQVIA

Table 6.76 Quintex Pharma Volume Forecast by Strength - Ceftriaxone

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	250mg (SU, Mn)				0.006	0.01	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
	500mg (SU, Mn)				0.06	0.13	0.17	0.18	0.19	0.20	0.21	0.22	0.23	0.23	0.23	0.23
	1000mg (SU, Mn)				0.62	1.42	1.86	1.99	2.10	2.21	2.30	2.38	2.44	2.48	2.50	2.50
	2000mg (SU, Mn)				0.02	0.04	0.05	0.06	0.06	0.06	0.07	0.07	0.07	0.07	0.07	0.07
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	250mg (SU, Mn)				0.003	0.01	0.02	0.02	0.02	0.02	0.03	0.03	0.03	0.03	0.04	0.04
	500mg (SU, Mn)				0.03	0.12	0.17	0.19	0.21	0.23	0.25	0.28	0.30	0.32	0.35	0.37

114 | Feasibility Studies Report

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	1000mg (SU, Mn)				0.35	1.34	1.86	2.07	2.29	2.52	2.76	3.01	3.26	3.51	3.75	4.00
	2000mg (SU, Mn)				0.01	0.04	0.05	0.06	0.06	0.07	0.08	0.08	0.09	0.10	0.11	0.11

Source: IQVIA

6.1.6 Forecast Revenues (top 11-20)

Table 6.77 Gross Revenue Forecast: Base Case for Molecules 11-20 ($, Mn)

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Molecules 11-20 Revenue for Quintex Pharma (Base case, $Mn)	Vancomycin				0.46	2.02	3.18	3.80	4.48	5.22	6.00	6.80	7.59	8.36	9.07	9.68
	Ceftriaxone				0.36	0.90	1.27	1.46	1.65	1.84	2.03	2.2	2.4	2.6	2.7	2.8
	Carbetocin				0.07	0.33	0.53	0.65	0.79	0.95	1.12	1.30	1.48	1.67	1.84	2.01
	Heparin				0.21	0.47	0.63	0.67	0.71	0.75	0.79	0.82	0.84	0.85	0.86	0.86
	Hydrocortisone				0.20	0.46	0.60	0.65	0.69	0.73	0.76	0.79	0.81	0.83	0.83	0.83
	Phenytoin				0.06	0.26	0.39	0.44	0.49	0.55	0.60	0.65	0.70	0.74	0.77	0.80
	Pethidine				0.06	0.13	0.22	0.28	0.33	0.35	0.38	0.40	0.43	0.46	0.48	0.51
	Metoclopramide				0.03	0.12	0.18	0.20	0.23	0.26	0.29	0.31	0.34	0.36	0.38	0.39
	Diazepam				0.02	0.09	0.14	0.16	0.18	0.19	0.21	0.23	0.24	0.26	0.27	0.27
	Ketamine				0.01	0.03	0.05	0.07	0.08	0.09	0.10	0.11	0.13	0.14	0.15	0.17
	Total				1.5	4.8	7.2	8.4	9.6	10.9	12.3	13.6	15.0	16.2	17.4	18.3

Source: IQVIA

6 Pricing Strategy

Table 6.78 Net Revenue Forecast: Base Case for Molecules 11-20 ($, Mn)

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Molecules 11-20 Revenue for Quintex Pharma (Base case, $Mn)	Vancomycin				0.41	1.77	2.79	3.34	3.94	4.59	5.28	5.98	6.68	7.36	7.98	8.52
	Ceftriaxone				0.32	0.79	1.12	1.28	1.45	1.62	1.79	1.95	2.11	2.25	2.36	2.46
	Carbetocin				0.06	0.29	0.47	0.58	0.70	0.84	0.98	1.14	1.31	1.47	1.62	1.76
	Heparin				0.18	0.42	0.55	0.59	0.63	0.66	0.69	0.72	0.74	0.75	0.76	0.76
	Hydrocortisone				0.17	0.40	0.53	0.57	0.61	0.64	0.67	0.69	0.71	0.73	0.73	0.73
	Phenytoin				0.06	0.23	0.34	0.39	0.43	0.48	0.53	0.57	0.61	0.65	0.68	0.70
	Pethidine				0.05	0.11	0.19	0.25	0.29	0.31	0.33	0.36	0.38	0.40	0.42	0.45
	Metoclopramide				0.03	0.10	0.16	0.18	0.20	0.23	0.25	0.27	0.30	0.32	0.33	0.35
	Diazepam				0.02	0.08	0.12	0.14	0.15	0.17	0.19	0.20	0.21	0.23	0.23	0.24
	Ketamine				0.01	0.02	0.04	0.06	0.07	0.08	0.09	0.10	0.11	0.12	0.14	0.15
	Total				1.3	4.2	6.3	7.4	8.5	9.6	10.8	12.0	13.2	14.3	15.3	16.1

Source: IQVIA

Table 6.79 Gross Revenue Forecast: Optimistic Case for Molecules 11-20 ($, Mn)

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Molecules 11-20 Revenue for Quintex Pharma (Optimistic case, $Mn)	Vancomycin				0.82	2.14	3.18	3.96	4.89	5.97	7.20	8.59	10.12	11.80	13.60	15.49
	Ceftriaxone				0.20	0.85	1.27	1.52	1.80	2.1	2.4	2.8	3.2	3.6	4.0	4.5
	Carbetocin				0.07	0.33	0.53	0.68	0.87	1.09	1.34	1.64	1.98	2.36	2.77	3.21
	Heparin				0.21	0.47	0.63	0.70	0.78	0.86	0.94	1.03	1.12	1.21	1.29	1.38

116 | Feasibility Studies Report

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Hydrocortisone				0.20	0.46	0.60	0.68	0.75	0.83	0.91	1.00	1.08	1.17	1.25	1.34
	Phenytoin				0.11	0.28	0.39	0.46	0.54	0.62	0.72	0.82	0.93	1.05	1.16	1.28
	Pethidine				0.08	0.17	0.29	0.38	0.43	0.47	0.50	0.54	0.57	0.61	0.64	0.68
	Metoclopramide				0.03	0.12	0.18	0.21	0.25	0.30	0.34	0.39	0.45	0.51	0.57	0.63
	Diazepam				0.04	0.10	0.14	0.16	0.19	0.22	0.25	0.29	0.32	0.36	0.40	0.44
	Ketamine				0.02	0.04	0.08	0.10	0.13	0.14	0.16	0.18	0.20	0.22	0.25	0.27
	Total				1.8	5.0	7.3	8.9	10.6	12.6	14.8	17.3	20.0	22.9	26.0	29.2

Source: IQVIA

Table 6.80 Net Revenue Forecast: Optimistic Case for Molecules 11-20 ($, Mn)

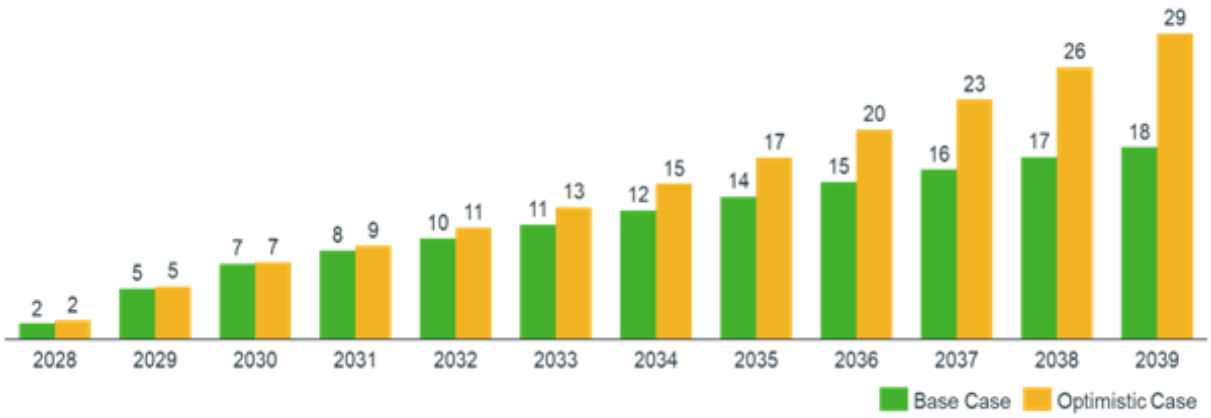
Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Molecules 11-20 Revenue for Quintex Pharma (Optimistic case, $Mn)	Vancomycin				0.73	1.89	2.79	3.49	4.30	5.25	6.33	7.56	8.91	10.39	11.97	13.63
	Ceftriaxone				0.18	0.75	1.12	1.34	1.58	1.85	2.1	2.5	2.8	3.2	3.5	3.9
	Carbetocin				0.06	0.29	0.47	0.60	0.76	0.96	1.18	1.44	1.74	2.07	2.44	2.82
	Heparin				0.18	0.42	0.55	0.62	0.68	0.76	0.83	0.91	0.98	1.06	1.14	1.21
	Hydrocortisone				0.17	0.40	0.53	0.60	0.66	0.73	0.80	0.88	0.95	1.03	1.10	1.17
	Phenytoin				0.10	0.24	0.34	0.40	0.47	0.55	0.63	0.72	0.82	0.92	1.02	1.13
	Pethidine				0.07	0.15	0.25	0.33	0.38	0.41	0.44	0.47	0.51	0.54	0.57	0.59
	Metoclopramide				0.03	0.10	0.16	0.19	0.22	0.26	0.30	0.35	0.40	0.45	0.50	0.55
	Diazepam				0.04	0.09	0.12	0.14	0.17	0.19	0.22	0.25	0.28	0.32	0.35	0.39
	Ketamine				0.02	0.04	0.07	0.09	0.11	0.13	0.14	0.16	0.18	0.20	0.22	0.24

6 Pricing Strategy

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Total				1.6	4.4	6.4	7.8	9.3	11.1	13.0	15.2	17.6	20.1	22.8	25.7

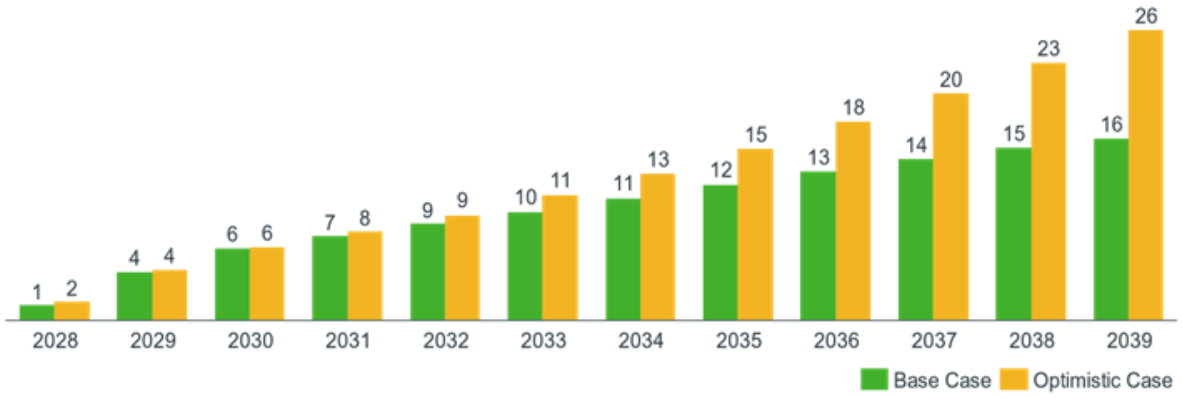
Source: IQVIA

Figure 6.3 Molecules 11-20 Gross Revenue Forecast – in $Mn



Source: IQVIA

Figure 6.4 Molecules 11-20 Net Revenue Forecast – in $Mn



Source: IQVIA

118 | Feasibility Studies Report

6.1.7 Forecast Summary (20 Molecules):

Table 6.81 Gross Revenue Forecast: Base Case for 20 Molecules ($, Mn)

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 20 Molecules Revenue for Quintex Pharma (Base case, $Mn)	Enoxaparin				0.93	2.33	3.35	3.90	4.48	5.08	5.68	6.28	6.84	7.35	7.79	8.12
	Omeprazole				0.20	0.57	0.95	1.27	1.65	2.09	2.58	3.10	3.62	4.12	4.55	4.88
	Furosemide				0.02	0.04	0.08	0.12	0.15	0.18	0.22	0.25	0.30	0.34	0.39	0.44
	Oxytocin				0.48	1.06	1.85	2.52	3.00	3.35	3.72	4.10	4.49	4.87	5.26	5.63
	Tranexamic Acid				0.14	0.56	0.81	0.91	1.00	1.09	1.18	1.26	1.33	1.39	1.44	1.46
	Diclofenac				0.02	0.06	0.09	0.11	0.12	0.13	0.14	0.15	0.16	0.17	0.17	0.18
	Dexamethasone				0.09	0.21	0.28	0.30	0.33	0.35	0.37	0.39	0.40	0.41	0.42	0.42
	Midazolam				0.15	0.35	0.49	0.55	0.62	0.68	0.75	0.81	0.87	0.92	0.96	0.98
	Phytomenadione				0.04	0.09	0.14	0.17	0.20	0.23	0.26	0.29	0.32	0.35	0.38	0.40
	Propofol				0.01	0.02	0.04	0.06	0.07	0.09	0.11	0.13	0.16	0.19	0.21	0.24
	Vancomycin				0.46	2.02	3.18	3.80	4.48	5.22	6.00	6.80	7.59	8.36	9.07	9.68
	Ceftriaxone				0.36	0.90	1.27	1.46	1.65	1.84	2.03	2.2	2.4	2.6	2.7	2.8
	Carbetocin				0.07	0.33	0.53	0.65	0.79	0.95	1.12	1.30	1.48	1.67	1.84	2.01
	Heparin				0.21	0.47	0.63	0.67	0.71	0.75	0.79	0.82	0.84	0.85	0.86	0.86
	Hydrocortisone				0.20	0.46	0.60	0.65	0.69	0.73	0.76	0.79	0.81	0.83	0.83	0.83
	Phenytoin				0.06	0.26	0.39	0.44	0.49	0.55	0.60	0.65	0.70	0.74	0.77	0.80
	Pethidine				0.06	0.13	0.22	0.28	0.33	0.35	0.38	0.40	0.43	0.46	0.48	0.51
	Metoclopramide				0.03	0.12	0.18	0.20	0.23	0.26	0.29	0.31	0.34	0.36	0.38	0.39
	Diazepam				0.02	0.09	0.14	0.16	0.18	0.19	0.21	0.23	0.24	0.26	0.27	0.27
	Ketamine				0.01	0.03	0.05	0.07	0.08	0.09	0.10	0.11	0.13	0.14	0.15	0.17
	Total				3.5	10.1	15.3	18.3	21.2	24.2	27.3	30.4	33.4	36.3	38.9	41.1

Source: IQVIA

Table 6.82 Net Revenue Forecast: Base Case for 20 Molecules ($, Mn)

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 20 Molecules Revenue for Quintex	Enoxaparin				0.82	2.05	2.95	3.43	3.94	4.47	5.00	5.53	6.02	6.47	6.85	7.15
	Omeprazole				0.17	0.50	0.84	1.12	1.45	1.84	2.27	2.72	3.19	3.62	4.00	4.29
	Furosemide				0.01	0.04	0.07	0.10	0.13	0.16	0.19	0.22	0.26	0.30	0.35	0.39
	Oxytocin				0.42	0.94	1.63	2.22	2.64	2.95	3.28	3.61	3.95	4.29	4.63	4.96

6 Pricing Strategy

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Tranexamic Acid				0.12	0.49	0.72	0.80	0.88	0.96	1.04	1.11	1.17	1.22	1.26	1.29
	Diclofenac				0.01	0.06	0.08	0.09	0.10	0.11	0.12	0.13	0.14	0.15	0.15	0.16
	Dexamethasone				0.08	0.18	0.25	0.27	0.29	0.31	0.32	0.34	0.35	0.36	0.37	0.37
	Midazolam				0.13	0.30	0.43	0.48	0.54	0.60	0.66	0.71	0.76	0.81	0.84	0.87
	Phytomenadione				0.03	0.08	0.12	0.15	0.17	0.20	0.23	0.26	0.28	0.31	0.33	0.35
	Propofol				0.01	0.02	0.03	0.05	0.07	0.08	0.10	0.12	0.14	0.16	0.19	0.21
	Vancomycin				0.41	1.77	2.79	3.34	3.94	4.59	5.28	5.98	6.68	7.36	7.98	8.52
	Ceftriaxone				0.32	0.79	1.12	1.28	1.45	1.62	1.79	1.95	2.11	2.25	2.36	2.46
	Carbetocin				0.06	0.29	0.47	0.58	0.70	0.84	0.98	1.14	1.31	1.47	1.62	1.76
	Heparin				0.18	0.42	0.55	0.59	0.63	0.66	0.69	0.72	0.74	0.75	0.76	0.76
	Hydrocortisone				0.17	0.40	0.53	0.57	0.61	0.64	0.67	0.69	0.71	0.73	0.73	0.73
	Phenytoin				0.06	0.23	0.34	0.39	0.43	0.48	0.53	0.57	0.61	0.65	0.68	0.70
	Pethidine				0.05	0.11	0.19	0.25	0.29	0.31	0.33	0.36	0.38	0.40	0.42	0.45
	Metoclopramide				0.03	0.10	0.16	0.18	0.20	0.23	0.25	0.27	0.30	0.32	0.33	0.35
	Diazepam				0.02	0.08	0.12	0.14	0.15	0.17	0.19	0.20	0.21	0.23	0.23	0.24
	Ketamine				0.01	0.02	0.04	0.06	0.07	0.08	0.09	0.10	0.11	0.12	0.14	0.15
	Total				3.1	8.9	13.4	16.1	18.7	21.3	24.0	26.7	29.4	32.0	34.2	36.1

Source: IQVIA

Table 6.83 Gross Revenue Forecast: Optimistic Case for 20 Molecules ($, Mn)

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 20 Molecules Revenue for Quintex Pharma (Optimistic case, $Mn)	Enoxaparin				0.93	2.33	3.35	4.07	4.88	5.80	6.82	7.93	9.12	10.3	11.6	13.0
	Omeprazole				0.20	0.57	0.95	1.33	1.80	2.39	3.09	3.91	4.83	5.81	6.82	7.80
	Furosemide				0.02	0.05	0.10	0.15	0.20	0.24	0.29	0.34	0.40	0.46	0.52	0.59
	Oxytocin				0.76	1.70	2.97	4.04	4.80	5.37	5.96	6.56	7.18	7.80	8.41	9.01
	Tranexamic Acid				0.25	0.59	0.81	0.95	1.09	1.25	1.42	1.59	1.78	1.96	2.15	2.34
	Diclofenac				0.03	0.07	0.09	0.11	0.13	0.15	0.17	0.19	0.21	0.24	0.26	0.28
	Dexamethasone				0.09	0.21	0.28	0.32	0.36	0.40	0.44	0.49	0.53	0.58	0.63	0.67
	Midazolam				0.15	0.35	0.49	0.57	0.67	0.78	0.90	1.03	1.16	1.30	1.44	1.58
	Phytomenadione				0.04	0.09	0.14	0.17	0.21	0.26	0.31	0.37	0.43	0.50	0.57	0.64
	Propofol				0.01	0.03	0.05	0.08	0.10	0.12	0.15	0.18	0.21	0.25	0.29	0.33

120 | Feasibility Studies Report

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Vancomycin				0.82	2.14	3.18	3.96	4.89	5.97	7.20	8.59	10.12	11.80	13.60	15.49
	Ceftriaxone				0.20	0.85	1.27	1.52	1.80	2.1	2.4	2.8	3.2	3.6	4.0	4.5
	Carbetocin				0.07	0.33	0.53	0.68	0.87	1.09	1.34	1.64	1.98	2.36	2.77	3.21
	Heparin				0.21	0.47	0.63	0.70	0.78	0.86	0.94	1.03	1.12	1.21	1.29	1.38
	Hydrocortisone				0.20	0.46	0.60	0.68	0.75	0.83	0.91	1.00	1.08	1.17	1.25	1.34
	Phenytoin				0.11	0.28	0.39	0.46	0.54	0.62	0.72	0.82	0.93	1.05	1.16	1.28
	Pethidine				0.08	0.17	0.29	0.38	0.43	0.47	0.50	0.54	0.57	0.61	0.64	0.68
	Metoclopramide				0.03	0.12	0.18	0.21	0.25	0.30	0.34	0.39	0.45	0.51	0.57	0.63
	Diazepam				0.04	0.10	0.14	0.16	0.19	0.22	0.25	0.29	0.32	0.36	0.40	0.44
	Ketamine				0.02	0.04	0.08	0.10	0.13	0.14	0.16	0.18	0.20	0.22	0.25	0.27
	Total				4.3	10.9	16.5	20.6	24.9	29.4	34.4	39.9	45.8	52.2	58.7	65.4

Source: IQVIA

Table 6.84 Net Revenue Forecast: Optimistic Case for 20 Molecules ($, Mn)

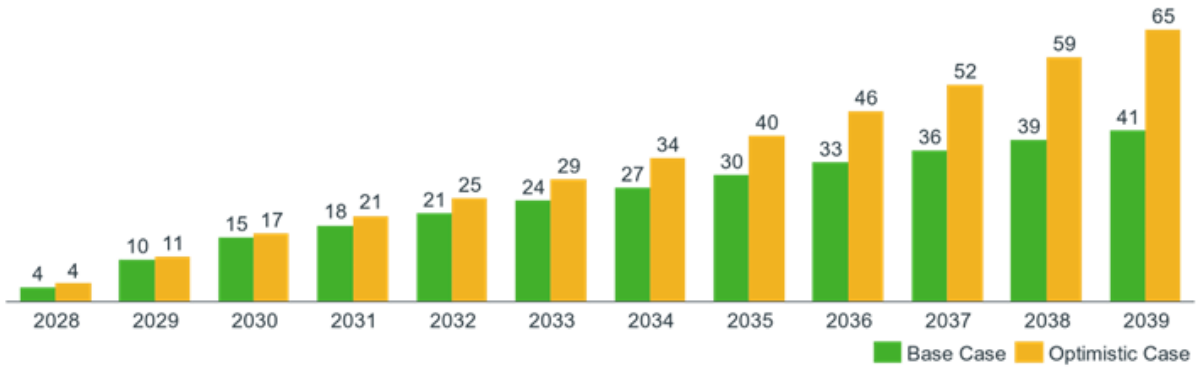
Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 20 Molecules Revenue for Quintex Pharma (Optimistic case, $Mn)	Enoxaparin				0.82	2.05	2.95	3.58	4.30	5.11	6.00	6.98	8.03	9.13	10.2	11.4
	Omeprazole				0.17	0.50	0.84	1.17	1.58	2.10	2.72	3.44	4.25	5.11	6.00	6.87
	Furosemide				0.02	0.05	0.09	0.14	0.18	0.21	0.25	0.30	0.35	0.40	0.46	0.52
	Oxytocin				0.67	1.50	2.61	3.55	4.23	4.72	5.24	5.77	6.32	6.86	7.40	7.93
	Tranexamic Acid				0.22	0.52	0.72	0.83	0.96	1.10	1.25	1.40	1.56	1.73	1.90	2.06
	Diclofenac				0.02	0.06	0.08	0.10	0.11	0.13	0.15	0.17	0.19	0.21	0.23	0.25
	Dexamethasone				0.08	0.18	0.25	0.28	0.31	0.35	0.39	0.43	0.47	0.51	0.55	0.59
	Midazolam				0.13	0.30	0.43	0.51	0.59	0.69	0.79	0.90	1.02	1.14	1.26	1.39
	Phytomenadione				0.03	0.08	0.12	0.15	0.19	0.23	0.27	0.32	0.38	0.44	0.50	0.57
	Propofol				0.01	0.02	0.04	0.07	0.09	0.11	0.13	0.16	0.19	0.22	0.25	0.29
	Vancomycin				0.73	1.89	2.79	3.49	4.30	5.25	6.33	7.56	8.91	10.39	11.97	13.63
	Ceftriaxone				0.18	0.75	1.12	1.34	1.58	1.85	2.1	2.5	2.8	3.2	3.5	3.9
	Carbetocin				0.06	0.29	0.47	0.60	0.76	0.96	1.18	1.44	1.74	2.07	2.44	2.82
	Heparin				0.18	0.42	0.55	0.62	0.68	0.76	0.83	0.91	0.98	1.06	1.14	1.21
	Hydrocortisone				0.17	0.40	0.53	0.60	0.66	0.73	0.80	0.88	0.95	1.03	1.10	1.17
	Phenytoin				0.10	0.24	0.34	0.40	0.47	0.55	0.63	0.72	0.82	0.92	1.02	1.13

6 Pricing Strategy

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Pethidine				0.07	0.15	0.25	0.33	0.38	0.41	0.44	0.47	0.51	0.54	0.57	0.59
	Metoclopramide				0.03	0.10	0.16	0.19	0.22	0.26	0.30	0.35	0.40	0.45	0.50	0.55
	Diazepam				0.04	0.09	0.12	0.14	0.17	0.19	0.22	0.25	0.28	0.32	0.35	0.39
	Ketamine				0.02	0.04	0.07	0.09	0.11	0.13	0.14	0.16	0.18	0.20	0.22	0.24
	Total				3.7	9.6	14.5	18.2	21.9	25.8	30.2	35.1	40.3	45.9	51.7	57.6

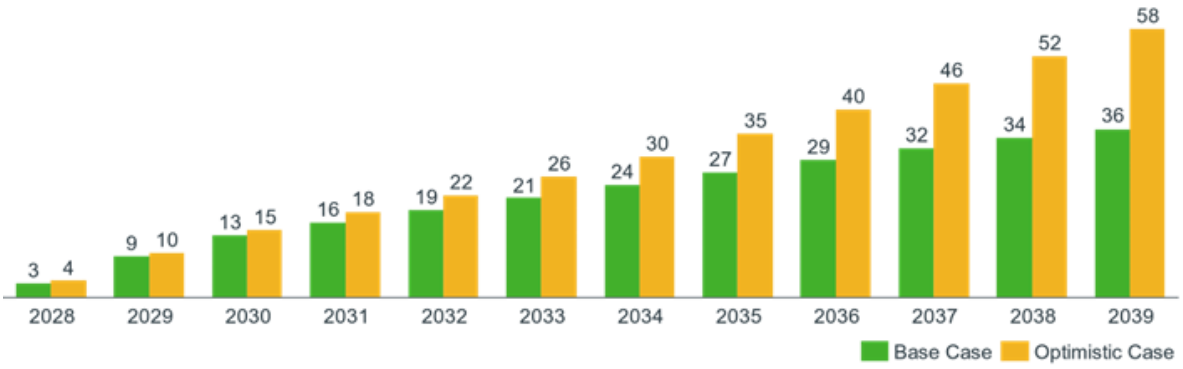
Source: IQVIA

Figure 6.5 Top 20 Molecules Gross Revenue – in $Mn



Source: IQVIA

Figure 6.6 Top 20 Molecules Net Revenue – in $Mn



Source: IQVIA

122 | Feasibility Studies Report

6.2 Forecast of Top 5 Molecules in ECOWAS

As per the aligned scope, IQVIA has developed a forecast for the 5 prioritized molecules in the top 3 countries within ECOWAS region in which IQVIA has sales data. These 3 countries have been selected based on the size of their injectable market in value. These 3 countries are Cote d'Ivoire, Senegal, and Burkina Faso. IQVIA has then scaled-up the forecast to the total ECOWAS countries based on the sales contribution of the top 3 countries.

Total ECOWAS countries in which IQVIA has sales data include: Cote d'Ivoire, Senegal, Burkina Faso, Benin, Congo, Guinee, Mali, Niger, and Togo.

6.2.1 Forecast Methodology

IQVIA forecasting is driven by 3 key elements: estimation of total molecule volumes in standard units, volume share of Quintex Pharma product and product pricing.

1. Estimation of total molecule volume in standard units: The molecule market in focused country is projected using exponential smoothing approach till end of forecast period.
2. Data Extrapolation: To ensure reflection of total market, retail data for the analysed FWA countries were extrapolated. This extrapolation was achieved based on IQVIA coverage in retail market. In addition, hospital data is also added to retail market based on segment contribution of each molecule in analogue countries i.e. Egypt, Tunisia, and Kenya to get total market.
3. Estimation of the achievable peak Market Share by molecule: IQVIA developed Quintex Pharma peak share assumptions taking into account availability of competitors in the country impacting the potential order of entry. To develop realistic assumptions of the peak share, IQVIA used its order of entry matrix to define peak share. This matrix has been developed by analysing market share captures by multiple new launched products in analogue countries.
4. Additionally, IQVIA applied an uptake curve to reach the estimated peak share. This uptake curve was derived from the analysis of the uptake of several new products in multiple countries.
5. Estimation of Quintex Pharma price for each molecule: Quintex Pharma price was estimated based on price of available competitors in the market. An additional discount of 5% was applied to provide Quintex Pharma products a price advantage versus existing players.

The revenue that Quintex Pharma can achieve from each molecule was then calculated using price & volume assumptions.

IQVIA created a base case scenario as well as an optimistic scenario assuming lesser competition and expected higher market share for Quintex Pharma.

6.2.2 Burkina Faso: Top 5 Molecule Forecast Assumptions & Outputs

6.2.2.1 Enoxaparin Forecast in Burkina Faso

Table 6.85 Enoxaparin Market in Burkina Faso

Parameters	Details
Molecule Size ($ K) (2024)	400

6 Pricing Strategy

Parameters	Details
Molecule Volume CAGR (2020-24)	8.2%
Vol PPG (2024 vs 2023)	-15%
No. of Competitors (2024)	3
Market Share % (2024)	Sanofi: 45% Troikaa: 40% Medis: 15%
Price (2024)	Highest: $ 4.01 (Sanofi) Lowest: $ 1.62 (Troikaa)

Source: IQVIA

Table 6.86 Forecast assumptions – Enoxaparin

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 5 Optimistic case: 4	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favourable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 11% Optimistic case: 15%	Based on Order of entry matrix, consider 11% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 15% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 1.54	Considered lowest SU price of the competitors in the market with 5% of price discount on the molecule to remain competitive
Price growth	2.2%	The price growth is assumed from the average growth of all competitors in the market
SU factor	2	Country Analysis (average)

124 | Feasibility Studies Report

Parameter	Assumption	Comments
Strength Split (2024)	2000IU: 3% 4000IU: 75% 6000IU: 18% 8000IU: 5%	

Source: IQVIA

Table 6.87 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Enoxaparin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.46	0.47	0.48	0.48	0.49	0.49	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.51	0.51
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				14	28	43	52	55	55	55	55	55	56	56	56
	Estimated Sales ($K)				24	48	75	93	101	103	106	108	111	114	116	119
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				19	38	58	70	75	75	75	75	76	76	76	76
	Estimated Sales ($K)				32	65	102	126	137	141	144	148	151	155	159	162

Source: IQVIA

Table 6.88 Quintex Pharma Volume Forecast by Strength - Enoxaparin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	2000 IU (SU, K)				0.4	1	1	2	2	2	2	2	2	2	2	2
	4000 IU (SU, K)				11	21	32	39	41	41	41	41	42	42	42	42
	6000 IU (SU, K)				3	5	8	9	10	10	10	10	10	10	10	10
	8000 IU (SU, K)				1	1	2	3	3	3	3	3	3	3	3	3
Potential Opportunity for	2000 IU (SU, K)				0.6	1	2	2	2	2	2	2	2	2	2	2

6 Pricing Strategy

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	4000 IU (SU, K)				14	28	44	53	56	56	56	57	57	57	57	57
	6000 IU (SU, K)				3	7	10	13	13	14	14	14	14	14	14	14
	8000 IU (SU, K)				1	2	3	4	4	4	4	4	4	4	4	4

Source: IQVIA

6.2.2.2 Furosemide Forecast in Burkina Faso

Table 6.89 Furosemide Market in Burkina Faso

Parameters	Details
Molecule Size ($ K) (2024)	1,856
Molecule Volume CAGR (2020-24)	27.6%
Vol PPG (2024 vs 2023)	6%
No. of Competitors (2024)	1
Market Share % (2024)	Sanofi: 99% IMEX Generics: 1%
Price (2024)	Highest: $ 1.17 (Reannon Pharma) Lowest: $ 0.02 (Renaudin)

Source: IQVIA

Table 6.90 Forecast Assumptions – Furosemide

Product launch year	2028	
Order of Entry	Base case:3 Optimistic case: 2	Sanofi dominates the market with over 99% share. Hence, assumed Quintex has to majorly compete with Sanofi. Hence, in base case assumed 3 order of entry for Quintex Pharma and 2nd in Optimistic scenario
Market share % (MS)	Base case: 20% Optimistic case: 36%	Based on Order of entry matrix, consider 20% peak share in Base case assuming entry of a new player in the market before Quintex Pharma

126 | Feasibility Studies Report

		In Optimistic case, assumed 36% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 0.79	Considered average SU price of competitors (lowest price of high selling products) in the market with 5% of price discount on the molecule to remain competitive
Price growth	2.2%	The price growth is assumed from the average growth of all competitors in the market
SU factor	3	Country Analysis (average)
Strength Split (2024)	20mg: 100%	

Source: IQVIA

Table 6.91 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Furosemide

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		1.9	1.9	2.0	2.0	2.0	2.1	2.1	2.1	2.1	2.1	2.2	2.2	2.2	2.2	2.2
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				106	210	325	395	422	426	429	433	435	438	440	442
	Estimated Sales ($K)				91	184	292	363	396	409	421	433	446	458	471	483
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				191	377	585	711	760	767	773	779	784	788	793	796
	Estimated Sales ($K)				164	332	526	653	713	735	758	780	802	825	847	870

Source: IQVIA

6 Pricing Strategy

6.2.2.3 Oxytocin Forecast in Burkina Faso

Table 6.92 Oxytocin Market in Burkina Faso

Parameters	Details
Molecule Size ($ K) (2024)	276
Molecule Volume CAGR (2020-24)	35.0%
Vol PPG (2024 vs 2023)	82%
No. of Competitors (2024)	3
Market Share % (2024)	Troikaa: 62% IMEX Generics: 38% Mylan: 0.3%
Price (2024)	Highest: $ 0.39 (Troikaa) Lowest: $ 0.35 (Mylan) & $ 0.36 (IMEX Generics)

Source: IQVIA

Table 6.93 Forecast Assumptions - Oxytocin

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 5 Optimistic case: 4	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favourable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 11% Optimistic case: 15%	Based on Order of entry matrix, consider 11% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 15% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 0.34	Considered lowest SU price considering sales availability for the molecule of the competitors in the market with 5% of price discount on the molecule to remain competitive

128 | Feasibility Studies Report

Parameter	Assumption	Comments
Price growth	2.2%	The price growth is assumed from the average growth of all competitors in the market
SU factor	5	Country Analysis (average)
Strength Split (2024)	5IU: 100%	

Source: IQVIA

Table 6.94 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Oxytocin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.3	0.4	0.5	0.5	0.6	0.6	0.7	0.7	0.7	0.8	0.8	0.8	0.8	0.9	0.9
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				16	34	55	71	79	82	85	88	90	92	94	96
	Estimated Sales ($K)				6	13	22	28	32	34	36	38	40	42	44	45
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				22	46	76	97	107	112	116	120	123	126	128	130
	Estimated Sales ($K)				8	18	29	38	44	47	49	52	55	57	59	62

Source: IQVIA

6.2.2.4 Omeprazole Forecast in Burkina Faso

Table 6.95 Omeprazole Market in Burkina Faso

Parameters	Details
Molecule Size ($ K) (2024)	1,495
Molecule Volume CAGR (2020-24)	29.7%
Vol PPG (2024 vs 2023)	9%

6 Pricing Strategy

Parameters	Details
No. of Competitors (2024)	8
Market Share % (2024)	Medical Pharmacy: 40% Caplin Point: 39% Dafra Pharma: 11% Others: 9%
Price (2024)	Highest: $ 5.27 (TLG Pharma) Lowest: $ 2.02 (BDA Pharma)

Source: IQVIA

6.2.2.5 Omeprazole Forecast

Table 6.96 Forecast Assumptions: Omeprazole

Parameters	Assumptions	Comments
Product launch year	2028	
Order of Entry	Base case: 10 Optimistic case: 9	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 3% Optimistic case: 4%	Based on Order of entry matrix, consider 3% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 4% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 2.16	Considered average SU price of competitors (lowest price of high selling products) in the market with 5% of price discount on the molecule to remain competitive
Price growth	2.2%	The price growth is assumed from the average growth of all competitors in the market
SU factor	1	Country Analysis (average)
Strength Split (2024)	40mg: 100%	

130 | Feasibility Studies Report

Source: IQVIA

Table 6.97 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Omeprazole

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		1.7	1.8	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.6	2.7	2.8	2.8	2.9	2.9
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				16	34	54	68	74	77	79	81	83	85	86	88
	Estimated Sales ($K)				39	81	133	170	191	202	212	222	233	243	253	263
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				22	45	72	90	99	102	105	108	111	113	115	117
	Estimated Sales ($K)				52	108	178	227	255	269	283	297	310	324	337	350

Source: IQVIA

6.2.2.6 Tranexamic Acid Forecast in Burkina Faso

Table 6.98 Tranexamic Acid Market in Burkina Faso

Parameters	Details
Molecule Size ($ K) (2024)	307
Molecule Volume CAGR (2020-24)	48.9%
Vol PPG (2024 vs 2023)	13%
No. of Competitors (2024)	2
Market Share % (2024)	Macleods: 56% Sanofi: 44%
Price (2024)	Highest: $ 2.14 (Sanofi) Lowest: $ 0.98 (Macleods)

Source: IQVIA

6 Pricing Strategy

Table 6.99 Forecast Assumptions Tranexamic Acid in Burkina Faso

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 4 Optimistic case: 3	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favourable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 15% Optimistic case: 20%	Based on Order of entry matrix, consider 15% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 20% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 0.93	Considered lowest SU price of the competitors in the market with 5% of price discount on the molecule to remain competitive
Price growth	2.2%	The price growth is assumed from the average growth of all competitors in the market
SU factor	5	Country Analysis (average)
Strength Split (2024)	500mg: 100%	

Source: IQVIA

132 | Feasibility Studies Report

Table 6.100 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts – Tranexamic Acid

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.3	0.4	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				16	33	53	66	72	74	76	77	79	80	81	82
	Estimated Sales ($K)				17	35	57	72	80	84	88	92	95	99	103	106
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				22	45	71	88	96	99	101	103	105	107	108	110
	Estimated Sales ($K)				22	46	75	96	107	112	117	122	127	132	137	142

Source: IQVIA

6.2.2.7 Burkina Faso: Revenue Forecast Summary

Table 6.101 Revenue Forecast: Base Case vs. Optimistic Case for Top 5 Molecules ($, K)

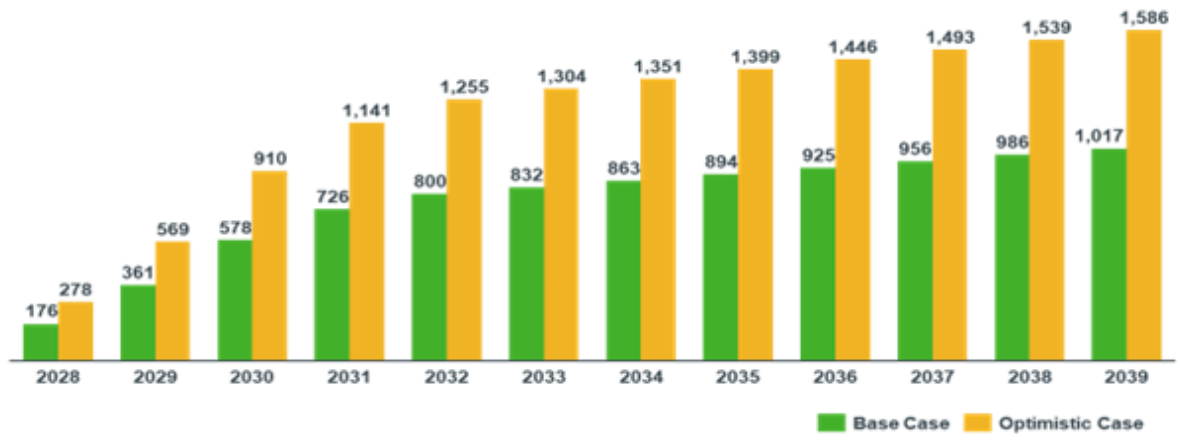
Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 5 Molecules Revenue for Quintex Pharma (Base case, $K)	Enoxaparin				24	48	75	93	101	103	106	108	111	114	116	119
	Furosemide				91	184	292	363	396	409	421	433	446	458	471	483
	Oxytocin				6	13	22	28	32	34	36	38	40	42	44	45
	Omeprazole				39	81	133	170	191	202	212	222	233	243	253	263
	Tranexamic Acid				17	35	57	72	80	84	88	92	95	99	103	106
	Total				176	361	578	726	800	832	863	894	925	956	986	1,017
Top 5 M	Enoxaparin				32	65	102	126	137	141	144	148	151	155	159	162

6 Pricing Strategy

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	Furosemide				164	332	526	653	713	735	758	780	802	825	847	870
	Oxytocin				8	18	29	38	44	47	49	52	55	57	59	62
	Omeprazole				52	108	178	227	255	269	283	297	310	324	337	350
	Tranexamic Acid				22	46	75	96	107	112	117	122	127	132	137	142
	Total				278	569	910	1,141	1,255	1,304	1,351	1,399	1,446	1,493	1,539	1,586

Source: IQVIA

Figure 6.7 Top 5 Molecules Revenue for Burkina Faso – in $K



Source: IQVIA

6.2.3 Cote d'Ivoire: Top 5 Molecule Forecast Assumptions & Outputs

6.2.3.1 Enoxaparin Forecast

Table 6.102 Enoxaparin Market in Cote d'Ivoire

Parameters	Details
Molecule Size ($ K) (2024)	372
Molecule Volume CAGR (2020-24)	20.1%
Vol PPG (2024 vs 2023)	31%
No. of Competitors (2024)	5

134 | Feasibility Studies Report

Parameters	Details
Market Share % (2024)	Sanofi: 52% Troikaa: 28% Medis: 18% Others: 1%
Price (2024)	Highest: $ 4.32 (Biogaran) Lowest: $ 1.71 (Troikaa)

Source: IQVIA

Table 6.103 Forecast assumptions - Enoxaparin

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 7 Optimistic case: 6	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 7% Optimistic case: 9%	Based on Order of entry matrix, consider 7% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 9% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 1.63	Considered lowest SU price of the competitors in the market with 5% of price discount on the molecule to remain competitive
Price growth	1.7%	The price growth is assumed from the average growth of all competitors in the market
SU factor	2	Country Analysis (average)
Strength Split (2024)	2000IU: 3.45% 4000IU: 91.72% 6000IU: 3.84% 8000IU: 1%	

Source: IQVIA

6 Pricing Strategy

Table 6.104 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Enoxaparin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.4	0.5	0.5	0.6	0.6	0.7	0.7	0.8	0.8	0.8	0.8	0.9	0.9	0.9	0.9
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				11	23	38	48	53	55	57	59	60	62	63	64
	Estimated Sales ($K)				19	41	68	88	99	104	110	115	120	125	129	134
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				14	30	49	62	68	71	73	75	77	79	81	82
	Estimated Sales ($K)				25	53	87	113	127	134	141	148	154	160	166	172

Source: IQVIA

Table 6.105 Quintex Pharma Volume Forecast by Strength - Enoxaparin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	2000 IU (SU, K)				0.4	0.8	1.3	1.7	1.8	1.9	2.0	2.0	2.1	2.1	2.2	2.2
	4000 IU (SU, K)				10.1	21.3	34.7	43.9	48.6	50.5	52.2	53.8	55.2	56.4	57.6	58.6
	6000 IU (SU, K)				0.4	0.9	1.5	1.8	2.0	2.1	2.2	2.3	2.3	2.4	2.4	2.5
	8000 IU (SU, K)				0.1	0.2	0.4	0.5	0.5	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	2000 IU (SU, K)				0.5	1.0	1.7	2.1	2.3	2.4	2.5	2.6	2.7	2.7	2.8	2.8
	4000 IU (SU, K)				13.0	27.4	44.6	56.4	62.4	64.9	67.1	69.1	70.9	72.6	74.0	75.3
	6000 IU (SU, K)				0.5	1.1	1.9	2.4	2.6	2.7	2.8	2.9	3.0	3.0	3.1	3.2

136 | Feasibility Studies Report

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	8000 IU (SU, K)				0.1	0.3	0.5	0.6	0.7	0.7	0.7	0.8	0.8	0.8	0.8	0.8

Source: IQVIA

6.2.3.2 Furosemide Forecast

Table 6.106 Furosemide Market in Cote d'Ivoire

Parameters	Details
Molecule Size ($ K) (2024)	1,022
Molecule Volume CAGR (2020-24)	18.6%
Vol PPG (2024 vs 2023)	28%
No. of Competitors (2024)	2
Market Share % (2024)	Sanofi: 96% IMEX Generics: 4%
Price (2024)	Highest: $ 0.94 (Sanofi) Lowest: $ 0.68 (IMEX Generics)

Source: IQVIA

Table 6.107 Forecast Assumptions – Furosemide

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 4 Optimistic case: 3	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 15% Optimistic case: 20%	Based on Order of entry matrix, consider 15% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 20% peak share with no new player entry in the market before Quintex Pharma

6 Pricing Strategy

Parameter	Assumption	Comments
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 0.77	Considered average SU price of existing competitors in the market with 5% of price discount on the molecule to remain competitive
Price growth	1.7%	The price growth is assumed from the average growth of all competitors in the market
SU factor	3	Country Analysis (average)
Strength Split (2024)	20mg: 100% 250mg: 0%	

Source: IQVIA

Table 6.108 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Furosemide

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		1.1	1.1	1.2	1.3	1.3	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.6	1.6	1.6
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				50	102	161	199	216	220	224	228	231	234	236	238
	Estimated Sales ($K)				41	85	137	172	190	197	204	211	217	224	230	236
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				67	136	215	266	288	294	299	304	308	311	315	317
	Estimated Sales ($K)				55	114	183	230	253	263	272	281	290	298	307	314

Source: IQVIA

138 | Feasibility Studies Report

Table 6.109 Quintex Pharma Volume Forecast by Strength - Furosemide

Key	Time Period	2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	20mg (SU, K)				50	102	161	199	216	220	224	228	231	234	236	238
	250mg (SU, K)				-	-	-	-	-	-	-	-	-	-	-	-
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	20mg (SU, K)				67	136	215	266	288	294	299	304	308	311	315	317
	250mg (SU, K)				-	-	-	-	-	-	-	-	-	-	-	-

Source: IQVIA

6.2.3.3 Oxytocin Forecast

Table 6.110 Oxytocin Market in Cote d'Ivoire

Parameters	Details
Molecule Size ($ K) (2024)	3,482
Molecule Volume CAGR (2020-24)	6.3%
Vol PPG (2024 vs 2023)	-10%
No. of Competitors (2024)	4
Market Share % (2024)	Troikaa: 74% IMEX Generics: 14% Mylan: 6% Pharmaco: 7%
Price (2024)	Highest: $ 0.43 (Mylan) Lowest: $ 0.31 (Pharmaco)

Source: IQVIA

6 Pricing Strategy

Table 6.111 Forecast Assumptions – Oxytocin

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 6 Optimistic case: 5	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 9% Optimistic case: 11%	Based on Order of entry matrix, consider 9% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 11% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 0.31	Considered average SU price of competitors (lowest price of high selling products) in the market with 5% of price discount on the molecule to remain competitive
Price growth	1.7%	The price growth is assumed from the average growth of all competitors in the market
SU factor	5	Country Analysis (average)

Source: IQVIA

140 | Feasibility Studies Report

Table 6.112 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Oxytocin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		3.9	4.3	4.5	4.8	4.9	5.1	5.2	5.3	5.4	5.5	5.5	5.6	5.6	5.7	5.7
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				113	229	361	445	479	487	493	498	503	506	509	511
	Estimated Sales ($K)				38	78	125	157	172	178	183	188	193	197	202	206
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				138	280	442	543	586	595	603	609	614	618	622	625
	Estimated Sales ($K)				46	95	153	192	210	217	224	230	236	241	247	252

Source: IQVIA

6.2.3.4 Omeprazole Forecast

Table 6.113 Omeprazole Market in Cote d'Ivoire

Parameters	Details
Molecule Size ($ K) (2024)	696
Molecule Volume CAGR (2020-24)	29.2%
Vol PPG (2024 vs 2023)	2%
No. of Competitors (2024)	6
Market Share % (2024)	Medical Pharmacy: 83% Dafra Pharma: 6% Strides: 5% Medis: 3% Caplin Point: 2%

6 Pricing Strategy

Parameters	Details
Price (2024)	Highest: $ 5.33 (TLG Pharma) Lowest: $ 2.45 (Medical Pharmacy)

Source: IQVIA

Table 6.114 Forecast Assumptions: Omeprazole

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 8 Optimistic case: 7	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 6% Optimistic case: 7%	Based on Order of entry matrix, consider 6% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 7% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 2.33	Considered lowest SU price of the competitors in the market with 5% of price discount on the molecule to remain competitive
Price growth	1.7%	The price growth is assumed from the average growth of all competitors in the market
SU factor	1	Country Analysis (average)
Strength Split (2024)	40mg: 100%	

Source: IQVIA

142 | Feasibility Studies Report

Table 6.115 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Omeprazole

Key \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.8	0.8	0.9	0.9	0.9	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				14	29	45	55	60	60	61	62	62	62	63	63
	Estimated Sales ($K)				36	73	117	145	159	163	168	172	176	181	184	188
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				17	34	53	65	69	70	71	72	72	73	73	73
	Estimated Sales ($K)				42	85	136	169	185	191	196	201	206	211	215	220

Source: IQVIA

6.2.3.5 Tranexamic Acid Forecast

Table 6.116 Tranexamic Market in Cote d'Ivoire

Parameters	Details
Molecule Size ($ K) (2024)	59
Molecule Volume CAGR (2020-24)	-14.4%
Vol PPG (2024 vs 2023)	-22%
No. of Competitors (2024)	3
Market Share % (2024)	Aguettant: 51% Zee Laboratories: 39% Sanofi: 10%
Price (2024)	Highest: $ 1.75 (Sanofi) Lowest: $ 1.19 (Zee Laboratories)

Source: IQVIA

6 Pricing Strategy

Table 6.117 Forecast Assumptions – Tranexamic Acid

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 5 Optimistic case: 4	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 11% Optimistic case: 15%	Based on Order of entry matrix, consider 11% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 15% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 1.13	Considered lowest SU price of the competitors in the market with 5% of price discount on the molecule to remain competitive
Price growth	1.7%	The price growth is assumed from the average growth of all competitors in the market
SU factor	5	Country Analysis (average)
Strength Split (2024)	100mg: 51% 500mg: 49%	

Source: IQVIA

144 | Feasibility Studies Report

Table 6.118 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts – Tranexamic Acid

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				3	5	8	10	10	10	10	10	10	10	10	10
	Estimated Sales ($K)				3	6	10	12	13	14	14	14	15	15	15	15
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				4	7	11	13	14	14	14	14	14	14	14	14
	Estimated Sales ($K)				4	9	14	17	18	19	19	19	20	20	20	21

Source: IQVIA

Table 6.119 Quintex Pharma Volume Forecast by Strength – Tranexamic Acid

Key \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	100mg (SU, K)				1.3	2.7	4.1	5.0	5.3	5.3	5.3	5.3	5.3	5.3	5.3	5.3
	500mg (SU, K)				1.3	2.6	3.9	4.8	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	100mg (SU, K)				1.8	3.6	5.6	6.8	7.2	7.3	7.3	7.3	7.3	7.3	7.3	7.3
	500mg (SU, K)				1.7	3.5	5.4	6.5	6.9	7.0	7.0	7.0	7.0	7.0	7.0	7.0

6 Pricing Strategy

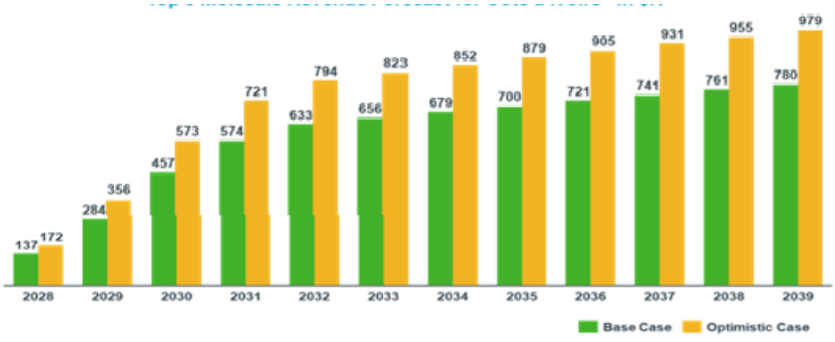
6.2.3.6 Cote d'Ivoire: Revenue Forecast Summary

Table 6.120 Revenue Forecast: Base Case vs. Optimistic Case for Top 5 Molecules ($, K)

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 5 Molecules Revenue for Quintex Pharma (Base case, $K)	Enoxaparin				19	41	68	88	99	104	110	115	120	125	129	134
	Furosemide				41	85	137	172	190	197	204	211	217	224	230	236
	Oxytocin				38	78	125	157	172	178	183	188	193	197	202	206
	Omeprazole				36	73	117	145	159	163	168	172	176	181	184	188
	Tranexamic Acid				3	6	10	12	13	14	14	14	15	15	15	15
	Total				137	284	457	574	633	656	679	700	721	741	761	780
Top 5 Molecules Revenue for Quintex Pharma (Optimistic case, $ K)	Enoxaparin				25	53	87	113	127	134	141	148	154	160	166	172
	Furosemide				55	114	183	230	253	263	272	281	290	298	307	314
	Oxytocin				46	95	153	192	210	217	224	230	236	241	247	252
	Omeprazole				42	85	136	169	185	191	196	201	206	211	215	220
	Tranexamic Acid				4	9	14	17	18	19	19	19	20	20	20	21
	Total				172	356	573	721	794	823	852	879	905	931	955	979

Source: IQVIA

Figure 6.8 Top 5 Molecule Revenue in Cote d'Ivoire – in $K



146 | Feasibility Studies Report

6.2.4 enegal: Top 5 Molecule Forecast Assumptions & Outputs

6.2.4.1 Enoxaparin Forecast in Senegal

Table 6.121 Enoxaparin FMarket in Senegal

Parameters	Details
Molecule Size ($ K) (2024)	652
Molecule Volume CAGR (2020-24)	9.5%
Vol PPG (2024 vs 2023)	-0.01%
No. of Competitors (2024)	5
Market Share % (2024)	Sothema: 50% Troikaa: 36% Sanofi: 12% Medis: 2%
Price (2024)	Highest: $ 4.51 (Amagen India) Lowest: $ 1.21 (Troikaa)

Source: IQVIA

Table 6.122 Forecast assumptions – Enoxaparin

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 7 Optimistic case: 6	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 7% Optimistic case: 9%	Based on Order of entry matrix, consider 7% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 9% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 1.15	Considered lowest SU price of the competitors in the market with 5% of price discount on the molecule to remain competitive

6 Pricing Strategy

Parameter	Assumption	Comments
Price growth	2.1%	The price growth is assumed from the average growth of all competitors in the market
SU factor	2	Country Analysis (average)
Strength Split (2024)	2000IU: 1% 4000IU: 83% 6000IU:12% 8000IU: 4%	

Source: IQVIA

Table 6.123 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Enoxaparin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				12	24	38	45	48	48	48	49	49	49	49	49
	Estimated Sales ($K)				16	31	49	60	65	67	68	70	72	73	75	77
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				16	31	48	58	62	62	62	62	63	63	63	63
	Estimated Sales ($K)				20	40	63	77	84	86	88	90	92	94	96	98

Source: IQVIA

148 | Feasibility Studies Report

Table 6.124 Quintex Pharma Volume Forecast by Strength - Enoxaparin

Key \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	2000 IU (SU, K)				0.1	0.2	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	4000 IU (SU, K)				10.4	20.3	31.2	37.6	39.9	40.1	40.2	40.3	40.4	40.5	40.5	40.6
	6000 IU (SU, K)				1.5	2.9	4.5	5.4	5.8	5.8	5.8	5.8	5.8	5.8	5.9	5.9
	8000 IU (SU, K)				0.5	1.0	1.5	1.8	1.9	1.9	1.9	1.9	1.9	1.9	2.0	2.0
Potential Opportunity for Quintex Pharma (Optimistic case) (by strength)	2000 IU (SU, K)				0.2	0.3	0.5	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
	4000 IU (SU, K)				13.3	26.1	40.1	48.4	51.3	51.5	51.7	51.8	51.9	52.0	52.1	52.2
	6000 IU (SU, K)				1.9	3.8	5.8	7.0	7.4	7.4	7.5	7.5	7.5	7.5	7.5	7.5
	8000 IU (SU, K)				0.6	1.3	1.9	2.3	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5

Source: IQVIA

6.2.4.2 Furosemide Forecast in Senegal

Table 6.125 Furosemide Market in Senegal

Parameters	Details
Molecule Size ($ K) (2024)	605
Molecule Volume CAGR (2020-24)	4.7%
Vol PPG (2024 vs 2023)	0.02%
No. of Competitors (2024)	2
Market Share % (2024)	Sanofi: 98% Pharmacie Nationale: 2%
Price (2024)	Highest: $ 0.52 (Sanofi) Lowest: $ 0.07 (Pharmacie Nationale)

Source: IQVIA

6 Pricing Strategy

Table 6.126 Forecast Assumptions – Furosemide

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 4 Optimistic case: 3	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 15% Optimistic case: 20%	Based on Order of entry matrix, consider 15% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 20% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 0.50	Considered SU price of competitors (lowest price of high selling product) in the market with 5% of price discount on the molecule to remain competitive
Price growth	2.1%	The price growth is assumed from the average growth of all competitors in the market
SU factor	3	Country Analysis (average)
Strength Split (2024)	20mg: 100%	

Source: IQVIA

150 | Feasibility Studies Report

Table 6.127 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Furosemide

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Potential Opportunity for	Estimated Volume (SU K)				26	51	79	96	103	104	105	106	107	108	109	110
	Estimated Sales ($K)				14	28	44	55	60	62	64	66	68	70	72	74
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				34	68	106	128	137	139	140	142	143	144	145	147
	Estimated Sales ($K)				19	37	59	74	80	83	86	88	91	94	96	99

Source: IQVIA

6.2.4.3 Forecast Oxytocin in Senegal

Table 6.128 Oxytocin Market in Senegal

Parameters	Details
Molecule Size ($ K) (2024)	1,515
Molecule Volume CAGR (2020-24)	-3.9%
Vol PPG (2024 vs 2023)	3%
No. of Competitors (2024)	2
Market Share % (2024)	Troikaa: 75% Pharmaco: 25%
Price (2024)	Highest: $ 0.28 (Pharmaco, Troikaa) Lowest: $ 0.28 (Pharmaco, Troikaa)

Source: IQVIA

6 Pricing Strategy

Table 6.129 Forecast Assumptions – Oxytocin

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case:4 Optimistic case: 3	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 15% Optimistic case: 20%	Based on Order of entry matrix, consider 15% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 20% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 0.26	Considered lowest SU price of the competitors in the market with 5% of price discount on the molecule to remain competitive
Price growth	2.1%	The price growth is assumed from the average growth of all competitors in the market
SU factor	5	Country Analysis (average)
Strength Split (2024)	5IU: 100%	

Source: IQVIA

152 | Feasibility Studies Report

Table 6.130 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Oxytocin

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		1.7	1.9	2.0	2.1	2.2	2.3	2.3	2.4	2.4	2.5	2.5	2.5	2.6	2.6	2.6
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				83	170	268	332	359	366	372	377	382	385	389	391
	Estimated Sales ($K)				24	50	80	101	112	116	121	125	129	133	137	141
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				111	226	358	442	479	488	496	503	509	514	518	522
	Estimated Sales ($K)				32	66	107	135	149	155	161	167	172	177	183	188

Source: IQVIA

6.2.4.4 Forecast Omeprazole in Senegal

Table 6.131 Omeprazole Market in Senegal Omeprazole Market in Senegal

Parameters	Details
Molecule Size ($ K) (2024)	1,085
Molecule Volume CAGR (2020-24)	36.3%
Vol PPG (2024 vs 2023)	24%
No. of Competitors (2024)	7
Market Share % (2024)	Arrow Generiques: 45% Medical Pharmacy: 23% Dafra Pharma: 12% Strides: 8% Caplin Point: 6% BDA Pharma: 5%

6 Pricing Strategy

Parameters	Details
Price (2024)	Highest: $ 4.86 (Strides) Lowest: $ 1.30 (BDA Pharma)

Source: IQVIA

Table 6.132 Forecast Assumptions: Omeprazole

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 9 Optimistic case: 8	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 4% Optimistic case: 6%	Based on Order of entry matrix, consider 6% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 7% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 1.80	Considered average SU price of competitors (lowest price of high selling products) in the market with 5% of price discount on the molecule to remain competitive
Price growth	2.1%	The price growth is assumed from the average growth of all competitors in the market
SU factor	1	Country Analysis (average)
Strength Split (2024)	40mg: 100%	

Source: IQVIA

154 | Feasibility Studies Report

Table 6.133 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts - Omeprazole

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		1.2	1.3	1.4	1.5	1.6	1.6	1.6	1.7	1.7	1.7	1.7	1.7	1.8	1.8	1.8
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				16	32	50	62	67	68	69	69	70	70	70	71
	Estimated Sales ($K)				31	64	103	129	142	147	151	156	160	165	169	173
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				24	48	76	93	100	102	103	104	104	105	106	106
	Estimated Sales ($K)				46	96	154	193	212	220	227	234	241	247	254	260

Source: IQVIA

6.2.4.5 Tranexamic Acid Forecast

Table 6.134 Tranexamic Acid Market in Senegal

Parameters	Details
Molecule Size ($ K) (2024)	31
Molecule Volume CAGR (2020-24)	20.6%
Vol PPG (2024 vs 2023)	534%
No. of Competitors (2024)	2
Market Share % (2024)	Sanofi: 72% Aguettant: 28%
Price (2024)	Highest: $ 1.73 (Sanofi) Lowest: $ 1.30 (Aguettant)

Source: IQVIA

6 Pricing Strategy

Table 6.135 Forecast Assumptions – Tranexamic Acid

Parameter	Assumption	Comments
Product launch year	2028	
Order of Entry	Base case: 4 Optimistic case: 3	The base case assumes a moderate scenario where one player will enter before Quintex Pharma, while the optimistic case anticipates a more favorable scenario where Quintex Pharma will be the first player
Market share % (MS)	Base case: 15% Optimistic case: 20%	Based on Order of entry matrix, consider 15% peak share in Base case assuming entry of a new player in the market before Quintex Pharma In Optimistic case, assumed 20% peak share with no new player entry in the market before Quintex Pharma
Uptake curve	Moderate 5 years	Moderate uptake curve is assumed considering existing competition
SU Price (2024)	$ 1.23	Considered lowest SU price of the competitors in the market with 5% of price discount on the molecule to remain competitive
Price growth	2.1%	The price growth is assumed from the average growth of all competitors in the market
SU factor	5	Country Analysis (average)
Strength Split (2024)	100mg: 28% 500mg: 72%	

Source: IQVIA

156 | Feasibility Studies Report

Table 6.136 Volume (Total Market & Quintex Pharma) and Sales (Quintex Pharma) Forecasts – Tranexamic Acid

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Total Molecule Volume (SU Mn)		0.03	0.04	0.04	0.04	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Potential Opportunity for Quintex Pharma (Base case)	Estimated Volume (SU K)				2	3	6	7	7	8	8	8	8	8	8	8
	Estimated Sales ($K)				2	5	8	10	11	11	12	12	13	13	13	14
Potential Opportunity for Quintex Pharma (Optimistic case)	Estimated Volume (SU K)				2	5	7	9	10	10	10	10	11	11	11	11
	Estimated Sales ($K)				3	6	10	13	15	15	16	16	17	17	18	18

Source: IQVIA

Table 6.137 Quintex Pharma Volume Forecast by Strength – Tranexamic Acid

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Potential Opportunity for Quintex Pharma (Base case) (by Strength)	100mg (SU, K)				0.47	0.98	1.56	1.93	2.10	2.14	2.17	2.20	2.22	2.24	2.25	2.26
	500mg (SU, K)				1.22	2.51	4.01	4.97	5.39	5.50	5.59	5.66	5.71	5.75	5.79	5.82
Potential Opportunity for Quintex Pharma (Optimistic	100mg (SU, K)				0.63	1.30	2.08	2.58	2.80	2.85	2.90	2.93	2.96	2.98	3.00	3.02

6 Pricing Strategy

Key Components \ Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
	500mg (SU, K)				1.63	3.35	5.34	6.63	7.19	7.33	7.45	7.54	7.61	7.67	7.72	7.76

Source: IQVIA

6.2.4.6 Senegal: Revenue Forecast Summary

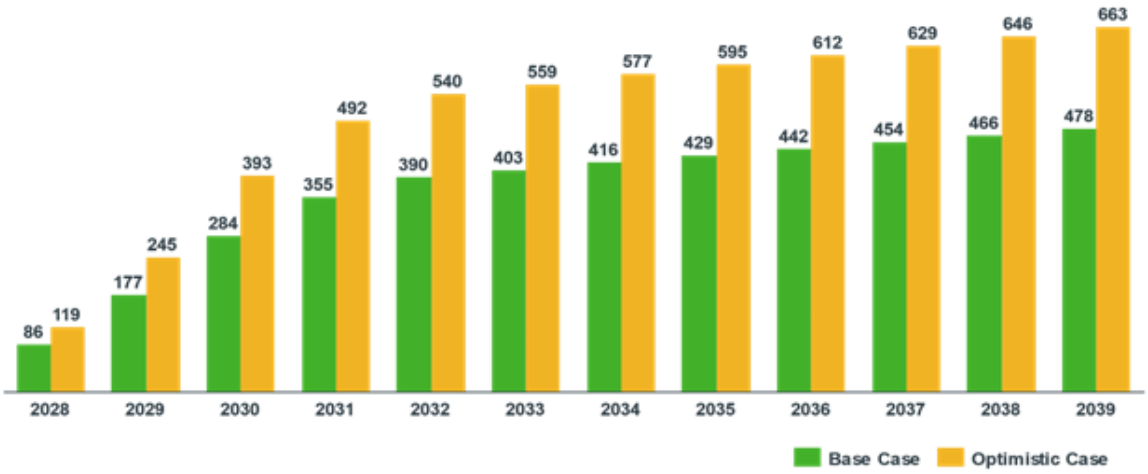
Table 6.138 Revenue Forecast: Base Case vs. Optimistic Case for Top 5 Molecules ($, K)

Key \ Time Period		2025F	2026F	2027F	2028F		2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F
Top 5 Molecules Revenue for Quintex Pharma (Base case, $K)	Enoxaparin				16		31	49	60	65	67	68	70	72	73	75
	Furosemide				14		28	44	55	60	62	64	66	68	70	72
	Oxytocin				24		50	80	101	112	116	121	125	129	133	137
	Omeprazole				31		64	103	129	142	147	151	156	160	165	169
	Tranexamic Acid				2		5	8	10	11	11	12	12	13	13	13
	Total				86		177	284	355	390	403	416	429	442	454	466
Top 5 Molecules Revenue for Quintex Pharma (Optimistic case, $ K)	Enoxaparin				20		40	63	77	84	86	88	90	92	94	96
	Furosemide				19		37	59	74	80	83	86	88	91	94	96
	Oxytocin				32		66	107	135	149	155	161	167	172	177	183
	Omeprazole				46		96	154	193	212	220	227	234	241	247	254
	Tranexamic Acid				3		6	10	13	15	15	16	16	17	17	18
	Total				119		245	393	492	540	559	577	595	612	629	646

Source: IQVIA

158 | Feasibility Studies Report

Figure 6.9 Top 5 Molecule Revenue Senegal in -$K_



Source: IQVIA

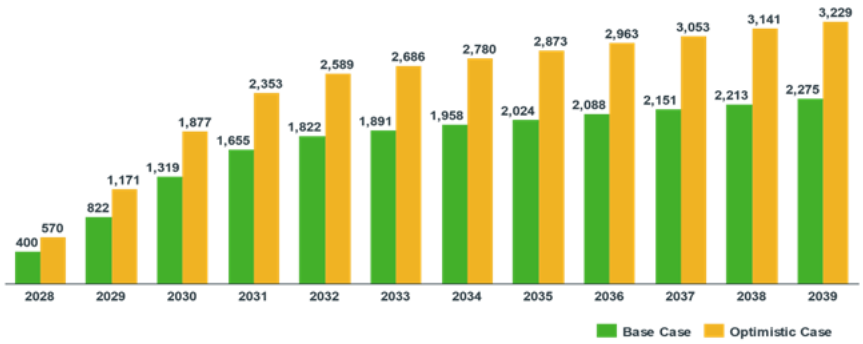
6.2.4.7 Burkina Faso, Cote d'Ivoire, and Senegal: Revenue Forecast Summary

Table 6.139 Revenue Forecast: Base Case vs. Optimistic Case for Top 5 Molecules ($, K)

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 5 Molecules Revenue for Quintex Pharma (Base case, $K)	Burkina Faso				176	361	578	726	800	832	863	894	925	956	986	1,017
	Cote d'Ivoire				137	284	457	574	633	656	679	700	721	741	761	780
	Senegal				86	177	284	355	390	403	416	429	442	454	466	478
	Total				400	822	1,319	1,655	1,822	1,891	1,958	2,024	2,088	2,151	2,213	2,275
Top 5 Molecules Revenue for Quintex Pharma (Optimistic case, $ K)	Burkina Faso				278	569	910	1,141	1,255	1,304	1,351	1,399	1,446	1,493	1,539	1,586
	Cote d'Ivoire				172	356	573	721	794	823	852	879	905	931	955	979
	Senegal				119	245	393	492	540	559	577	595	612	629	646	663
	Total				570	1,171	1,877	2,353	2,589	2,686	2,780	2,873	2,963	3,053	3,141	3,229

160 | Feasibility Studies Report

Figure 6.10 Top 5 Molecule Revenue Forecast for Burkina Faso, Cote d'Ivoire & Senegal – in $K



Source: IQVIA

6.2.5 ECOWAS: Revenue Forecast

To forecast the revenue for the ECOWAS region, IQVIA focused on the contributions from Burkina Faso, Côte d'Ivoire, and Senegal. These three countries collectively account for 49% of the total market within ECOWAS. By analyzing their revenue contributions, IQVIA extrapolated the overall revenue for entire ECOWAS region.

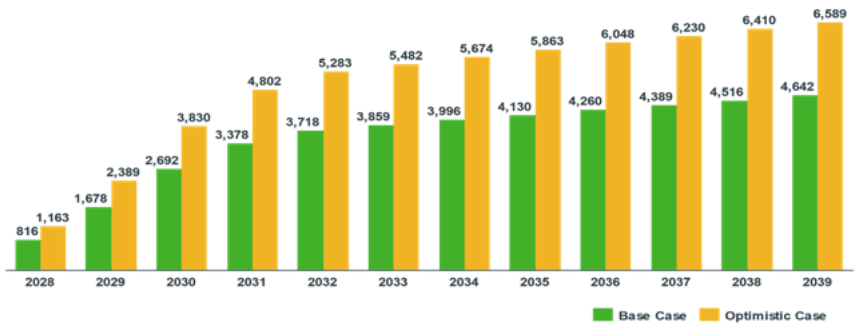
Table 6.140 Revenue Forecast: Base Case vs. Optimistic Case for Top 5 Molecules ($, K)

Key Components / Time Period		2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
Top 5 Molecules Revenue for Quintex Pharma (Base case, $K)	ECOWAS				816	1,678	2,692	3,378	3,718	3,859	3,996	4,130	4,260	4,389	4,516	4,642
Top 5 Molecules Revenue for Quintex Pharma (Optimistic case, $ K)	ECOWAS				1,163	2,389	3,830	4,802	5,283	5,482	5,674	5,863	6,048	6,230	6,410	6,589

Source: IQVIA

162 | Feasibility Studies Report

Figure 6.11 Top 5 Molecule Revenue Forecast for ECOWAS– in $K



Source: IQVIA

7 Stakeholder Engagement Strategy and Communication Plan

7.1 Objectives of the present chapter

1. To identify the key stakeholders crucial to Quintex Pharma business and understand the relationship and influence between all stakeholders.
2. To enable alignment of strategy in line with changing trends and behaviours of the key stakeholders
3. To enable effective and efficient engagement and communication channels with key stakeholders across all stages of the development of the biopharmaceutical injectable manufacturing plant, to build trust and ensure alignment of expectations.
4. To drive stakeholder-driven decision-making by integrating feedback from stakeholders like investors, suppliers, healthcare providers, and policymakers into the plant's development strategy, ensuring commercial viability and long-term sustainability

7.2 Stakeholders Mapping

7.2.1 Stakeholder identification and analysis

For the purposes of this plan, and consistent with Quintex Pharma terminology, Stakeholders are persons or groups who are directly or indirectly affected by the activities of this project or business, as well as those who may have interests in the project or business and/or the ability to influence its outcome, either positively or negatively.

Engagement is a two-way process whereby information is exchanged, and ideas and concerns are communicated and genuinely considered to inform and guide key business decisions and activities.

The stakeholders relevant to this project are categorized into the following groups:

7.2.1.1 Government & Regulatory Bodies

- Ministry of Health (MoH) – Policy direction and regulatory oversight.
- Ghana Health Service – Oversees public healthcare institutions and procurement.
- Ghana Food and Drugs Authority (FDA) – Product approval, compliance, and Good Manufacturing Practice (GMP) certification.
- Pharmacy Council of Ghana – Regulation of pharmaceutical professionals.
- Ghana Standards Authority (GSA) – Quality and safety standards.
- Ghana Investment Promotion Centre (GIPC) – Investment facilitation and incentives.

164 | Feasibility Studies Report

- Ministry of Trade, Agribusiness, and Industry – Industrial policy alignment and incentives.
- Ghana Revenue Authority (GRA) – Taxation and fiscal policy.
- Environmental Protection Agency (EPA) – Environmental impact assessments.

7.2.1.2 Healthcare Ecosystem & End Users (Customers)

- Public Health Institutions (Korle-Bu Teaching Hospital, Komfo Anokye Teaching Hospital, regional hospitals, district hospitals etc.) – Key end-users (customers) of biopharmaceutical injectables.
- Private Hospitals & Clinics (Nyaho Medical Centre, Trust Hospital, Focos Orthopaedics Hospital, Lister Hospital etc) – Key end-users (customers) of biopharmaceutical injectables.
- National Health Insurance Authority (NHIA) – Reimbursement and insurance coverage for injectables.
- Healthcare Professional Associations (Ghana Medical Association, Pharmaceutical Society of Ghana, etc.) – Advocacy and collaboration.

7.2.1.3 Industry & Business Partners

- Local Pharmaceutical Manufacturers – Potential collaborators and competitors.
- International Pharma Partners – Joint venture partners.
- Raw Material Suppliers – Local and international sourcing.
- Distributors & Wholesalers – Supply chain partners.
- Retail Pharmacies – Downstream distribution.

7.2.1.4 Financial & Investment Institutions

- Local & International Banks – Project financing.
- Development Finance Institutions (e.g., AfDB, World Bank, IFC) – Potential funding and technical assistance.
- Private Equity & Venture Capital Firms – Investment opportunities.

7.2.1.5 Regional, Continental, and international stakeholders

- World Health Organization – Public health impact, quality standards
- Africa CDC – Public health impact
- AfCFTA/African Union – Regional development, trade implications
- International Donors/Aid Organizations – Healthcare improvement, economic development

7.3 Stakeholder Engagement Plan

The following Stakeholder Engagement Plan (SEP) has been developed relative to the four key stages of this project and the necessary engagement activities. Each stage presents unique requirements and challenges necessitating targeted engagement with relevant stakeholders. These stages include:

7.3.1 Stage 1: Feasibility / Exploration

This stage focuses on assessing the viability of the manufacturing plant. It involves conducting in-depth feasibility studies, market research, regulatory assessments, and technical evaluations to determine the demand, operational requirements, and potential challenges. Key activities include; Market and demand analysis for injectable pharmaceuticals, regulatory and policy landscape assessment, site selection and infrastructure feasibility studies, stakeholder identification and preliminary engagement, cost estimation and initial business case development.

7.3.2 Stage 2: Financing / Strategic investment

During this stage, efforts are directed toward securing the necessary financial resources to develop the manufacturing facility. This involves engaging investors, financial institutions, and development partners. Key activities include; Development of a detailed investment and financing strategy, identification and engagement of potential investors and funding agencies, securing government incentives, grants, or public-private partnerships (PPPs), negotiations with financial institutions for loans or credit facilities, finalizing financial models and return-on-investment projections.

7.3.3 Phase 3: Operational Readiness / Commissioning

This stage marks the transition from plant construction to operational readiness. It includes the setup, installation, validation, and certification of manufacturing processes. Key activities include: construction and installation of manufacturing equipment, regulatory approvals and compliance validation, staff recruitment and training for plant operations, test production runs and quality assurance checks, official commissioning and launch of the facility.

7.3.4 Phase 4: Production / Commercialization

This final stage signifies full-scale manufacturing and distribution of injectable pharmaceutical products. The focus shifts to optimizing operations, ensuring product quality, and maintaining regulatory compliance. Key activities include: Full-scale production and quality control measures, market entry and product distribution strategies, continuous stakeholder engagement and regulatory reporting, process optimization and expansion planning, post-market surveillance and

166 | Feasibility Studies Report

Table 7.1 Stakeholder Engagement Plan

Stage	Stakeholder type	Area of influence	Engagement Purpose	Engagement approach
Feasibility	• International partner	• Providing technical expertise from operating in multiple markets. • Ensuring alignment with GMP, WHO guidelines and country specific requirements • Providing steer regarding decisions on licensing, technology sharing agreements and capacity building for local biopharma expertise within Ghana and ECOWAS region.	• Alignment, transparency, collaborative planning, and decision making	• Regular meeting schedules and reporting mechanisms for the findings from feasibility studies
• Financing	• Banks and Development Finance Institutions (e.g., AfDB, World Bank, IFC) • Multilateral & bilateral donors (The Global Fund, WHO, UNDP, EU, GIZ etc.) • Private investors & Venture capital firms	• Potential funding and technical assistance • Provision of investment opportunities • Managing financial risk	• Securing funding from the right mix of investors while ensuring transparency, credibility, and alignment with stakeholder expectations	• Engage donors to explore grant funding • Conduct investment roadshows and presentations (e.g. utilize Ghana's health and investment forums to pitch to investors) • Organize regular investor briefings and provision of access to due

Feasibility Studies Report | 167

Stage	Stakeholder type	Area of influence	Engagement Purpose	Engagement approach
				diligence reports as well as detailed financial projections and reports.
	• International partner	• Access to industry and investor networks • Guidance on financial modelling to ensure sustainability. • Strengthening international investor confidence	• Securing financial structuring support, risk mitigation and access to development finance	• Organize regular briefings and provide access to due diligence reports as well as detailed financial projections and reports.
	• Government agencies (MoH, GIPC)	• Shaping investment climate through policies that affect financing risk and ROI.		• Government engagement on incentive negotiations and public-private partnerships
• Operational Readiness	• Ghana Food and Drugs Authority (FDA) • Ghana Standards Authority (GSA) • Environmental Protection Agency (EPA) • Ghana Revenue Authority (GRA)	• Regulatory, quality and standards compliance	• Ensuring regulatory compliance, as well as market entry in-country.	• Regular communication with FDA on dossier submissions, inspections, and approvals • Organize quality and safety compliance checks or audits before production.
	• Regional, Continental, and international stakeholders (WHO,	• Enhanced market access, regional integration, and trade facilitation	• Ensuring regulatory alignment, market access (regionally, across	• Attend industry forums and policy dialogues by

168 | Feasibility Studies Report

Stage	Stakeholder type	Area of influence	Engagement Purpose	Engagement approach
	AfCFTA, Africa CDC, Africa Medicines Agency		the continent and internationally) and public health impact	AMA, Africa CDC, AfCFTA etc.
	• Ministry of Health • Ghana Health Service • Healthcare institutions, • Healthcare Professional Associations • Healthcare Federation of Ghana • Christian Health Association of Ghana (CHAG)	• Demand for manufactured injectable products. • Distribution of manufactured injectable products • Clinical adoption and confidence building	• Ensuring market readiness and demand alignment • Building strategic partnerships for smooth adoption and distribution of products manufactured • Strengthening public confidence and healthcare provider buy-in • Secure endorsements from healthcare professionals	• Organize briefings with key government agencies, healthcare institutions (Public hospitals and private hospitals) to introduce the plant's capacity and potential impact on local healthcare delivery. • Partner with professional associations on clinical awareness and training programs (e.g. CPD) • Collaborate with FDA and medical associations to organize scientific and regulatory forums (e.g. product standards, product education, quality assurance, GMP etc.)
	• Raw material suppliers	• Availability of raw materials (APIs,	• Ensuring reliable, compliant, and cost-	• Identify potential suppliers of raw

Stage	Stakeholder type	Area of influence	Engagement Purpose	Engagement approach
	• Pharmaceutical distributors and wholesalers • Pharmaceutical Manufacturing Association of Ghana	excipients, packaging etc.) for production • Distribution of manufactured injectable products	effective supply chain for the manufactured injectable products • Identify partnership opportunities with other local manufacturing companies.	materials (APIs, excipients, packaging etc.) and conduct supplier audit & due diligence to verify compliance, quality, and supply reliability. • Establish agreements with key suppliers for raw materials. • Identify and onboard key pharmaceutical distributors though distributors partnerships.
• Production	• Banks and development finance institutions (e.g., AfDB, World Bank, IFC) • Multilateral & bilateral donors WHO, UNDP, EU, GIZ etc.) • Private investors & Venture capital firms	• Provision of Financing and credit facilities • Market access and partnerships • Provision of equity investment opportunities • Managing financial risk	• Acquiring financing and credit facilities to enable operations. • Leveraging technical assistance to improve financial sustainability. • Developing strategic partnerships for market expansion and international collaboration	• Engage DFIs to obtain and utilize blended financing (concessional loans, grants, equity investments) to de-risk commercial loans. • Participate in donor-sponsored initiatives and forums to align with donor priorities and investment focus in healthcare and industrialization.

170 | Feasibility Studies Report

Stage	Stakeholder type	Area of influence	Engagement Purpose	Engagement approach
				• Leverage industry networks and investment platforms
•	• Ghana Food and Drugs Authority (FDA) • Ghana Standards Authority (GSA) • Environmental Protection Agency (EPA) • Ghana Revenue Authority (GRA)	• Regulatory, quality and standards compliance	• Ensuring compliance to all regulatory and quality standards in the country • Ensuring sustainable operations	• Organize regular quality and safety compliance checks or audits. • Establish pharmacovigilance reporting systems. • Maintain an open communication channel with all regulatory bodies
•	• Regional, Continental, and international stakeholders (WHO, AfCFTA, Africa CDC, Africa Medicines Agency	• Regulatory harmonization • Market access • Trade facilitation	• Ensuring regulatory alignment, improving market access and public health impact	• Establish formal communication channels. • Attend relevant stakeholder events. • Leverage government partnerships with these stakeholders.
•	• Ministry of Health • NHIA • Ghana Health Service • Healthcare institutions • Healthcare Professional Associations	• Shaping of market access through policies • Pricing and reimbursement	• Ensuring policy alignment, public procurement inclusion and health financing support	• Engage with government agencies on policy dialogues, MOU, and technical presentations. • Ensure Public Procurement Authority

Stage	Stakeholder type	Area of influence	Engagement Purpose	Engagement approach
	• Healthcare Federation of Ghana • Christian Health Association of Ghana (CHAG)	• Demand generation for manufactured injectable products. • Distribution of manufactured injectable products • Clinical adoption and confidence building	• Ensuring market uptake, supply chain integration	compliance for government contracts. • Organize hospital visits for round table discussions and product demonstrations and establishment of partnerships for distribution. • Conduct pharmacovigilance programs for adverse event reporting. • Engage Key Opinion Leaders (KOLs) for advocacy to improve adoption. • Continue to partner with professional associations to provide capacity building initiatives (CPDs, Workshops etc.) • Run patient awareness campaigns on treatment benefits and safety of injectable products (especially locally manufactured ones)

172 | Feasibility Studies Report

Stage	Stakeholder type	Area of influence	Engagement Purpose	Engagement approach
•	• Raw material Suppliers • Pharmaceutical distributors and wholesalers • Pharmaceutical Manufacturing Association of Ghana	• Supply of raw materials (APIs, excipients, packaging etc.) to maintain production schedules. • Cost of production and pricing strategy for final injectable products • Quality of the final injectable products	• Ensuring reliable, compliant, and cost-effective supply chain for the manufactured injectable products • Establishing collaborative rather than purely competitive relationships with other local manufacturers	• Improve strategic alliances with suppliers and distributors for supply chain efficiency. • Offer incentives for distributors to increase market reach.

Source: IQVIA

7.4 Communication Plan

7.4.1 Background

As part of the biopharmaceutical injectable manufacturing plant feasibility study, Quintex Pharma has identified the need for a Strategic Communications Plan to assist in the implementation of the biopharmaceutical injectable plant, positioning the company to be a trusted industry leader while contributing to Ghana's health security as well as pharmaceutical self-sufficiency.

Effective communication is essential to building trust, securing stakeholder buy-in, and ensuring the smooth execution of the project. This Communication Plan outlines a structured approach to engaging key stakeholders—including government agencies, regulatory bodies, healthcare providers, investors, and the public. By fostering transparency, alignment, and support, the plan aims to drive awareness, manage expectations, and facilitate collaboration throughout the project lifecycle.

7.4.2 Objectives

1. Establish credibility and trust with all stakeholder groups through maintaining clear, transparent, consistent, and timely communication throughout the project phases.
2. Highlight Quintex Pharma's commitment to quality, safety, and compliance with international regulatory standards.
3. Position the project as a strategic contributor to Ghana's healthcare sector.
4. Support advocacy efforts for favourable policy and regulatory environment for biopharmaceutical manufacturing in Ghana.

7.4.3 Communication methods and strategic key messages

Effectively reaching each target audience requires a tailored communication approach. Different stakeholders have varying preferences for receiving information, and using the right channels ensures that messages are not only delivered but also understood and acted upon.

To maximize engagement and impact, it is crucial to select communication mediums that align with the audience's habits, expectations, and level of involvement in the project. Whether through traditional media, digital platforms, direct engagement, or industry events, the goal is to ensure clear, consistent, and impactful messaging.

Below is a breakdown of the recommended communication mediums and channels best suited for each audience, ensuring that Quintex Pharma's key messages are effectively conveyed to build awareness, foster collaboration, and drive stakeholder support

174 | Feasibility Studies Report

Table 7.2 Communication methods and strategic key messages

Target Audience	Specific objectives	Communication channels	Strategic key messages
• **Government & Regulatory Bodies** ○ Ministry of Health (MoH) ○ Ghana Health Service ○ National Health Insurance Authority (NHIA) ○ Ghana Food and Drugs Authority (FDA) ○ Pharmacy Council of Ghana ○ Ghana Standards Authority (GSA) ○ Ghana Investment Promotion Centre (GIPC) ○ Ministry of Trade, Agribusiness, and Industry ○ Ghana Revenue Authority (GRA) ○ Environmental Protection Agency (EPA)	• Obtain necessary approvals and align with government policies	• Formal letters • Official meetings • Policy papers • Public-private dialogue platforms	• "A strategic investment to strengthen Ghana's pharmaceutical industry and enhance self-sufficiency in biopharmaceuticals". • "Our plant will be built to meet the highest international quality standards, ensuring that locally produced injectables are both safe and effective for patients". • "By localizing the production of biopharmaceutical injectables, we will support Ghana's efforts to achieve Universal Health Coverage (UHC), ensuring that all citizens have access to high-quality healthcare services".
• **Healthcare Ecosystem & End Users (Customers)** ○ Public Health Institutions (All six (6) public teaching hospitals, all regional hospitals, All district hospitals etc.	• Gain the trust and support of healthcare providers and professionals	• Conferences • Workshops • Newsletters • Featured articles • Webinar	• "We will ensure affordable and high-quality injectables for Ghana's healthcare needs". • "Our products will meet stringent quality and safety standards".

Feasibility Studies Report | 175

Target Audience	Specific objectives	Communication channels	Strategic key messages
○ Private Hospitals & Clinics (Nyaho Medical Centre, Trust Hospital, Focos Orthopedics Hospital, Lister Hospital etc.) ○ Healthcare Professional Associations (Ghana Medical Association, Pharmaceutical Society of Ghana, Ghana National Chamber of Pharmacy etc.)			• "Healthcare professionals will receive comprehensive product education and support".
• **Industry & Business Partners** ○ International Pharma Partners – Joint venture partners. ○ Raw Material Suppliers. ○ Distributors & Wholesalers ○ Retail Pharmacies ○ Pharmaceutical Manufacturers Association of Ghana	• Build credibility and support within the pharmaceutical sector	• Business roundtable meetings • Trade fairs • Investor briefings • Conferences	• "We are committed to strengthening Ghana's healthcare system by establishing a world-class biopharmaceutical injectable plant that will enhance the availability of life-saving treatments for patients across the nation". • "This project will contribute to reducing Ghana's reliance on imported medicines and will help position Ghana as a regional pharmaceutical manufacturing hub". • "We will engage local suppliers, contractors, and businesses, stimulating economic activity and

176 | Feasibility Studies Report

Target Audience	Specific objectives	Communication channels	Strategic key messages
			fostering the growth of local industries".
• **Financial & Investment Institutions** ○ Local & International Banks Project financing. ○ Development Finance Institutions (e.g., AfDB, World Bank, IFC) – Potential funding and technical assistance. ○ Private Equity & Venture Capital Firms – Investment opportunities.	• Secure funding and technical collaboration	• Investment proposals • Presentations • Financial reports	• "A high-growth investment opportunity with strong market potential and government support". • "The project has a robust business plan with clear milestones and returns". • "Risk management strategies are comprehensive and proactive to address regulatory, financial, and operational challenges". • "The business model balances commercial viability with social impact". • "The joint venture structure leverages the strengths of both partners".
• **Regional, Continental, and international stakeholders** ○ World Health Organization – Public health impact, quality standards ○ Africa CDC ○ AfCFTA/African Union	• Ensure regulatory compliance, access investment and funding opportunities as well as market expansion and trade facilitation	• Official Letters • Regulatory dossier submissions • Conferences and forums • Business roundtable meetings	• "Regional market access will be pursued through regulatory harmonization initiatives". • "We are dedicated to collaborating with local, regional, and international regulatory bodies, healthcare providers, and industry partners to ensure the

Target Audience	Specific objectives	Communication channels	Strategic key messages
○ International Donors/Aid Organizations			successful development of the injectable plant and maximize its impact on public health"
• General public	• Foster public awareness and local support	• Press releases • Website • Social media & digital platforms	• "Advancing healthcare security and local production capacity in Ghana". • "The establishment of the plant will create hundreds of direct and indirect job opportunities for skilled workers, supporting the local economy and workforce development". • "We are committed to strengthening Ghana's healthcare system by establishing a world-class biopharmaceutical injectable plant that will enhance the availability of life-saving treatments for patients across the nation".

Source: IQVIA

178 | Feasibility Studies Report

Table 7.3 Stakeholders list

Stakeholder	Type	Contact	Geography level	Power-Interest plotting	Stakeholder
Government & Regulatory Bodies					
Ministry of Health (MOH)	Government Agency	Chief Director	Local	Regularly engage	Ministry of Health (MOH)
Ghana Health Service	Government Agency	Director General	Local	Regularly engage	Ghana Health Service
National Health Insurance Authority (NHIA)	Government Agency	Director (Strategic Health Purchasing)	Local	Actively consult	National Health Insurance Authority (NHIA)
Environmental Protection Agency (EPA)	Regulatory body	Ag. Deputy Chief Executive Officer (Operations)	Local	Regularly engage	Environmental Protection Agency (EPA)
Ghana Revenue Authority (GRA)	Regulatory body	Commissioner (Domestic Tax and Revenue Division) Commissioner (Customs Division)	Local	Regularly engage	Ghana Revenue Authority (GRA)
Ghana Investment Promotion Centre (GIPC)	Government Agency	Chief Executive Officer	Local	Actively consult	Ghana Investment Promotion Centre (GIPC)
Ghana Standards Authority (GSA)	Regulatory body	Ag. Director Standards Division Ag. Director Certification Division	Local	Regularly engage	Ghana Standards Authority (GSA)
Ghana Food and Drugs Authority (FDA)	Regulatory body	Head of Drugs and Herbal Medicine	Local	Regularly engage	Ghana Food and Drugs Authority (FDA)
Ministry of Trade, Agribusiness, and Industry	Government Agency	Chief Director	Local	Actively consult	Ministry of Trade, Agribusiness, and Industry
Healthcare Ecosystem & End Users (Customers)					

Feasibility Studies Report | 179

Stakeholder	Type	Contact	Geography level	Power-Interest plotting	Stakeholder
Korle-Bu Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest	Korle-Bu Teaching Hospital
Komfo Anokye Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest	Komfo Anokye Teaching Hospital
Cape coast Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest	Cape coast Teaching Hospital
Ho Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest	Ho Teaching Hospital
Tamale Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest	Tamale Teaching Hospital
Sunyani teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest	Sunyani teaching Hospital
Greater Accra Regional Hospital (Accra)	Public Hospital	Medical Director	Local	Maintain Interest	Greater Accra Regional Hospital (Accra)
Kumasi South Hospital (Kumasi)	Public Hospital	Medical Director	Local	Maintain Interest	Kumasi South Hospital (Kumasi)
Effia Nkwanta Regional Hospital (Takoradi)	Public Hospital	Medical Director	Local	Maintain Interest	Effia Nkwanta Regional Hospital (Takoradi)
Tema General Hospital (Tema)	Public Hospital	Medical Director	Local	Maintain Interest	Tema General Hospital (Tema)
37 Military Hospital	Quasi-government	Medical Director	Local	Maintain Interest	37 Military Hospital
Police Hospital	Quasi-government	Medical Director	Local	Maintain Interest	Police Hospital
The Bank Hospital (Accra)	Quasi-government	Medical Director / Managing Director	Local	Maintain Interest	The Bank Hospital (Accra)
International Maritime Hospital (Tema)	Quasi-government	Medical Director / Managing Director	Local	Maintain Interest	International Maritime Hospital (Tema)
Volta River Authority Hospital (Akosombo	Quasi-government	Medical Director / Managing Director	Local	Maintain Interest	Volta River Authority Hospital (Akosombo

180 | Feasibility Studies Report

Stakeholder	Type	Contact	Geography level	Power-Interest plotting	Stakeholder
Ghana Ports and Harbours Authority Hospital (Takoradi)	Quasi-government	Medical Director / Managing Director	Local	Maintain Interest	Ghana Ports and Harbours Authority Hospital (Takoradi)
Nyaho Medical Centre (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	Nyaho Medical Centre (Accra)
Lister Hospital and Fertility Centre (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	Lister Hospital and Fertility Centre (Accra)
The Trust Hospital (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	The Trust Hospital (Accra)
Medifem Multi-Specialist Hospital (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	Medifem Multi-Specialist Hospital (Accra)
Focos Orthopedic Hospital (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	Focos Orthopedic Hospital (Accra)
Holy Trinity Hospital (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	Holy Trinity Hospital (Accra)
CNJ Hospital (Tema)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	CNJ Hospital (Tema)
UQ Specialist Hospital (Takoradi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	UQ Specialist Hospital (Takoradi)
TrustCare Hospital (Kumasi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	Trust Care Hospital (Kumasi)
Asafo Boakye Specialist Hospital (Kumasi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	Asafo Boakye Specialist Hospital (Kumasi)
A1 Hospital (Kumasi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	A1 Hospital (Kumasi)
Sycamore Hospital (Takoradi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	Sycamore Hospital (Takoradi)

Stakeholder	Type	Contact	Geography level	Power-Interest plotting	Stakeholder
Family Health Hospital	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest	Family Health Hospital
Christian Health Association of Ghana (CHAG)	Private, not-for-profit organization	Director	Local	Maintain Interest	Christian Health Association of Ghana (CHAG)
Ghana Medical Association	Association	President	Local	Maintain Interest	Ghana Medical Association
Pharmaceutical Society of Ghana	Association	President	Local	Maintain Interest	Pharmaceutical Society of Ghana
Healthcare Federation of Ghana	Private, not-for-profit organization	Chief Executive Officer	Local	Maintain Interest	Healthcare Federation of Ghana
Industry and Business Partners					
International Partner	Joint-venture Partner	Managing Director / Chief Executive Officer	International	Regularly engage	International Partner
Ernest Chemist Ltd	Distributor / Manufacturer	Managing Director	Local	Maintain Interest	Ernest Chemist Ltd
Gokals Laborex Ltd	Distributor	Managing Director	Local	Maintain Interest	Gokals Laborex Ltd
Osons Chemist Ltd	Distributor	Managing Director	Local	Maintain Interest	Osons Chemist Ltd
East Cantonments Pharmacy Ltd	Distributor	Managing Director	Local	Maintain Interest	East Cantonments Pharmacy Ltd
Unichem Ghana group	Distributor	Managing Director	Local	Maintain Interest	Unichem Ghana group
Pharmaceutical Manufacturing Association of Ghana (PMAG)	Association	Executive Secretary	Local	Maintain Interest	Pharmaceutical Manufacturing Association of Ghana (PMAG)
Financial and Investment Institutions					
International finance Corporation (IFC)	Multilateral DFI	Country Director	International	Actively consult	International finance Corporation (IFC)
African Development Bank (AfDB)	Multilateral DFI	Country Director	International	Actively consult	African Development Bank (AfDB)

182 | Feasibility Studies Report

Stakeholder	Type	Contact	Geography level	Power-Interest plotting	Stakeholder
European Investment Bank (EIB)	Multilateral DFI	Country Representative	International	Actively consult	European Investment Bank (EIB)
UK Foreign, Commonwealth & Development Office (FCDO)	Bilateral DFI	British high Commission	International	Actively consult	UK Foreign, Commonwealth & Development Office (FCDO)
Deutsche Gesellschaft Fur Internationale Zusammenarbeit (GIZ)	Bilateral DFI	Country Director	International	Actively consult	Deutsche Gesellschaft Fur Internationale Zusammenarbeit (GIZ)
Japan International Cooperation Agency (JICA)	Bilateral DFI	Chief Representative	International	Actively consult	Japan International Cooperation Agency (JICA)
West African Development Bank (WADB)	Regional DFI	Country Representative	Regional	Actively consult	West African Development Bank (WADB)
Ghana Exim Bank	Bank	Managing Director	Local	Actively consult	Ghana Exim Bank
Regional, Continental and International Stakeholders					
World Health Organization (WHO)	Development Partner	Country Representative	International	Actively consult	World Health Organization (WHO)
Africa CDC	Health Agency	Senior Country Representative	International	Actively consult	Africa CDC
Africa Medicines Agency	Health Agency	Director General	International	Actively consult	Africa Medicines Agency
Africa Continental Free Trade Area	Trade organization	Secretary General	International	Actively consult	Africa Continental Free Trade Area

Source: IQVIA

8 Technical Feasibility

8.1 Purpose of an injectable manufacturing plant

An injectable manufacturing plant is a highly controlled pharmaceutical production facility designed for the sterile manufacturing of parenteral drug products. The word 'parenteral' is derived from the Greek words 'para' and 'enteron', meaning 'outside of intestine'. It is used for pharmaceutical dosage forms administered by routes other than the oral (by mouth) route. This can include injections, topical (onto the skin), and inhalation routes.

Parenterally administered drugs are often chosen for medications that require precise dosing and rapid onset of action. Certain pharmaceutical agents – particularly peptides, proteins, and many chemotherapeutic agents – can only be given parenterally, because they are inactivated in the gastrointestinal tract when given by mouth. Due to the advance of biotechnology, parenteral products have grown in number and usage around the world.

Injectable manufacturing plants serve a critical function in modern healthcare by producing sterile, ready-to-use liquid medications. These are administered via injection for a wide range of therapeutic uses, such as:

- Intravenous (IV) fluids – Used for hydration, electrolyte balance, and drug delivery.
- Vaccines – Prevent infectious diseases.
- Antibiotics & Pain Management – Used to treat bacterial infections and post-operative pain.
- Oncology Medications & Biologics – Targeted therapies for cancer and autoimmune diseases.

Unlike tablets or capsules, injectables must be completely sterile and free from particulate contamination, requiring controlled environments, advanced sterilization techniques, and high-purity water systems.

An injectable plant is not just another pharmaceutical facility. It is a highly specialized, regulated, and precision-engineered sterile environment. To ensure product safety, injectable manufacturing requires:

- Compliance with GMP and regulatory approvals.
- Cleanroom-controlled environments to prevent contamination.
- Automated aseptic processing for precise and sterile production.
- Continuous monitoring & validation to ensure product integrity.

8.2 Injectables

Injectables are a crucial category of parenteral pharmaceuticals, playing an essential role in modern medical treatment. They are used for rapid drug administration, fluid therapy, vaccinations, and other therapeutic applications. Since injectables are directly introduced into the body, they require

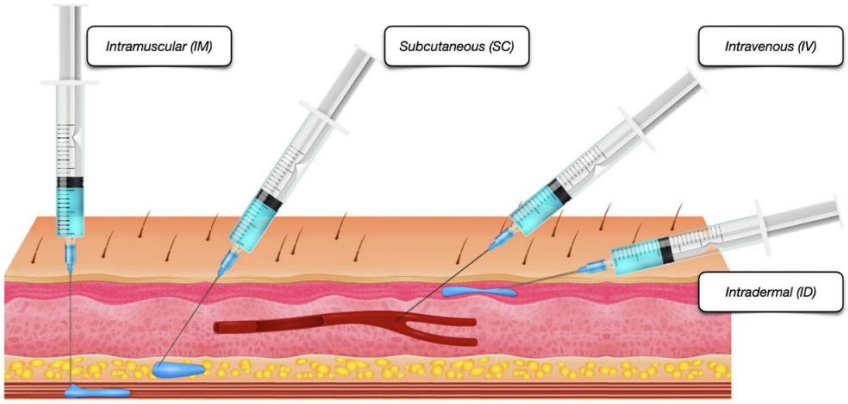
184 | Feasibility Studies Report

strict sterility control, rigorous quality testing, and regulatory compliance to prevent contamination and adverse reactions.

Unlike oral medications, injectables bypass the digestive system and enter the body through various routes, each affecting the speed and efficiency of drug absorption. The four main injection routes are:

- Intravenous (IV): Delivered directly into the bloodstream for immediate absorption, commonly used in emergencies, fluid replacement, and precise dosing. This method ensures rapid effects, but it also poses the highest risk if contamination occurs. Even the smallest impurity can lead to severe health risks, including infections, toxic reactions, or even death.
- Intramuscular (IM): Injected into the muscle, allowing for faster absorption than subcutaneous injections. Often used for vaccines, antibiotics, and hormones.
- Subcutaneous (SC): Administered into the fatty tissue under the skin, leading to slower absorption. Used for insulin, anticoagulants, and some vaccines.
- Intradermal (ID): Injected into the skin's top layer for very slow absorption, mainly used for diagnostic tests and certain vaccines.

Figure 8.1 Types of injection



In pharmacy parenteral preparations (i.e. drug formulations) refer to sterile preparations intended for administration by injection, infusion, or implantation into the human or animal body. Hence, there are generally four main forms of parenteral preparations:

- Injectables (small volume parenteral/SVP)
- Intravenous infusions (large volume parenteral/LVP)
- Powders for injections
- Implants

The proposed pharmaceutical plant will focus on injectables.

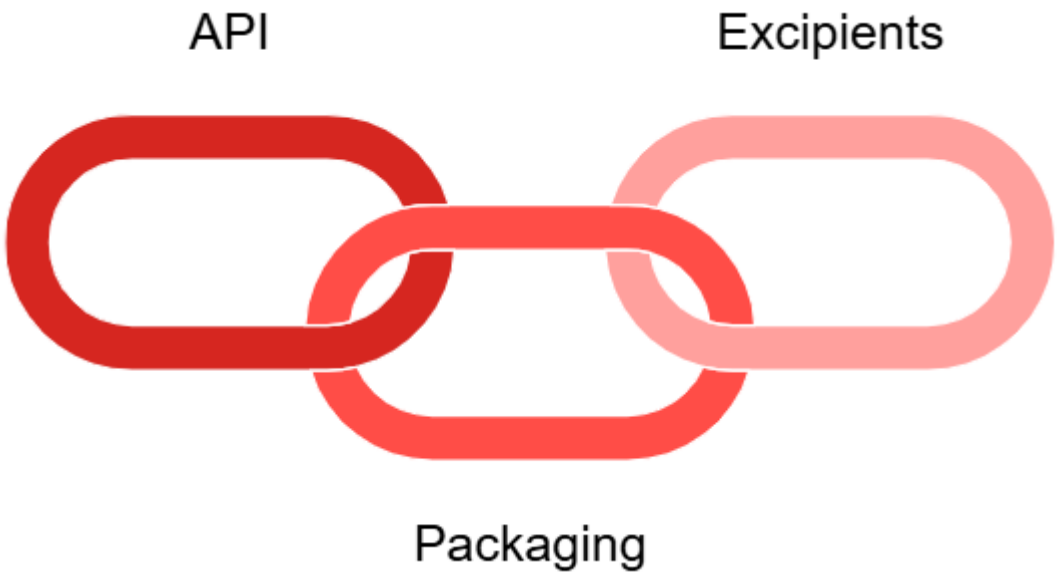
8 Technical Feasibility

8.3 Components of parenteral preparations

The formulation of injectables involves three essential components:

5. Active Pharmaceutical Ingredient (API) – The main therapeutic component responsible for therapeutic effect of the medication.
6. Excipients – Inactive substances added to support the formulation, ensuring stability, pH balance, tonicity, solubility, and sterility.
7. Packaging – The container that maintains sterility and facilitates safe administration.

Figure 2: Key elements in injection formulation



8.3.1 Active Pharmaceutical Ingredient (API)

The Active Pharmaceutical Ingredient (API)[1] is the core component of any medication, responsible for the drug's therapeutic effect. In parenteral preparations, APIs must meet strict purity, sterility, and stability requirements due to direct administration into the body.

APIs directly interact with biological targets to produce the desired physiological response. Whether it's relieving pain, reducing inflammation, or targeting specific pathogens, APIs are responsible for the efficacy of pharmaceutical products.

Active pharmaceutical ingredients can take various forms such as liquids, powders, crystals, and extracts. The physical form of APIs plays a crucial role in their handling, storage, and formulation. Below are the main physical forms used in injectables, along with additional explanations:

- Sterile Liquid Solution: APIs that are pre-dissolved in a solvent and require cold storage (2°C–8°C) or room temperature storage depending on stability.
- Lyophilized Powder: APIs that are freeze-dried to enhance stability and require mixing before use.

[1] https://extranet.who.int/prequal/medicines/active-pharmaceutical-ingredients

186 | Feasibility Studies Report

- Crystalline Powder: Highly pure API in solid form, often requiring dissolution in a sterile solvent before formulation.
- Sterile Emulsion: For lipid-based drugs like Propofol, which contain oil-in-water emulsions to facilitate IV administration.

To ensure the quality and safety of APIs used in pharmaceutical formulations, compliance with Good Manufacturing Practices (GMP) is critical. The WHO's GMP guidelines[2] for APIs outline the necessary controls in the production, processing, and distribution of active ingredients to minimize risks and maintain product integrity.

Key GMP principles for APIs include:

- Quality Management System (QMS): Establishing a structured system to document and control every stage of API production.
- Raw Material Control: Ensuring all raw materials used in API production meet strict quality and purity standards.
- Process Validation: Demonstrating that API manufacturing processes consistently produce high-quality products meeting predefined specifications.
- Contamination and Cross-Contamination Control: Implementing measures to prevent impurities, microbial contamination, and mix-ups during production.
- Documentation and Traceability: Maintaining comprehensive records of batch production, testing, and deviations for regulatory compliance.
- Regulatory Compliance: Adhering to international standards such as WHO GMP, ICH Q7 (for APIs used in human medicines), FDA, and EMA guidelines.

8.3.2 Excipients

Parenteral preparations may require the use of excipients. An excipient is an inactive substance that serves as the vehicle or medium for a drug or other active substance. The purpose of adding excipients in parenteral preparations are:

- To make the preparation in the same concentration as blood (isotonic)
- To adjust the acidity level (pH)
- To increase solubility
- To prevent deterioration of the active substances
- To provide adequate antimicrobial properties

The addition of excipients should be kept to a minimum. When excipients are used they must not adversely affect the stability, safety, or efficacy of the active ingredient(s), or cause toxicity or local irritation. There must be no incompatibility between any of the components of the dosage form. There are different types of excipients, each with its own purpose, as displayed in the table below.

[2] World Health Organization (WHO). (2011). Annex 6: Good Manufacturing Practices for Sterile Pharmaceutical Products. WHO Technical Report Series No. 961. Geneva: WHO.

8 Technical Feasibility

Table 8.1 Excipients and their functions

Excipient Type	Examples	Purpose
Solvents	Water for Injection (WFI), Ethanol, Glycerin	Dissolve APIs and adjust viscosity
Buffers	Phosphate, Citrate, Acetate Buffers	Maintain acidity (pH) stability
Stabilizers	EDTA, Polysorbate 80 (for emulsions like Propofol)	Prevent degradation and aggregation
Preservatives	Benzyl Alcohol, Phenol, Methylparaben (for multi-dose vials)	Inhibit microbial growth in multi-dose formulations
Antioxidants	Ascorbic Acid, Sodium Metabisulfite	Prevent oxidation of active ingredients
Osmotic Adjusters	Sodium Chloride, Mannitol	Regulate osmolarity for isotonicity
Lipids (for emulsions)	Soybean Oil, Lecithin, Medium Chain Triglycerides (MCTs) (used in Propofol)	Aid in emulsification and drug solubility

In contrast to active ingredients, excipients are inert substances added to pharmaceutical formulations to facilitate drug delivery, stability, and patient admission. While active ingredients exert the desired pharmacological effects, excipients play essential roles in ensuring proper dosage form, solubility, and bioavailability.

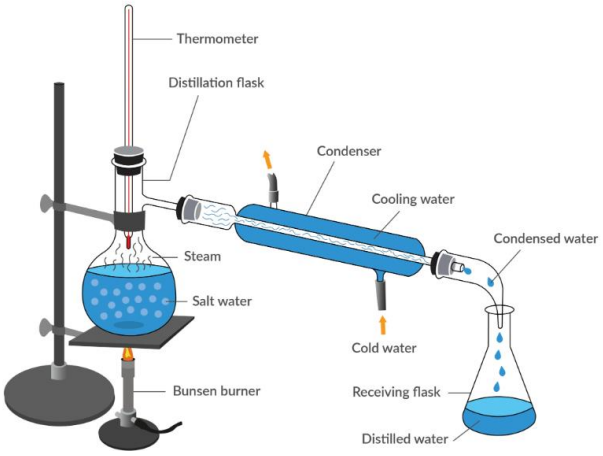
8.3.2.1 Water for Injection and Sterile Water Systems

Water for Injection (WFI) is an essential component and excipient in the production of parenteral preparations. Since injectables bypass the body's natural defense mechanisms, WFI must meet the highest purity standards.

There are two main methods for producing WFI:

1. Distillation: The most common method, using special distillers to remove bacteria, toxins and dissolved impurities effectively. Distillation produces water with consistent quality, meeting regulatory standards such as United States Pharmacopeia (USP), and European Pharmacopeia (EP).

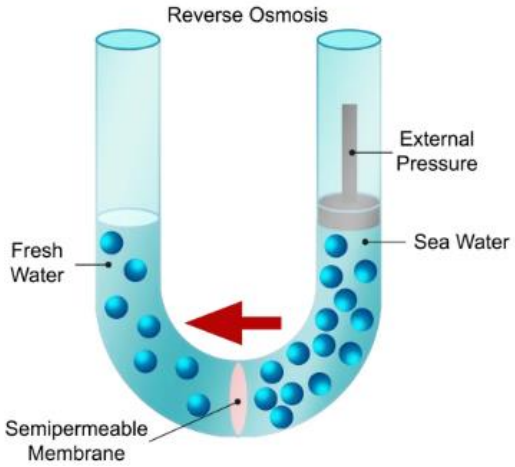
Figure 8.3 Distillation process



188 | Feasibility Studies Report

2. Reverse Osmosis (RO) with Ultrafiltration (UF): A membrane filtration system that removes ions, bacteria, and particles, commonly used in non-EU regions where distillation isn't required. To ensure endotoxin removal, additional steps like ultrafiltration may be needed.

Figure 8.4 Reverse osmosis process



Distillation remains the preferred method for WFI production due to its robust ability to eliminate endotoxins and microbial contaminants through phase separation and high-temperature operation[3].

Water for injection should be produced, stored and distributed in a manner which prevents the growth of microorganisms, e.g. by constant circulation at a temperature above 70 °C or not more than 4 °C[4].

8.3.3 Packaging

The containment of the product is the most fundamental function of packaging for medicinal products[5]. Packaging may be defined as the collection of different components (e.g. bottle, vial, closure, cap, ampoule, blister) which surround the pharmaceutical product from the time of production until its use. The design of high-quality packaging must take into account both the needs of the product and of the manufacturing and distribution system. This packaging must:

- prevent leaks and stop the product from spreading or seeping out;
- be strong enough to hold the contents during normal handling;
- Stay unchanged and not react with the medicine inside.

[3] World Health Organization (WHO). (2012). Annex 2: Good Manufacturing Practices for Water for Pharmaceutical Use. WHO Technical Report Series No. 970. Geneva: WHO.
[4] Good manufacturing practices for pharmaceutical products: water for pharmaceutical use. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 3; and in Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Vol. 2. 2nd updated ed. Good manufacturing practices and inspection. Geneva, World Health Organization, 2007.
[5] World Health Organization (WHO). (2002). Guidelines on packaging for pharmaceutical products. WHO Technical Report Series No. 902, Annex 9.

8 Technical Feasibility

The packaging must protect the product against all adverse external influences that may affect its quality or potency, such as:

- light
- moisture
- oxygen
- biological contamination
- mechanical damage.

The choice of packaging material depends on the formulation, stability, and administration route of the pharmaceutical product. Glass, plastic, and metal are the most commonly used materials, each with distinct advantages and regulatory considerations:

- Glass is widely used for oral and injectable pharmaceuticals, such as tablet bottles, ampoules, vials, and prefilled syringes. Its suitability depends on the drug's properties, with classifications provided in the European and U.S. pharmacopoeias.
- Plastics are increasingly used, particularly for parenteral solution bags, due to their unbreakable, collapsible, and lightweight properties. While all major pharmacopoeias specify plastic materials, the European Pharmacopoeia provides the most detailed requirements.
- Metal is primarily used for non-parenteral products, such as tubes, blisters, and aerosol cans. Aluminium and stainless steel offer tamper resistance, gas impermeability, and durability, making them ideal for pressurized containers. While pharmacopoeias do not cover metal packaging, ISO standards and stability studies ensure compatibility with pharmaceutical formulations.

Parenteral products can be categorized based on volume and packaging type. The two primary categories are:

- Small Volume Parenterals (SVPs): Solutions of 100 mL or less, intended for intermittent intravenous administration (e.g., injections, vaccines, diagnostic agents).
- Large Volume Parenterals (LVPs): Solutions of 100 mL or more, typically used for continuous intravenous infusion (e.g., hydration, electrolyte balance, total parenteral nutrition).

8.3.3.1 Characteristics of LVPs and SVPs

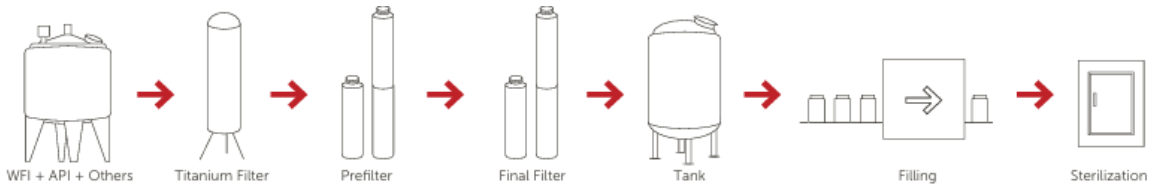
While both Small Volume Parenterals (SVPs) and Large Volume Parenterals (LVPs) require strict sterility, they differ significantly in terms of formulation, packaging, administration, and regulatory requirements. SVPs are generally used for precise drug delivery, such as injections, vaccines, and biologics, whereas LVPs are designed for continuous intravenous infusion, primarily for hydration, electrolyte balance, and drug dilution.

LVPs are usually packaged in glass bottles or flexible IV bags, which must undergo terminal sterilization to ensure microbial safety. Unlike SVPs, LVPs do not contain preservatives, as they are meant for single-use administration. Their large-scale production requires bulk sterile processing, strict endotoxin control, and high-purity water systems to maintain product safety and efficacy. See the figure below for examples of LVPs.

190 | Feasibility Studies Report

Figure 8.5 Examples of LVP packaging

Figure 8.6 Typical LVP manufacturing proces



Drugs and vaccines are packaged in SPVs. SVPs are usually packaged in ampoules, vials or pre-filled syringes, as can be seen in the figure below. Vials are made of glass or plastic and are sealed with a rubber stopper. A needle is used to add contents to or withdraw contents from the vial. Before withdrawing contents from a vial, an equal volume of air is usually injected into the vial to pressurize the vial and aid in withdrawing the contents. However, some medications are packaged under pressure or may produce gas (and therefore pressure) upon reconstitution. In these situations, air should not be injected into the vial before withdrawing the solution. Vials may be designated for single-dose or multi-dose use. Single-dose vials do not contain preservatives and should be discarded after one use. Multidose vials contain a preservative to inhibit bacterial contamination once the vial has been used. Also, the rubber closure will reseal on a multidose vial.

There are two varieties of prefilled syringes. One type, a cartridge type package, is a single syringe and needle unit which is to be placed in a special holder before use. Once the syringe and needle unit are used, they are discarded but the holder is used again with a new unit. The other type of prefilled syringe consists of a glass tube closed at both ends with rubber stoppers. The prefilled tube is placed into a specially designed syringe that has a needle attached to it. After using this type or prefilled syringe, all the pieces are discarded.

8 Technical Feasibility

Figure 8.7 Ampoules (left) and Vials (middle) and Prefilled syringes (Right)

Figure 8.8 Typical SVP manufacturing process

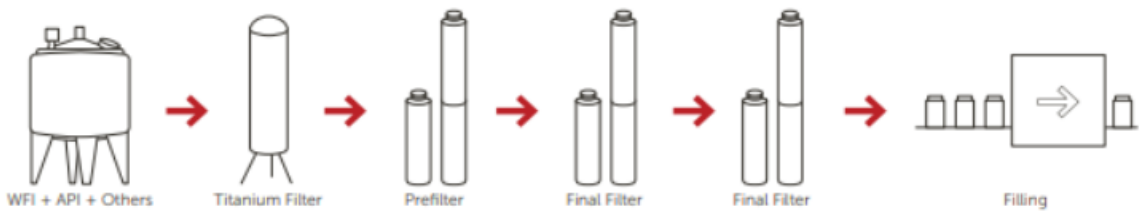


Table 8.2 Key differences between SVPs and LVPs

Feature	Small Volume Parenterals (SVPs)	Large Volume Parenterals (LVPs)
Volume	≤ 100 mL	≥ 100 mL
Use Case	Injections, vaccines, diagnostics	Hydration, electrolyte balance, drug delivery
Administration	Intramuscular, subcutaneous, IV push	Continuous IV infusion
Sterilization	Aseptic processing or terminal sterilization	Terminal sterilization preferred
Packaging	Ampoules, vials, cartridges, PFS	Glass bottles, IV bags
Preservatives	May contain preservatives	Typically preservative-free
Regulatory Focus	Precision dosing, stability	Bulk sterile processing, endotoxin control

8.3.4 Scope of the manufacturing plant

For this manufacturing plant, the production focus is on Small Volume Parenterals (SVPs), specifically vials and prefilled syringes. This means that only the injectable formulations from the product list apply, excluding any large-volume parenterals (LVPs) or non-injectable dosage forms.

The medications produced at this facility primarily include anesthetics, anticoagulants, analgesics, antibiotics, hormonal therapies, and emergency care drugs.

192 | Feasibility Studies Report

8.3.4.1 Types of API in this manufacturing plant

The APIs used in this facility can be categorized based on their physical state upon receipt and processing:

Liquid APIs (Sterile Solutions & Emulsions)

- Used for injectable solutions and emulsions, requiring strict sterility control.
- Commonly applied for biological APIs, lipid-based drugs, and heat-sensitive compounds.
- Examples:
  - Sterile Liquid Solutions → Oxytocin, Enoxaparin, Erythropoietin
  - Lipid-Based Emulsions → Propofol

Powder APIs (Lyophilized & Crystalline Powders)

- Typically reconstituted with sterile solvents before administration.
- Used for heat-sensitive or unstable compounds requiring lyophilization.
- Examples:
  - Lyophilized Powders → Omeprazole
  - Crystalline Powders → Phenobarbitone, Tranexamic Acid

Aqueous & Concentrated Solutions

- APIs that are received as highly concentrated liquid formulations, requiring dilution or direct aseptic filling.
- Examples:
  - Haloperidol (Concentrated Solution)
  - Ketamine Hydrochloride (Aqueous Solution)

8.3.4.2 Types of excipients in this manufacturing plant

Excipients play a key role in ensuring drug stability, sterility, and bioavailability. They come in different forms based on their function in formulation:

Liquid Excipients

- Sterile Water for Injection (WFI) – Primary solvent for injectable formulations.
- Ethanol, Glycerin – Used as solvents and stabilizers.
- Soybean Oil, Medium Chain Triglycerides (MCTs) – Used in lipid-based emulsions (e.g., Propofol).

Powder & Granular Excipients

- Phosphate, Citrate, Acetate Buffers – Maintain pH stability.
- Mannitol, Sodium Chloride – Used as osmotic adjusters for isotonicity.
- EDTA, Polysorbate 80 – Act as stabilizers for biologics and emulsions.

Preservatives & Antioxidants (liquid or powder)

- Benzyl Alcohol, Phenol – Used in multi-dose formulations to prevent microbial growth.
- Ascorbic Acid, Sodium Metabisulfite – Protect against oxidation and degradation.

For the whole target product list, including a more detailed description of the APIs and the excipients, see **Error! Reference source not found.**.

8 Technical Feasibility

The selection of APIs and excipients directly impacts the choice of filling line and processing steps. The physical form of the raw materials (whether liquid, powder, or lyophilized) determines how they are processed, sterilized, and filled into the final container.

8.4 Quality control

Quality Control (QC) is a critical component of Good Manufacturing Practices (GMP)[6] in pharmaceutical production. It ensures that raw materials, in-process products, and finished pharmaceutical products meet established quality standards for safety, efficacy, and consistency. Effective QC practices help prevent contamination, ensure regulatory compliance, and maintain the integrity of pharmaceutical products before they reach patients.

8.4.1 Design and organization of QC laboratories

QC laboratories must be separate from production areas to prevent cross-contamination. Within QC facilities, areas for biological, microbiological, and radioisotope testing should also be segregated to avoid cross-interference between test methods. Adequate ventilation and fume prevention are essential, requiring separate air-handling units for QC and production areas.

QC laboratories should be designed to suit their operational needs, with sufficient space to allow organized workflows and minimize mix-ups. Proper storage must be available for:

- Samples and reference standards, including temperature-controlled units if necessary.
- Solvents and reagents, ensuring chemical stability and safe handling.
- Testing records and documentation, which must be securely maintained for audits and traceability.

Additionally, some sensitive analytical instruments (e.g., mass spectrometers, high-performance liquid chromatography (HPLC) systems) may require a dedicated room to protect them from electrical interference, vibration, excess moisture, or contamination.

8.4.2 Role of QC in pharmaceutical testing

The QC department is responsible for conducting comprehensive testing at various stages of manufacturing, including:

- Raw material testing: Ensuring incoming active pharmaceutical ingredients (APIs), excipients, and packaging materials meet specifications.
- In-process quality checks: Monitoring critical manufacturing parameters to maintain batch consistency.
- Finished product testing: Conducting chemical, physical, and microbiological tests to verify compliance with pharmacopoeial standards (e.g., USP, EP)

Microbiological testing is particularly important for sterile pharmaceuticals, requiring endotoxin testing, sterility testing, and microbial limits tests to prevent contamination risks.

[6] World Health Organization (2011). *WHO good manufacturing practices for pharmaceutical products: main principles*. Annex 3, WHO Technical Report Series, No. 961.

194 | Feasibility Studies Report

8.4.3 Environmental Monitoring and Quality Assurance

To maintain product sterility and quality, QC teams conduct routine environmental monitoring in cleanrooms, aseptic processing areas, and packaging zones. This includes:

- Particulate and microbial air sampling to detect contamination risks.
- Surface and personnel monitoring to verify aseptic processing standards.
- Water and compressed gas quality tests to ensure purity levels for production.

Additionally, QC works closely with Quality Assurance (QA) to oversee deviation investigations, out-of-specification (OOS) results, and corrective actions (CAPA), ensuring compliance with GMP regulations.

8.4.4 Good Manufacturing Practices (GMP) and Regulatory Compliance

Ensuring that pharmaceutical production meets strict regulatory requirements is fundamental. Compliance with GMP, ISO, and environmental regulations is necessary for maintaining product safety and quality. Key aspects include:

- Good Manufacturing Practices (GMP): Compliance with USP, EP, and WHO standards through regular audits, inspections, and implementation of SOPs.
- Quality Assurance (QA): Developing robust QA programs that include in-process controls, final product testing, and stability studies to ensure product consistency and safety.
- ISO 14644-1 (Cleanroom Standards): Injectable plants must operate in classified cleanrooms with controlled air quality, particle count, and microbial contamination, as defined by ISO 14644-1.
- Validation & Documentation: All processes must be thoroughly documented to comply with regulatory guidelines. Validation records should be maintained to demonstrate compliance with GMP, ISO, and industry standards.
- Environmental & Waste Management Compliance: Proper disposal of waste materials and adherence to environmental regulations are crucial for sustainable manufacturing.

8.4.5 Documentation and Record-Keeping

Accurate record-keeping is a fundamental aspect of QC. All laboratory activities, including test results, calibration records, equipment validation, and analytical method validation, must be documented in compliance with GMP guidelines.

Regulatory bodies such as the WHO, FDA, EMA, and PIC/S require pharmaceutical manufacturers to maintain detailed QC documentation for batch release, stability studies, and product recalls, ensuring traceability and accountability.

9 Facility layout and workflow

9.1 Key specifications for an injectable plant

The facility layout of an injectable manufacturing plant is one of the most critical factors in ensuring sterility, efficiency, and regulatory compliance. The design must support a unidirectional workflow, prevent cross-contamination, and maintain cleanroom classifications according to ISO 14644-1 standards.

9.1.1 Cleanroom classifications

A cleanroom in a manufacturing plant is a controlled environment designed to minimize contamination from airborne particles, microorganisms, and chemical vapours. These environments are critical for maintaining sterility and ensuring high-quality production, particularly in the manufacturing of injectables, medical devices, and biopharmaceuticals.

Cleanrooms are classified according to ISO 14644-1, which defines the maximum allowable particle count per cubic meter of air. The classification system ranges from ISO 1 to ISO 9, with lower numbers indicating stricter contamination control. For example ISO 1 permits no more than 10 particles per cubic meter (≥0.1 microns) and ISO 2 allows up to 100 particles per cubic meter (≥0.1 microns).

Pharmaceutical manufacturing plants, especially those producing injectable drugs, require strict cleanroom classifications to prevent contamination. The most common classifications include:

- ISO 5 (Class 100, EU Grade A) – Highest sterility used for sterile drug filling and open processing under unidirectional airflow
- ISO 7 (Class 10,000, EU Grade C) – Used for compounding and preparation rooms.
- ISO 8 (Class 100,000, EU Grade D) – Used for supporting areas like corridors.

To ensure compliance with WHO Good Manufacturing Practices (GMP) and ISO 14644-1 standards, as well as EU GMP Annex 1 (Grades A-D), each area within an injectable manufacturing facility must meet specific cleanroom classifications. These standards regulate air cleanliness, particulate control, and contamination prevention to maintain the sterility and safety of pharmaceutical products.

9.1.2 Cleanroom air flow filter and filtration systems

Clean rooms and clean-air devices should be routinely monitored while in operation and the monitoring locations based on a formal risk analysis study and the results obtained during the classification of rooms and/or clean-air devices. Cleanrooms must maintain controlled air pressure, temperature, and humidity to prevent contamination.

High-Efficiency Particulate Air (HEPA) filters (see figure below) are a key component in achieving laminar and particle-free airflow. A laminar airflow is a unidirectional flow (see figure below), which

196 | Feasibility Studies Report

is required for aseptic filling and open product handling. Laminar airflow in a cleanroom moves the air in a straight path without any obstacles, which reduces contamination effectively. The HEPA filters are capable of trapping particles as small as 0.3 microns, ensuring that the air entering the cleanroom is free of contaminants. HEPA filters should be regularly maintained and replaced to ensure optimal performance.

Figure 9.1 HEPA filter

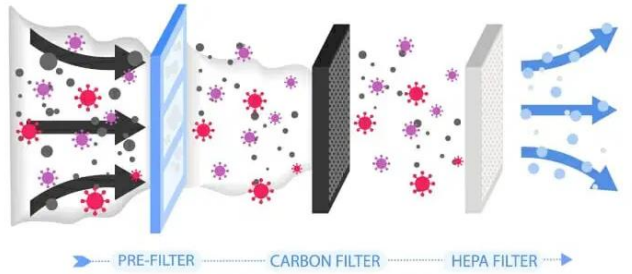
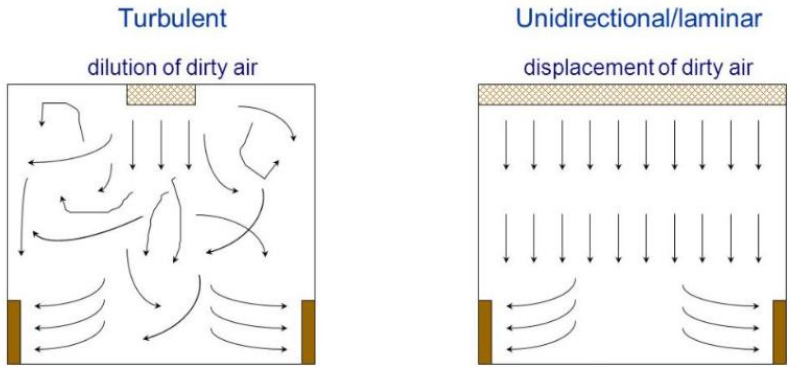


Figure 9.2 Laminar flow



9.1.3 Cleanroom construction

Cleanroom surfaces and materials must be non-shedding, easy to clean, and resistant to disinfectants.

Construction materials:

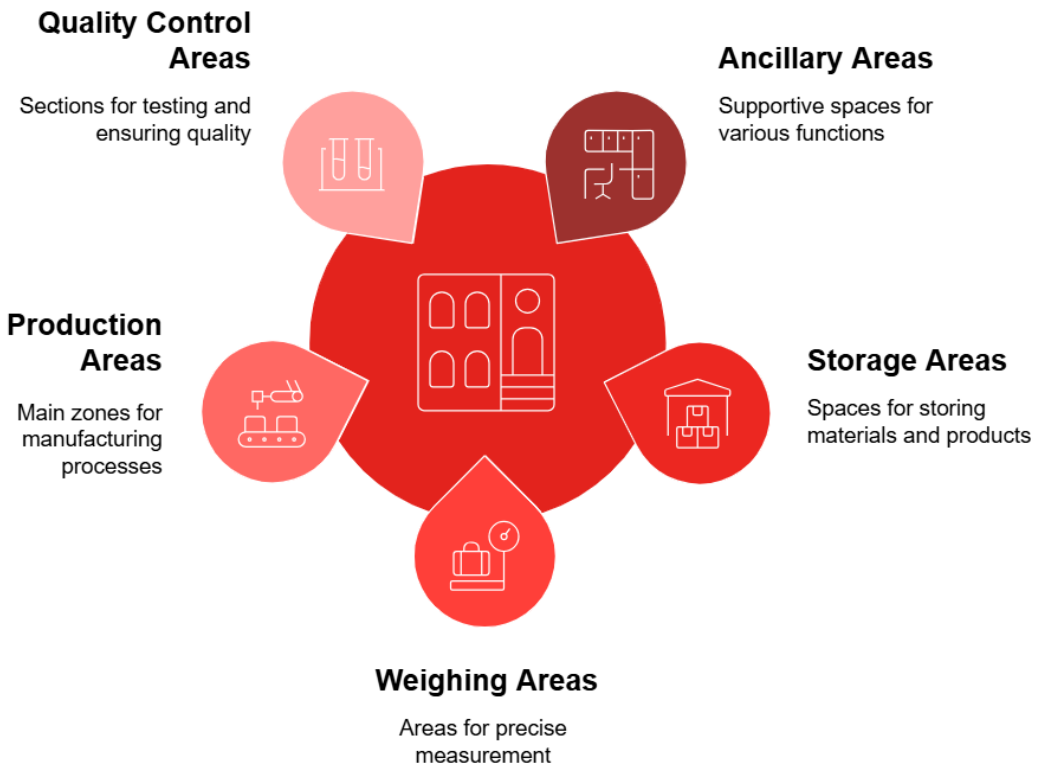
- Walls & Ceilings: Non-porous panels (stainless steel, aluminium, PVC-coated gypsum).
- Floors: Seamless, antimicrobial vinyl or epoxy-coated for chemical resistance.
- Doors: Air-tight, automatic, interlocked to maintain pressure differentials.
- Pass-Through Chambers: Installed between clean zones to reduce contamination risks.
- Lighting: Flush-mounted LED fixtures, with sealed housings to prevent particle shedding.

9 Facility layout and workflow

9.2 Sections of a manufacturing plant

The production area where the fluids are manufactured can be divided into the following sections[7]:

Figure 9.3 Production facility



9.2.1 Ancillary Areas

Ancillary areas are non-production spaces that support pharmaceutical manufacturing operations. These include rest and refreshment rooms, which must be separate from manufacturing and control areas to prevent contamination. Changing rooms, washrooms, and toilets should be easily accessible and maintained in a hygienic condition, ensuring they do not have direct access to production or storage areas. Maintenance workshops should ideally be located separately from production zones to avoid any risk of contamination; if tools or parts must be stored within production, they should be placed in dedicated rooms or lockers.

9.2.2 Storage Areas

Storage areas are critical for organizing and maintaining the quality of raw materials, packaging components, intermediates, and finished products. These spaces must be large enough to allow clear separation between different categories of materials, including quarantined, released, rejected, and recalled products. The environmental conditions within these storage areas should be closely controlled and monitored, ensuring that temperature, humidity, and cleanliness do not compromise material integrity. Receiving and dispatch bays should be distinctly separated from other operations to prevent contamination during the movement of goods. Additionally, certain materials, such as

[7] World Health Organization (WHO). (2011). WHO Good Manufacturing Practices for pharmaceutical products: main principles. WHO Technical Report Series No. 961.

198 | Feasibility Studies Report

narcotics, hazardous chemicals, flammable substances, and radioactive materials, must be stored in secure, dedicated sections with restricted access to ensure compliance with safety regulations.

9.2.3 Weighing Areas

Weighing areas are designated spaces where raw materials are carefully measured and prepared before being introduced into the production process. These areas must be separate from general storage and production zones to avoid cross-contamination. They should also be equipped with appropriate dust control systems to minimize the risk of airborne contamination, particularly when handling fine powders or active pharmaceutical ingredients (APIs). Proper environmental conditions, including ventilation and air filtration, must be maintained to ensure precision and prevent contamination of materials. Depending on facility design, weighing areas may be integrated within storage or production sections but must remain controlled and compliant with hygiene and safety standards.

9.2.4 Production Areas

Production areas are the core zones where pharmaceutical formulations are manufactured, requiring strict environmental control to ensure product safety and compliance with regulatory standards. The layout of these areas must follow a logical sequence to minimize processing errors and prevent contamination. Walls, floors, and ceilings should be smooth, non-porous, and easy to clean, reducing the risk of microbial or particulate contamination. Air-handling systems, including HEPA filtration and humidity control, are essential in maintaining sterility and preventing cross-contamination between different manufacturing stages. For high-risk products, such as antibiotics, hormones, cytotoxic drugs, and live biological preparations, dedicated production facilities are necessary to prevent contamination with other pharmaceutical products. In cases where complete separation is not feasible, validated cleaning and decontamination procedures must be implemented.

9.2.5 Quality Control Areas

Quality Control (QC) areas play a crucial role in ensuring that raw materials, intermediates, and finished products meet required specifications before being approved for release. These areas must be physically separated from production environments to prevent interference and cross-contamination. QC laboratories should be designed with specialized sections for microbiological, chemical, and radiological testing, each maintaining specific environmental conditions appropriate for the testing procedures. Storage space should be available for reference samples, which need to be kept under controlled conditions to ensure long-term stability and reproducibility of test results. Additionally, QC areas must have independent air-handling and ventilation systems to prevent contamination from external sources or production activities.

9.2.6 Adjacency matrix

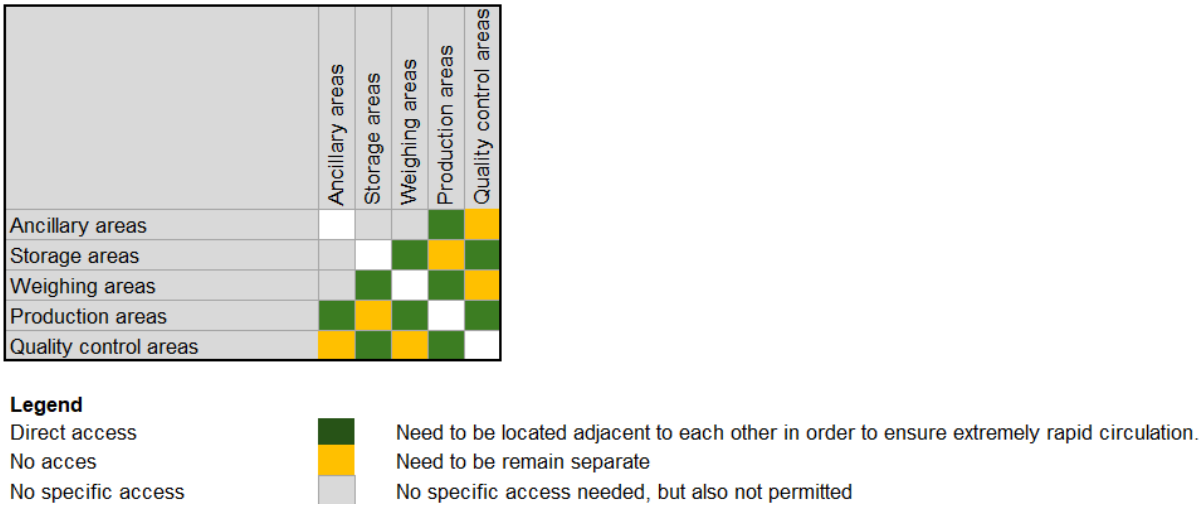
The Figure below displays the adjacency matrix suggested for the injectable plant. The adjacency matrix is a structured representation of spatial and functional relationships between the different departments and services. Each row and column corresponds to a specific department, with the colours indicating the required level of accessibility between them. The colours are defined as follows:

- Dark green = Direct Access: Indicating frequent connections where immediate adjacency is necessary in order to ensure extremely rapid circulation.
- Grey: No specific access needed, but also not permitted.

9 Facility layout and workflow

- Orange = No Access: No access between the departments

Figure 9.4 Adjacency matrix



Based on the cleanroom classifications and their corresponding areas in injectable manufacturing, the list summarizing which areas fall under which classification is as follows:

Table 9.1 Cleanroom classificiation

Area	Recommended ISO Classification	EU GMP Grade
Storage Areas (Raw Material Storage, Quarantine)	ISO 8 or Unclassified Controlled Area	Grade D (if needed)
Weighing Areas (Preparation Area)	ISO 8 (ISO 7 if handling hazardous materials)	Grade C
Production Areas (Aseptic Manufacturing, Processing)	ISO 7 (General production) / ISO 5 (Critical aseptic operations)	Grade B (Background for A) / Grade A (Critical aseptic operations)
Ancillary Areas (Clean-up Area, Gowning, Changing Rooms)	ISO 8 (Entry) / ISO 7 (Gowning)	Grade C / Grade B (for sterile entry)
Quality Control (QC) Areas	ISO 8 or Controlled Non-Classified (ISO 7 for sterility testing)	Grade D / Grade C (for sterility testing

9.3 Material & Personnel Flow

The design of the manufacturing plant ensures a controlled and unidirectional flow of both materials and personnel to maintain sterility, GMP compliance, and operational efficiency. A well-structured material movement system prevents cross-contamination, while strict personnel controls ensure that only properly gowned staff enter critical production areas.

Material flow follows a strict one-way direction from entry to final dispatch. Raw materials and packaging components enter through a dedicated non-sterile receiving area, where they undergo

200 | Feasibility Studies Report

inspection, cleaning, and sterilization if necessary before being transferred into classified zones. Once inside the sterile areas, materials are carefully handled through segregated storage systems and pass-through chambers to minimize unnecessary exposure. After production, finished products are directed to packaging and quarantine areas, ensuring they do not re-enter sterile zones. Waste disposal is conducted via dedicated routes to prevent contamination risks within production areas.

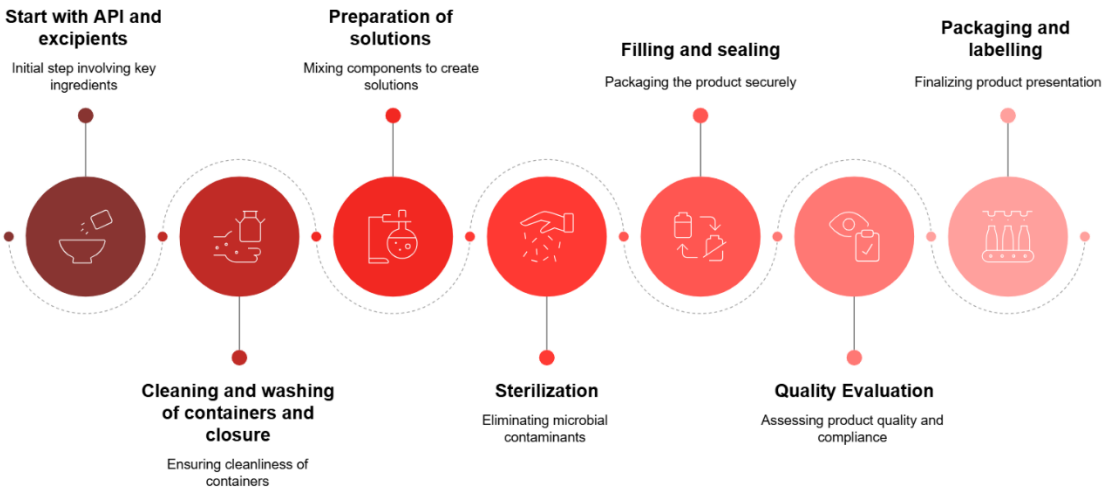
Personnel movement is equally controlled to uphold cleanroom integrity. Employees access the facility through gowning rooms, where they follow a stepwise gowning procedure according to cleanroom classification levels. Only fully gowned personnel are permitted entry into ISO 5 critical areas, reducing contamination risks. Access is restricted through biometric controls and airlocks equipped with HEPA filtration, ensuring that only trained and authorized personnel enter sterile zones. Regular training and compliance monitoring reinforce strict hygiene protocols, safeguarding both product quality and regulatory adherence.

10 Production process of injectables

10.1 Production proces: From API to final product

The manufacturing of injectables is a highly controlled process to ensure the highest standards of quality and safety. The production process involves multiple stages, from cleaning the containers to final quality control and distribution. Below is an overview of the key steps involved in the manufacturing process of injectables:

Figure 10.1 Pharmaceutical manufacturing process



10.1.1 Start with API and excipients

The manufacturing process begins with the Active Pharmaceutical Ingredient (API) and excipients, which are carefully measured, mixed, and processed according to the required formulation. Once the sterile solution is prepared, it must be filled into appropriate containers under aseptic conditions.

At this stage, there is a choice to either purchase ready-to-use (RTU) containers or produce them in-house, depending on the supply chain strategy and production capabilities. Since this plant will mainly produce vials and prefilled syringes, here is an outline of the available options:

202 | Feasibility Studies Report

10.1.1.1 Vials

Option 1: Ready-to-Use (RTU) Vials

- Pre-sterilized and delivered in nest or tray packaging.
- Can be directly filled in aseptic conditions without additional washing or sterilization.
- Minimizes the risk of contamination and simplifies processing.
- Requires a sterile filling and sealing machine to complete the process.

Option 2: Bulk Vials

- Supplied unsterilized and require additional processing.
- In-house preparation involves:
- Ultrasonic Washing Machine – Removes particulates.
- Depyrogenation Tunnel – Uses dry heat sterilization to eliminate pyrogens (fever triggers).
- Sterile Transport System – Ensures vials remain aseptic before filling.

Allows more flexibility in sourcing but requires additional equipment, space, and validation processes.

10.1.1.2 Prefilled syringes

Option 1: Ready-to-Fill (RTF) Syringes

- Delivered pre-sterilized in nests or tubs, reducing contamination risks.
- Only require filling, plunger insertion, and final sealing before packaging.
- Requires a sterile syringe filling line with precise stoppering.

Option 2: Bulk Syringes

- Require in-house assembly, washing, and sterilization before filling.
- Preparation process includes:
- Syringe Assembly Machine – Assembles plunger, stopper, and barrel.
- Washing & Depyrogenation Systems – Ensure sterility before filling.
- Sterile Handling System – Facilitates aseptic processing.

More cost-effective for high-volume production, but demands additional sterilization validation.

10.1.2 Cleaning and washing of containers and closure

Containers, closures, and equipment used in injectables production undergo a thorough cleaning process to eliminate contaminants. This involves:

- Initial washing with detergent to remove residues.
- Multiple rinses with distilled water to remove detergent traces.
- A final rinse with Water for Injection (WFI) to ensure sterility before use in production.
- Drying and sterilization of cleaned components before filling.

10 Production process of injectables

Figure 10.2 Cleaning and washing process

10.1.3 Preparation of solutions

The preparation of solutions requires precise weighing, mixing, and control under aseptic conditions. This stage includes:

- Weighing and dissolving the required active pharmaceutical ingredients (APIs) and excipients in WFI.
- Use of mixing tanks with controlled temperature and stirring speed to ensure uniformity.
- pH and osmolarity adjustments to meet physiological requirements.
- Filtration of the solution through 0.22-micron filters to remove particulate matter before sterilization.

Figure 10.3 Preparation of solutions

10.1.4 Sterilization

Sterilization is a critical step in ensuring the safety and efficacy of injectables. There are two primary sterilization methods[8]:

Terminal Sterilization: This is the preferred method, where the product is sterilized in its final container using heat (autoclaving at 121°C for 15-20 minutes). It is the most reliable method for microbial inactivation.

Aseptic Processing: Used when terminal sterilization is not feasible due to heat sensitivity of the product. This method involves:

- Sterile filtration (through 0.22-micron filters) to remove microorganisms.
- Aseptic filling and sealing inside ISO 5 (Grade A) cleanrooms.
- Media fill tests to validate sterility assurance levels.

[8] World Health Organization (WHO). (2011). WHO good manufacturing practices for sterile pharmaceutical products.

204 | Feasibility Studies Report

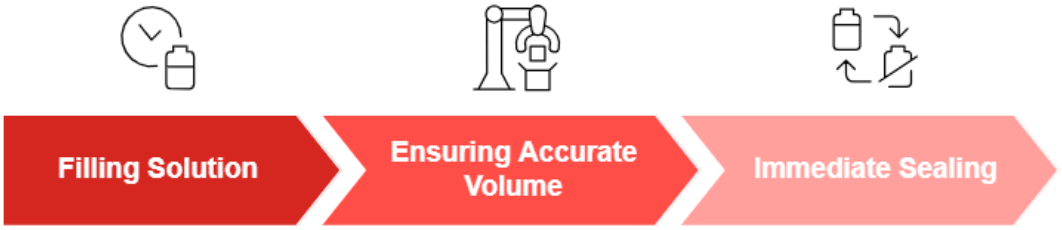
Whenever possible, products intended to be sterile should undergo terminal sterilization in their final container.

10.1.5 Filling and sealing

After sterilization, the solution is transferred into final pre-sterilized containers under aseptic conditions. The process includes:

- Filling of the solution into ampoules, vials, and transfusion bottles in an ISO 5 (Grade A) clean environment.
- Ensuring accurate filling volume using automated filling machines.
- Immediate sealing of containers to prevent contamination and evaporation.
- Sealing methods such as fusion sealing for ampoules or rubber stopper crimping for vials.

Figure 10.4 Filling and sealing process



Pharmaceutical manufacturers have multiple options for filling and sealing different types of containers, depending on the packaging format, level of automation, and sterility requirements. The production process varies significantly for PP bottles, plastic or glass vials, prefilled syringes, and soft IV bags, each requiring specialized filling lines and auxiliary equipment.

For this manufacturing plant, vials and prefilled syringes (PFS) are the primary packaging formats. Since these two formats have different handling, filling, and sealing requirements, separate dedicated filling lines are typically required. Based on the choice of the preparation of the container (already sterilized or not), extra steps for filling are necessary. Also, selection of APIs and excipients directly impacts the choice of filling line and processing steps. The physical form of the raw materials (whether liquid, powder, or lyophilized) determines how they are processed, sterilized, and filled into the final container. Below is an overview of the general aspects of the filling lines.

10.1.5.1 Vial Filling Line

The Vial Filling Line consists of the following steps:

- Filling
  - Liquid product is dosed into vials using peristaltic pumps, rotary piston pumps, or time-pressure filling systems.
  - Nitrogen purging may be used before or after filling to minimize oxygen exposure.
- Stoppering
  - Partially or fully inserting a rubber stopper immediately after filling to maintain sterility.
  - Lyophilization (if applicable)

10 Production process of injectables

- Vials with partially inserted stoppers are transferred to a freeze dryer for lyophilization.
- After drying, stoppers are fully inserted inside the freeze dryer.

- Capping
  - Vials are sealed with aluminium caps and crimped to ensure closure integrity.

Figure 10.5 Filling of vials

10.1.5.2 PFS Filling Line

The PFS Filling Line consist of the following steps:

- Filling
  - Liquid drug is filled into syringes using rotary piston pumps, peristaltic pumps, or time-pressure filling.
  - Vacuum filling or nitrogen flushing can be used to reduce air bubbles or oxygen exposure.
- Stoppering (Plunger Insertion)
  - Rubber plungers are inserted into the syringes in a controlled manner to prevent air entrapment.
- Needle Shielding (if applicable)
  - Some syringes have a fixed needle that requires a protective shield.

206 | Feasibility Studies Report

Figure 10.6 Filling of PFS

10.1.6 Quality Evaluation

The finished parenteral products undergo extensive quality testing to ensure compliance with pharmacopeial standards. The main tests include:

1. Sterility Test: Confirms that no microbial contamination is present.
2. Clarity Test: Ensures the absence of particulate matter.
3. Leakage Test: Detects any defects in container closure integrity.
4. Pyrogen Test: Determines the presence of endotoxins that could cause fever in patients.
5. pH and Osmolarity Tests: Ensures the solution matches physiological requirements for safe administration.
6. Particulate Matter Testing: Conducted using light obscuration or microscopy.

10.1.7 Packaging and labelling

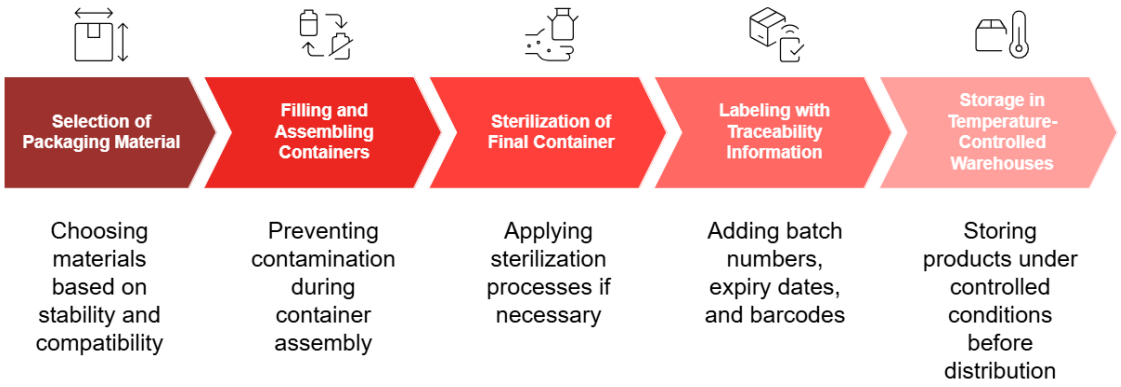
Approved products are labelled and packaged for storage or distribution. The packaging process includes[9]:

- Selection of appropriate packaging material based on stability and compatibility.
- Filling and assembling containers in secondary packaging to prevent contamination.
- Sterilization in the final container, if applicable.
- Labelling with batch numbers, expiry dates, and barcodes to ensure traceability
- Storage in temperature-controlled warehouses before distribution.

[9] World Health Organization (WHO). (2002). Guidelines on packaging for pharmaceutical products. WHO Technical Report Series No. 902, Annex 9.

10 Production process of injectables

Figure 10.7 Pharmaceutical packaging process



The packaging process is not uniform and depends on the specific format of the final product. When multiple types of packaging are required, such as vials, pre-filled syringes, or ampoules, different workflows must be implemented. These variations can impact the production setup, automation level, regulatory compliance, and storage requirements. As a result, multiple packaging streams may be necessary, each with its own considerations in terms of equipment, process flow, and quality control measures.

10.1.8 Key manufacturing steps

The table below outlines the key manufacturing steps for injectables and the corresponding facility areas where these steps are performed.

Production Step	Area
Cleaning and washing of containers and Closures	Ancillary Areas
Preparation of solutions	Weighing Areas
Sterilization	Production Areas
Filling and sealing	Production Areas
Quality evaluation	Quality Control Areas
Packaging and labelling	Storage Areas & Ancillary Areas

208 | Feasibility Studies Report

11 Waste management

11.1 Various types of waste

Pharmaceutical manufacturing generates various types of waste, each requiring specific handling and disposal methods to minimize environmental and health risks. The main categories of waste include:

- Packaging Waste – Includes both contaminated and uncontaminated materials such as paper, cardboard, glass, and plastics from packaging processes.
- Process Wastewater – Water used for cleaning, rinsing, or cooling during manufacturing, which may contain active pharmaceutical ingredients (APIs), solvents, or chemical residues.
- Pharmaceutical Residues – Unused or expired medications, active ingredients, and excipients that require careful disposal to prevent contamination of water sources and ecosystems.
- Hazardous Waste – Includes flammable, toxic, or cytotoxic substances that must be managed according to strict regulations.

Each of these waste streams must be handled in compliance with national and international guidelines to ensure environmental safety and regulatory compliance.

It is obliged to identify waste streams and provisions for reuse, recycling or disposal, including antimicrobial substances[10]. Waste material should not be allowed to accumulate. It should be collected in suitable receptacles for removal to collection points outside the buildings and disposed of safely and in a sanitary manner at regular and frequent intervals[11].

11.1.1 Packaging waste

Pharmaceutical packaging represents a small percentage of total waste, but its disposal can have significant environmental consequences. Proper waste management strategies should be in place to[12]:

- Store waste materials safely while awaiting disposal, ensuring that toxic and flammable substances are kept in separate, enclosed areas.
- Prevent accumulation by collecting waste in designated receptacles and removing it at regular intervals.
- Dispose of packaging waste according to its type:
  - Uncontaminated packaging waste (paper, cardboard, glass, plastic) can often be recycled.
  - Contaminated packaging waste (materials that have been in contact with blood, radioactive products, or cytotoxic drugs) requires specialized disposal, often through incineration.

[10] World Health Organization (WHO) (2022) Annex 4: Guidelines on the transfer of technology in pharmaceutical manufacturing. WHO Technical Report Series, No. 1044.
[11] World Health Organization (WHO) (2010) Good manufacturing practices for active pharmaceutical ingredients. WHO Technical Report Series, No. 957, Annex 2.
[12] World Health Organization (WHO) (2002) Good manufacturing practices for pharmaceutical products: main principles. WHO Technical Report Series, No. 902, Annex 9.

Feasibility Studies Report | 209

11 Waste management

11.1.2 Process wastewater

Wastewater generated during pharmaceutical production can contain chemical residues, solvents, or active pharmaceutical ingredients. This waste must be treated before discharge to minimize environmental impact.

- Wastewater should be assessed for contaminants and treated through appropriate filtration, neutralization, or biological treatment processes.
- In cases where hazardous chemicals are present, wastewater must be collected separately and disposed of according to hazardous waste regulations.

11.1.3 Pharmaceutical residues

Residual pharmaceutical products, including unused or expired drugs, pose a risk if disposed of improperly. To mitigate risks:

- Unused pharmaceuticals should be returned to authorized disposal facilities rather than being discarded in regular waste streams.
- Some pharmaceutical residues may require incineration or controlled chemical treatment to prevent environmental contamination.

11.1.4 Hazardous waste

Hazardous materials such as flammable solvents, cytotoxic drugs, and other toxic substances require specialized handling. Key principles include:

- Storing hazardous waste in dedicated, properly labelled containers to prevent cross-contamination.
- Disposing of these materials through authorized hazardous waste facilities or high-temperature incineration.
- Ensuring that national and international regulations are followed for the transport and disposal of hazardous waste.

210 | Feasibility Studies Report

12 Conceptual Design and Equipment Planning

12.1 Assumptions

The conceptual design and equipment planning is based on the assumptions listed below. Please note that if changes are made to the assumptions, that this will also result in changes in the conceptual design and equipment planning.

The following main assumptions were made:

- The target product list, including the projected quantities, listed in **Error! Reference source not found.** is used for determining the size of the facility and its equipment. This target product list includes 30 million vials and 6 million PFS per year at full production capacity.
- To include maintenance time and holidays, the facility is assumed to operate 40 hours per week, for 40 operational weeks per year. This totals to 1,600 production hours per year. With this number of operational hours, the vial filling line will need to operate at a rate of approximately 300 vials per minute and the PFS filling line at approximately 65 PFS per minute.
- The SVP formulations will be delivered in glass vials. The glass vials will be washed and sterilized in-house.
- The PFSs will be delivered in plastic syringes. These are usually delivered pre-sterilized and ready-to-fill (RTF). Additional washing and sterilization equipment will therefore not be needed.
- The vial and PFS filling lines will be strictly separated to minimize changeover time.

12.2 Filling Line Requirements for the Injectable Manufacturing Plant

Based on the product list and the technical feasibility requirements, the following filling lines and associated equipment are required to support the production of sterile injectables.

12.2.1 Types of Filling Lines Required

To accommodate the production of both vials and prefilled syringes, separate dedicated filling lines will be implemented:

Vial Filling Line (SVP - Small Volume Parenterals)

- Designed for liquid formulations (e.g., anaesthetics, anticoagulants, antibiotics)
- Supports vial sizes ranging from 1mL to 50mL
- Includes options for lyophilization (freeze drying) when applicable.

Prefilled Syringe (PFS) Filling Line

- Required for products such as Erythropoietin (PFS) and Oxytocin.

Feasibility Studies Report | 211

12 Conceptual Design and Equipment Planning

- Designed for syringe volumes between 0.5mL and 5mL.
- Equipped with automatic plunger insertion and sealing mechanisms.

12.2.2 Filling Line Differentiation Based on Volume

Certain injectable products require different production capabilities based on their volume. In general:

Table 12.1 Filling line differentiation

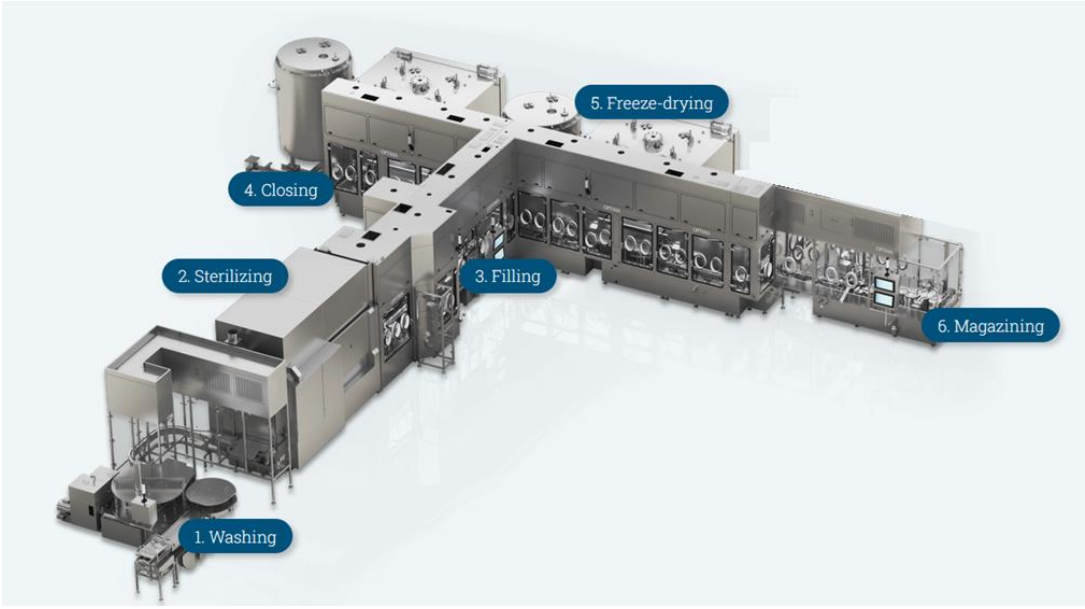
Container Type	Volume Range	Filling Line Required
Vials (Glass/Plastic)	1mL - 10mL	Standard Vial Filling Line
Vials (Larger)	20mL - 50mL	Large Vial Filling Line
Prefilled Syringes	0.5mL - 5mL	Prefilled Syringe (PFS) Line
Lyophilized Powders	Any volume	Requires freeze-drying module

The number of different product volumes directly impacts the required filling line setup. Generally, the more diverse the volume range, the more filling lines are needed to handle production efficiently. While some volume ranges may be combined on the same line, this depends on equipment flexibility and compatibility with different container sizes.

Switching between different volumes on the same filling line requires setup adjustments and changeover time, which can impact production efficiency. For this analysis, we assume two filling lines:

- One dedicated to vials (covering both standard and larger vial volumes).
- One dedicated to prefilled syringes (PFS).

Figure 12.1 General filling line



212 | Feasibility Studies Report

Source: https://www.optima-packaging.com/en/industries/pharma-and-biotech/aseptic-filling/solutions-for-vials-bulk

12.3 Vial filling line equipment

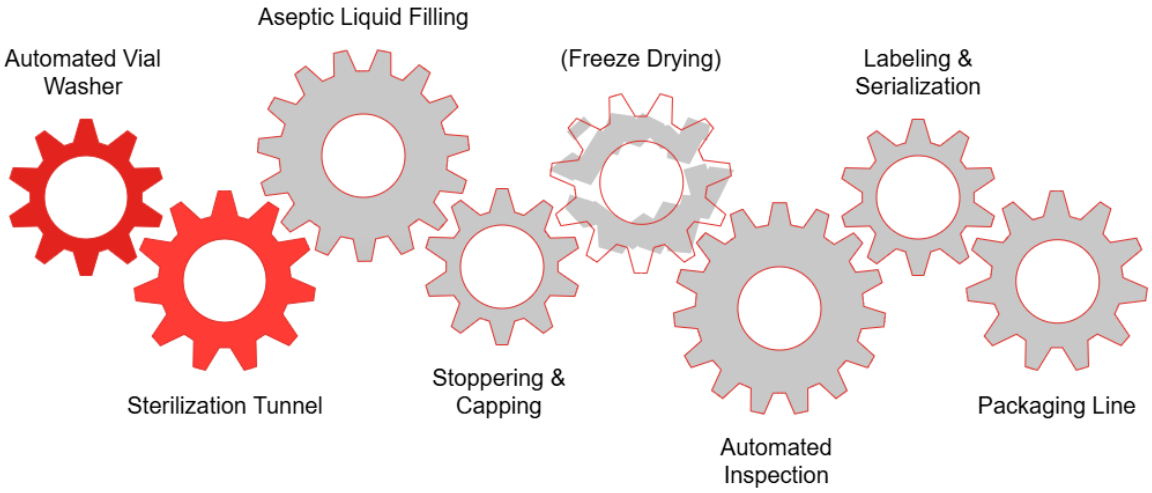
This line is dedicated to the liquid vial filling process (excluding freeze-drying).

12.3.1 Washing & Sterilization

Before filling, vials undergo a thorough cleaning and sterilization process to eliminate contaminants. A fully automated vial washer and sterilization tunnel ensures this step is carried out with precision, utilizing high-temperature dry heat sterilization to remove microbial contaminants. For enhanced cleanliness, an optional ultrasonic pre-treatment can be integrated.

To maintain sterility, a pure steam generator provides sterile steam for the sanitization of equipment and contact surfaces, ensuring compliance with GMP and ISO cleanroom standards. Additionally, a Water for Injection (WFI) system produces Purified Water (PW), Highly Purified Water (HPW), and Water for Injection (WFI) through an energy-efficient process. The system includes modular storage and distribution skids to ensure consistent quality and sterility in all stages of production.

Figure 12.2 Washing and sterilization steps in vial filling line



12.3.2 Filling & Closing

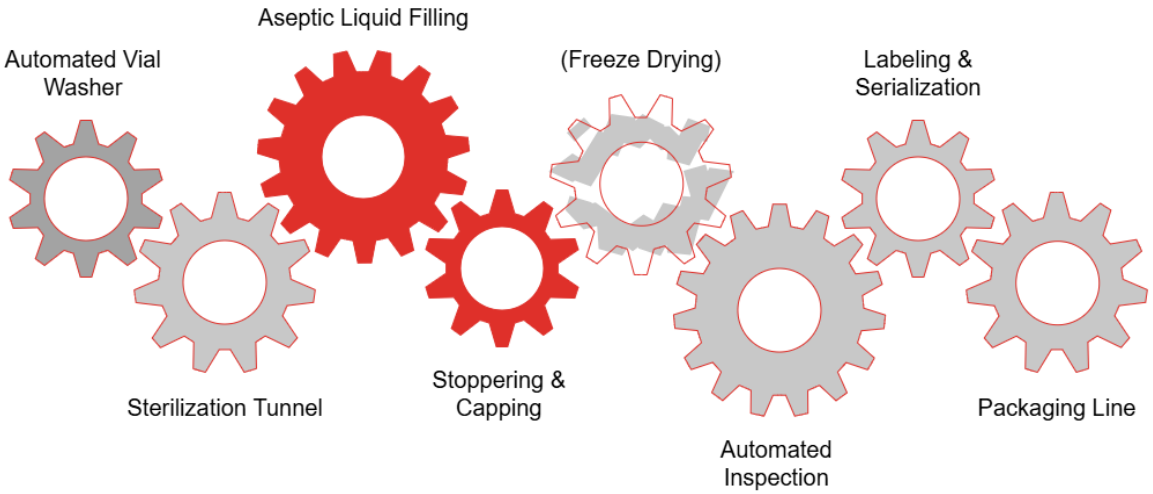
The aseptic liquid filling machine, equipped with an integrated stoppering system, operates in a sterile environment to ensure precise dosing of liquid products into vials. The system is adaptable to various filling technologies, including rotary piston pumps, peristaltic pumps, and time-pressure filling systems, making it suitable for a wide range of liquid viscosities.

Once filled, vials are sealed using a capping and sealing machine, which provides a fully automated crimping process to maintain sterility and product integrity. For oxygen-sensitive formulations, the system includes inert gas flushing, minimizing residual oxygen content and preserving product stability.

12 Conceptual Design and Equipment Planning

214 | Feasibility Studies Report

Figure 12.3 Asceptic liquid filling and stopering & capping steps in vial filling line

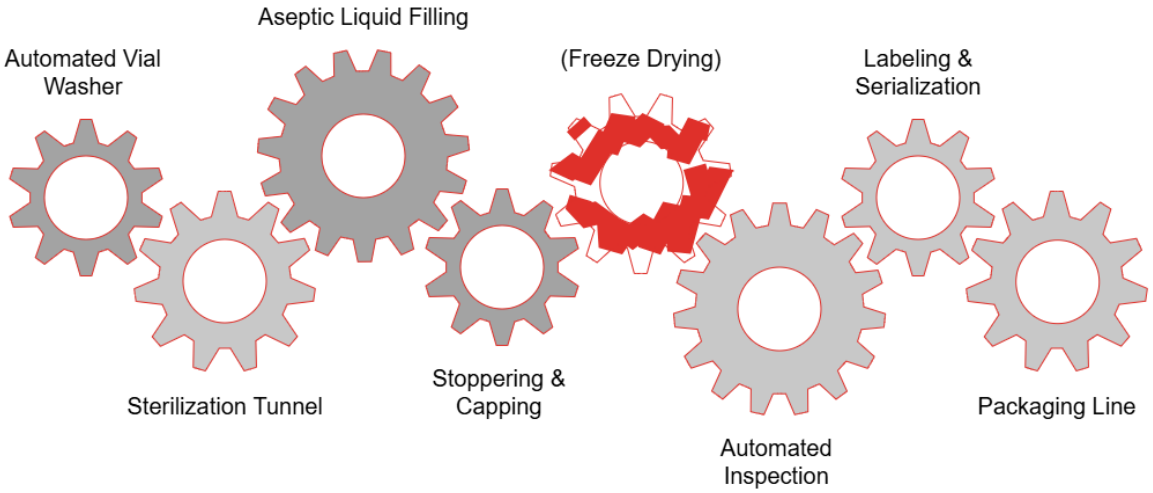


12.3.3 Freeze-Drying (if required)

For formulations requiring freeze-drying, an integrated freeze-drying module is available to extend the product's shelf life. The system includes automated or manual loading and unloading mechanisms, ensuring a seamless transition between the filling and freeze-drying stages. Designed to be scalable, this module supports both small clinical batches and large-scale commercial production, offering flexibility based on production needs.

Currently, the target product list does not include any items that require freeze-drying. However, it may be beneficial to incorporate the necessary equipment now to facilitate the addition of this process in the future.

Figure 12.4 Optional freeze-drying step in vial filling line

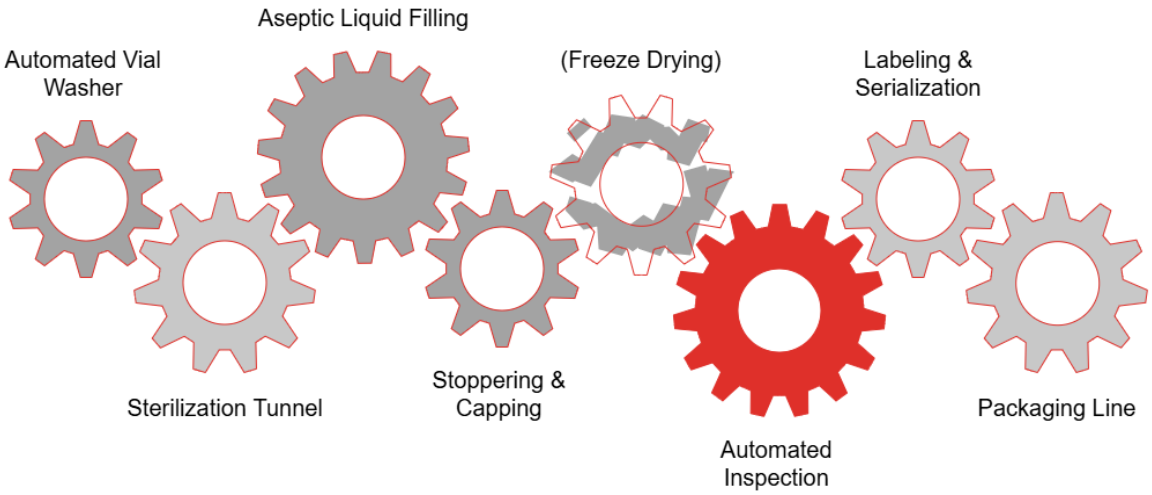


12 Conceptual Design and Equipment Planning

12.3.4 Inspection & Quality Control

Ensuring product quality is a critical aspect of the vial filling process. An automated visual inspection system detects particulates, cosmetic defects, and closure integrity using advanced camera and illumination technology. This system guarantees that every vial meets the highest safety and quality standards before packaging.

Figure 12.5 Automated inspection step in vial filling line



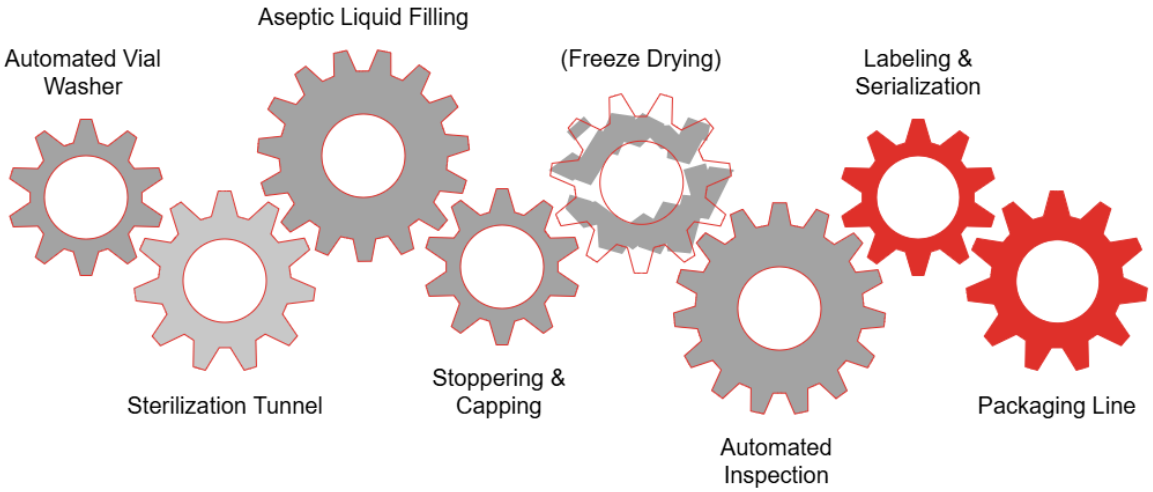
12.3.5 Packaging & Labelling

Once inspected, vials are labelled and packaged to comply with serialization and regulatory labelling requirements. The labelling and packaging machines accommodate multiple vial sizes and label formats, ensuring flexibility in production.

To streamline the packaging process, magazining units provide automated storage and batch separation of finished vials. The system supports two or four magazines alternately, allowing continuous operation and reducing downtime between batch changes.

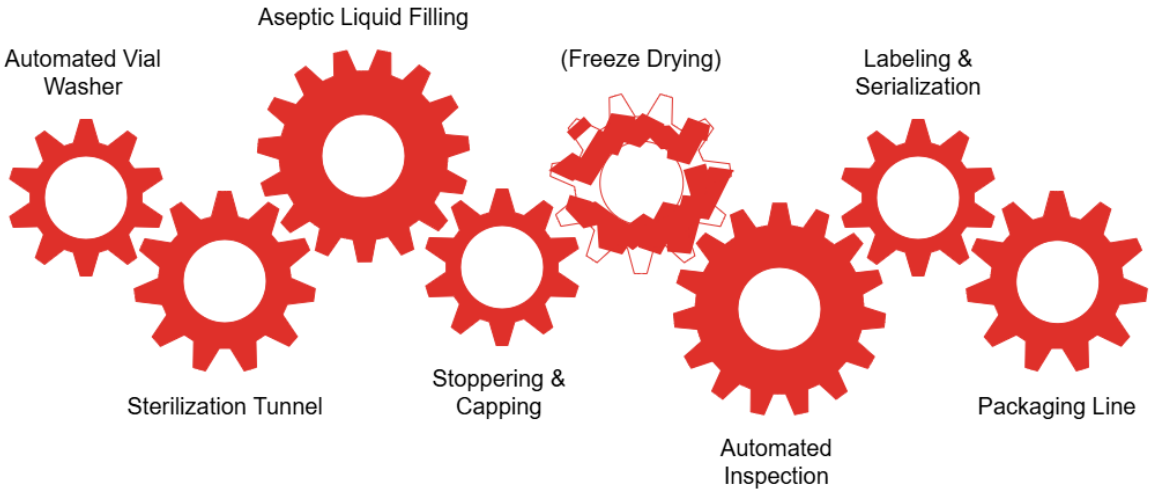
Figure 12.6 Labelling & Serialization and packaging step in vial filling line

216 | Feasibility Studies Report



In total, the vial filling line itself requires the following equipment:

Figure 12.7 Complete vial filling line



12.4 PFS filling line equipment

This line is dedicated to the sterile filling and sealing of prefilled syringes.

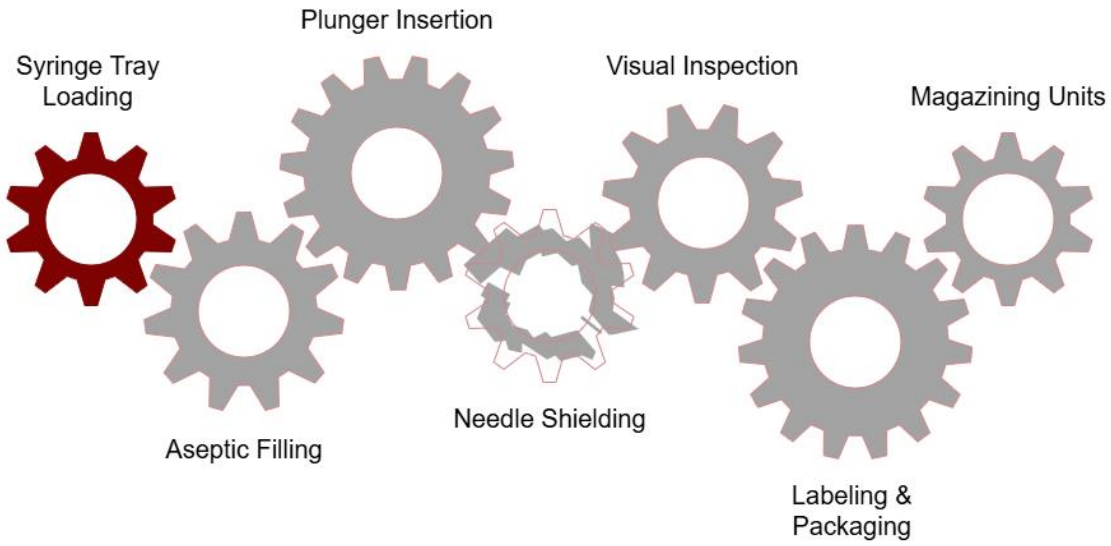
12.4.1 Washing & Sterilization

Unlike vials, which require washing and sterilization, prefilled syringes (PFS) are typically supplied pre-sterilized in nests or tubs. Instead of a vial washer and depyrogenation tunnel, the Sterile Syringe Tray Loader is used to ensure controlled loading while minimizing contamination risks.

The Pure Steam Generator and Water for Injection (WFI) System are identical to those used in the vial filling line, providing essential sterile steam for equipment sterilization and high-purity water for solution preparation and cleaning.

12 Conceptual Design and Equipment Planning

Figure 12.8 Syringe tray loading step in PFS filling line



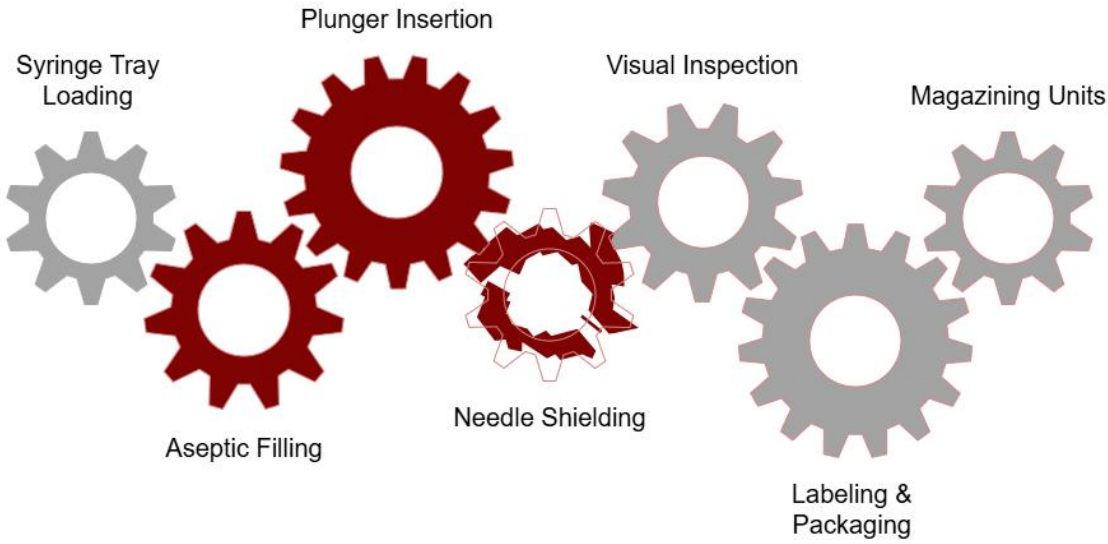
12.4.2 Filling & Closing

The Aseptic Liquid Filling Machine used for PFS filling operates similarly to the vial filling system, handling aseptic dosing of liquid formulations using rotary piston pumps, peristaltic pumps, or time-pressure filling systems. However, instead of stoppering and capping, syringe-specific closing mechanisms are used.

After filling, the Plunger Insertion Machine precisely inserts rubber stoppers or plungers into the syringes, ensuring controlled closure and preventing air entrapment. For syringes with fixed needles, an additional Needle Shielding System is incorporated to apply protective caps.

Figure 12.9 Asceptic filling, plunger insertion and optional needle shielding step in PFS filling line

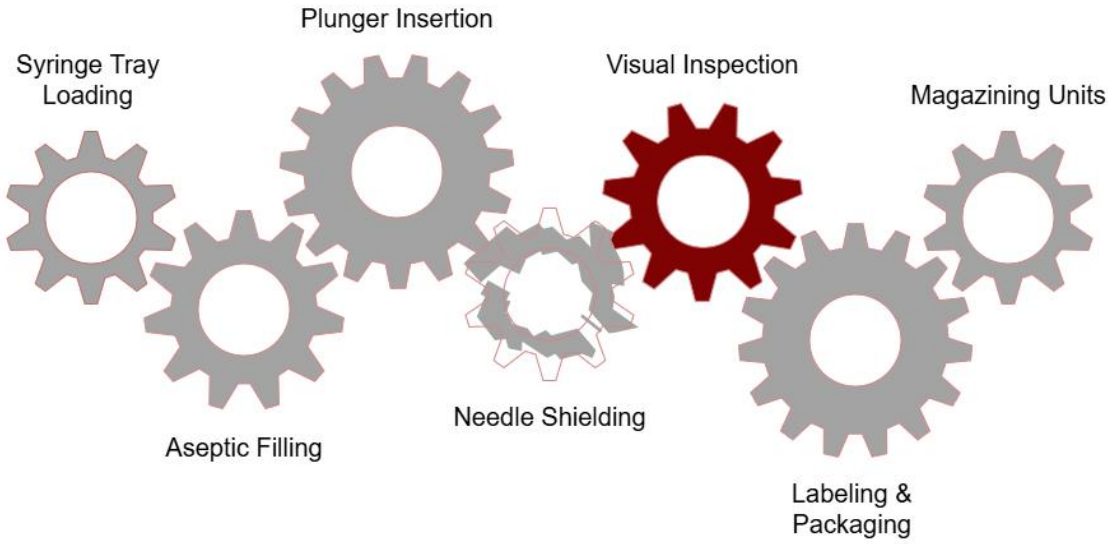
218 | Feasibility Studies Report



12.4.3 Inspection & Quality Control

As in the vial filling line, an Automated Visual Inspection System ensures syringe integrity and sterility, detecting particulates, cosmetic defects, and closure issues using camera and illumination technology. This system is identical to the one used in vial production but configured for the specific dimensions and characteristics of syringes.

Figure 12.10 Asceptic filling, plunger insertion and optional needle shielding step in PFS filling line



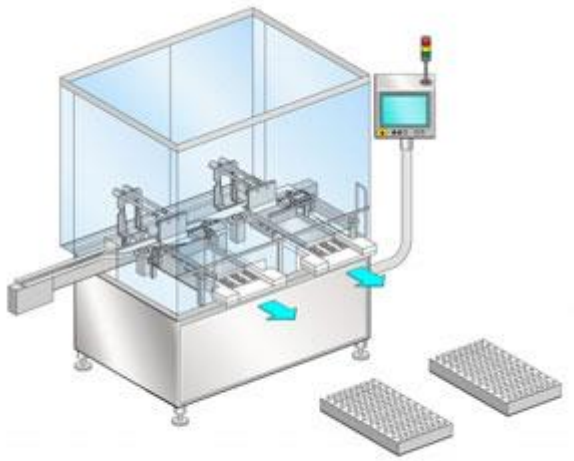
12.4.4 Packaging & Labelling

Following inspection, the Labelling & Packaging Machines apply serialization codes and regulatory labels, ensuring compliance across different markets. Since syringe packaging formats differ from vials, the machine must accommodate various syringe sizes and label orientations.

To streamline packaging, Magazining Units automate the storage and batch separation of syringes, supporting continuous operation through alternating magazine systems—a feature identical to the vial line.

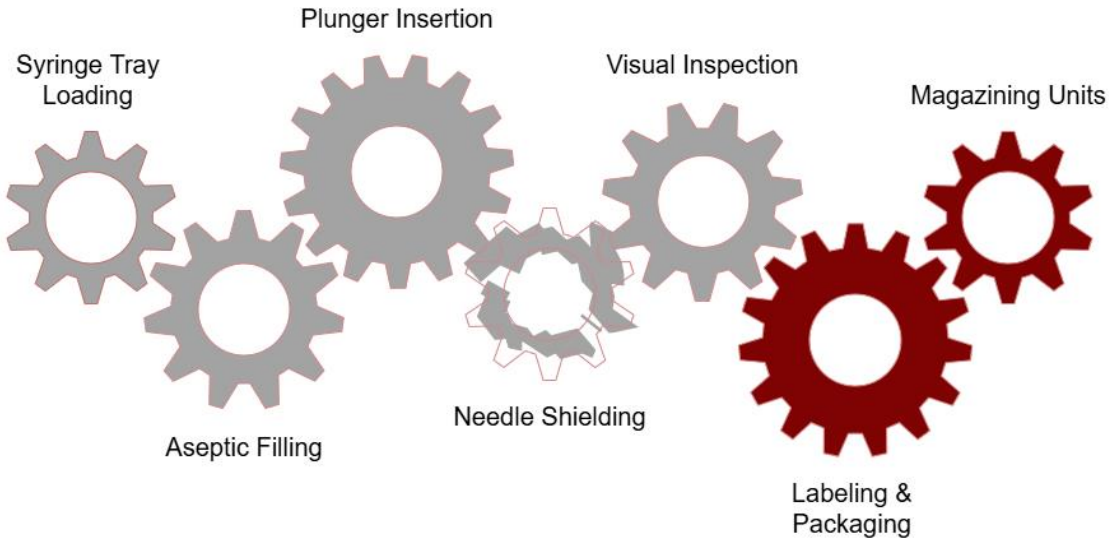
12 Conceptual Design and Equipment Planning

Figure 12.11 Magazining Units



Source: https://acetechnologiesgroup.com/product/magazining-unit-3/

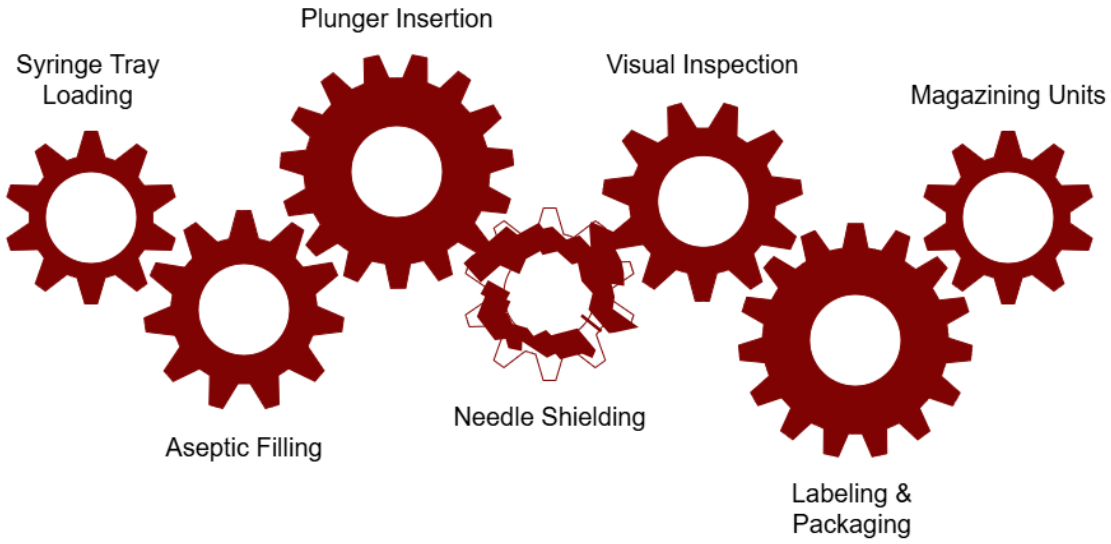
Figure 12.12 Labelling & Packaging and magazining steps in PFS filling line



In total, the PFS line requires the following equipment:

220 | Feasibility Studies Report

Figure 12.13 Complete PFS filling line



12.4.5 Key differences between vial and PFS filling lines

While both lines share core systems like WFI, pure steam, inspection, and labeling, the handling, filling, and closing processes differ significantly:

Table 12.2 Key differences between vial and PFS filling lines

Stage	Vial Filling Line	Prefilled Syringe (PFS) Filling Line
Container Preparation	Vials require washing & depyrogenation.	PFS are pre-sterilized and require tray loading.
Filling Mechanism	Liquid is filled into vials, then stoppered.	Liquid is filled into syringes, then plunger-inserted.
Sealing Process	Vials are sealed with rubber stoppers and crimped caps.	Syringes are plunger-inserted, with optional needle shielding.
Inspection & Labelling	Standardized process for vials.	Requires customized handling for different syringe sizes.

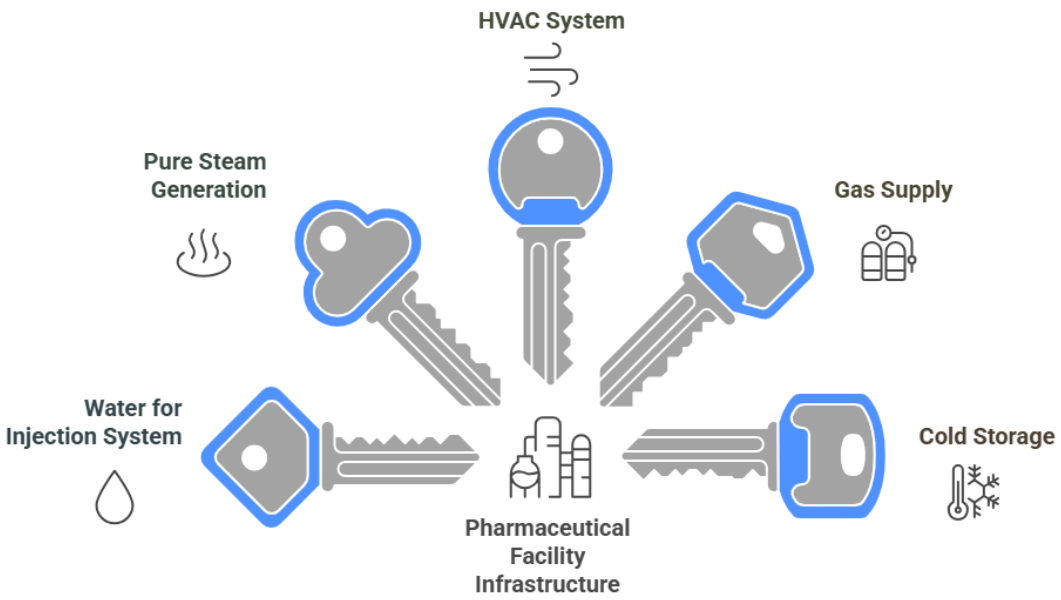
12.5 Utility and supporting equipment

To ensure full compliance with Good Manufacturing Practices (GMP)[13] and maintain sterility throughout the manufacturing process, the following supporting equipment will be included:

[13] World Health Organization (WHO), 2011. Annex 6: Good manufacturing practices for sterile pharmaceutical products. WHO Technical Report Series 961.

12 Conceptual Design and Equipment Planning

Figure 12.14 Utility and supporting equipment for the vial and PFS filling lines



12.5.1 Water for Injection (WFI) System

Water for Injection (WFI) is an essential component in pharmaceutical manufacturing, used for solution preparation, cleaning, and sterilization. The preferred production method is distillation, which removes pyrogens and microbial contaminants, ensuring high-purity water. Alternatively, reverse osmosis combined with ultrafiltration can be used, though it requires additional purification steps to meet regulatory standards.

To maintain sterility and prevent microbial growth, WFI is stored and circulated through sanitary stainless-steel piping at temperatures above 70°C or below 4°C. This ensures a continuous, contamination-free supply throughout the facility.

12.5.2 Pure steam generation

A pure steam generator provides sterile steam for equipment sterilization, including autoclaves, clean-in-place (CIP) systems, and steam-in-place (SIP) sterilization of critical components. Additionally, it supports cleanroom humidity control, ensuring compliance with ISO 14644 cleanroom standards.

To prevent contamination, the system is constructed from pharmaceutical-grade stainless steel and includes an integrated condensate removal system to eliminate impurities from the steam cycle.

12.5.3 HVAC and Cleanroom air handling system

A high-performance Heating, Ventilation, and Air Conditioning (HVAC) system is essential for maintaining cleanroom classifications, preventing contamination, and ensuring a controlled production environment. The system integrates HEPA filters that remove airborne contaminants as small as 0.3 microns, while laminar airflow systems provide controlled, unidirectional airflow in critical aseptic areas.

222 | Feasibility Studies Report

To maintain sterility, positive air pressure prevents cross-contamination between classified areas, while temperature and humidity control mechanisms ensure compliance with ISO 14644 and GMP regulations.

12.5.4 Compressed air & nitrogen supply

A reliable supply of sterile compressed air and nitrogen is required for multiple manufacturing processes. Compressed air is used for cleaning and drying vials and syringes before filling, as well as powering pneumatic valves and process equipment.

Nitrogen is primarily used for flushing vials before filling to reduce oxidation and overlaying in storage tanks to maintain product stability. Both systems must meet pharmaceutical-grade purity standards to ensure product integrity.

12.5.5 Cold storage & warehouse facilities

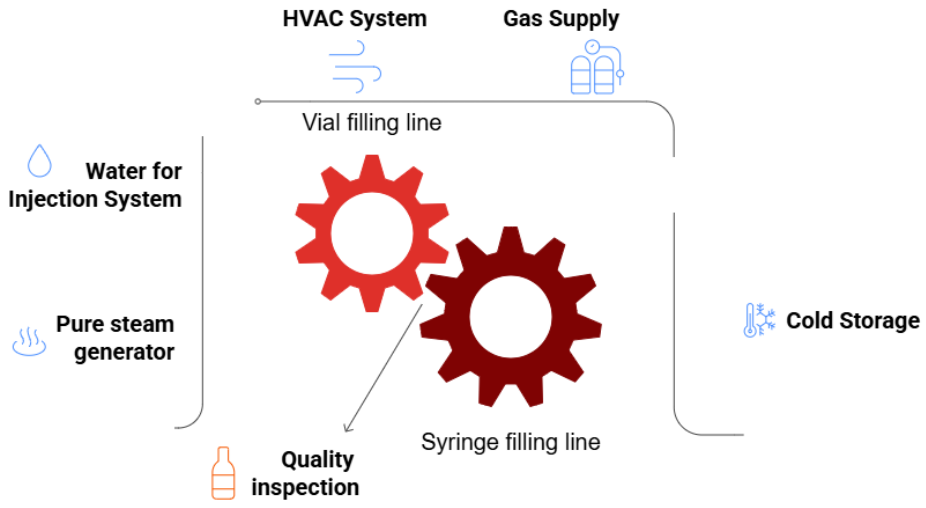
Proper storage conditions are critical for preserving the stability and efficacy of temperature-sensitive pharmaceutical products. The facility includes refrigeration units (2-8°C) for products such as Erythropoietin, Enoxaparin, and Oxytocin, along with ultra-low temperature freezers (-20°C or below) for specific APIs and biologics. A temperature monitoring and alarm system ensures real-time tracking to prevent deviations from required storage conditions.

The warehouse is structured with separate areas for quarantine, raw materials, packaging components, and finished products, along with dedicated storage zones for hazardous materials and controlled substances to ensure compliance with pharmaceutical storage regulations.
Proper storage conditions are critical to maintain the stability and efficacy of temperature-sensitive pharmaceutical products.

12.6 Equipment list

The table below consolidates all equipment required for both filling lines and supporting systems. In total the facility requires two filling lines and additional supporting equipment:

Figure 12.15 Vial and PFS filling lines with supporting equipment



12 Conceptual Design and Equipment Planning

Table 12.3 Equipment list

Category	Machine	Used for
Vial Filling Line	Vial Washer + Depyrogenation Tunnel	Vial cleaning and sterilization
	Aseptic Liquid Filling Machine	Filling of vials
	Stoppering & Capping Machine	Closing vials
	Automated Inspection System	Checking vials for defects
	Labelling & Serialization Machine	Labelling and regulatory compliance
	Packaging Line	Final packaging of vials
PFS Filling Line	Sterile Syringe Tray Loader	Loading empty syringes
	Aseptic Liquid Filling Machine	Filling of syringes
	Plunger Insertion Machine	Closing syringes
	Automated Inspection System	Checking syringes for defects
	Labelling & Serialization Machine	Labelling and regulatory compliance
	Packaging Line	Final packaging of syringes
Utilities & Support Systems	WFI Generation System	Producing sterile water
	WFI Storage & Distribution System	Providing continuous WFI supply
	Pure Steam Generator	Producing sterile steam
	Compressed Air & Nitrogen System	Clean air supply and nitrogen purging
Storage & Warehousing	Cold Storage Units (2-8°C)	Storing temperature-sensitive APIs/products
	Deep Freezer (-20°C or below)	Storing ultra-low temperature products
	Warehouse & Bulk Storage	General storage for raw materials & packaging
	Temperature & Humidity Monitoring System	Ensuring compliance with storage conditions
Cleanroom & Environmental Control	HVAC System with HEPA Filtration	Maintaining sterile environments
	Laminar Flow Workstations	Aseptic processing areas
	Airlocks & Pass-Through Chambers	Safe material transfer
Cleaning & Sterilization	CIP & SIP Systems	Cleaning process equipment
	Autoclave (if applicable)	Terminal sterilization
	Ultrasonic Cleaning System	Pre-treatment for vials

12.6.1 Shared equipment

While vial and PFS filling lines require distinct machines for key operations (e.g., filling, closing, and packaging), certain machines and systems can be shared to optimize costs and space utilization. However, shared equipment introduces changeover time and may impact efficiency depending on production scheduling. The figure below illustrates the advantages and disadvantages of sharing equipment between the two filling lines. The table below lists the equipment that can possibly be shared.

224 | Feasibility Studies Report

Figure 12.16 Advantages and disadvantages of sharing equipment

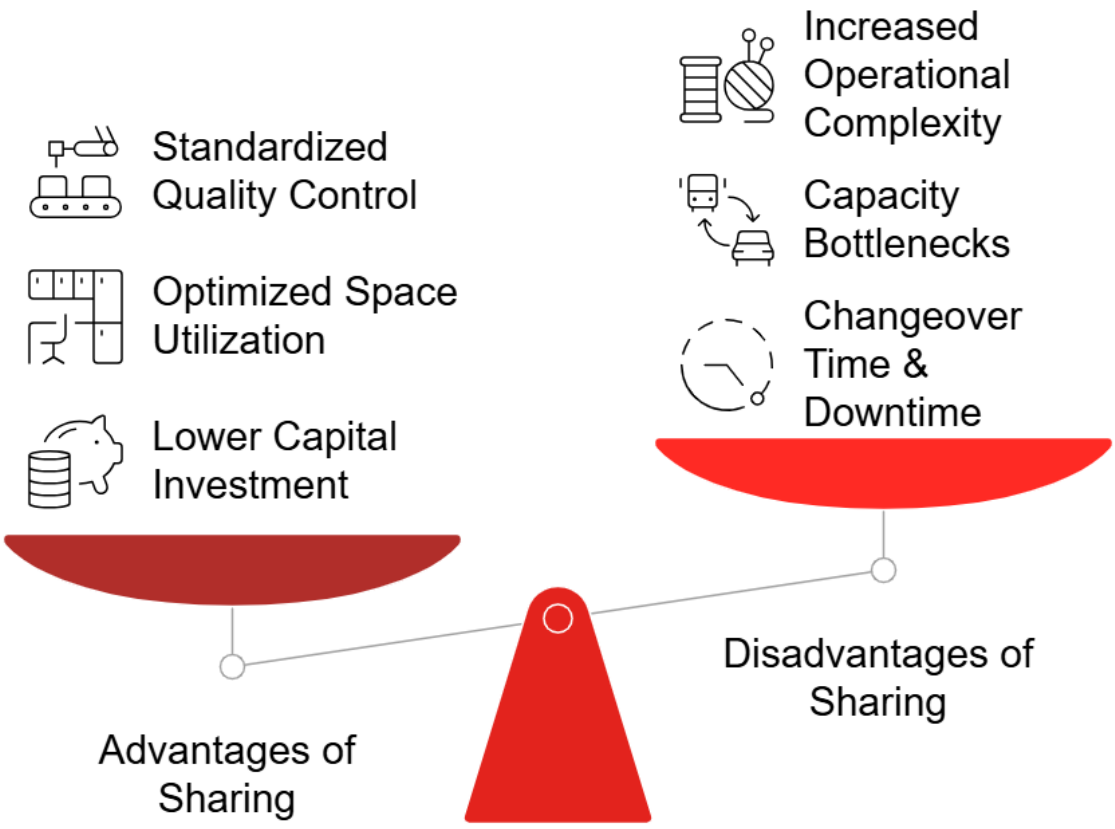


Table 12.4 Shared equipment

Equipment	Recommendation
WFI, Pure Steam, Compressed Air, HVAC	Can be shared if designed for high capacity.
Automated Visual Inspection	Can be shared, but requires changeover.
Labeling & Serialization	Can be shared, but frequent changeover may impact efficiency.
Packaging Line	Can be shared, but different product formats must be accounted for.
Filling & Stoppering Machines	Should be separate to avoid cross-contamination and maximize uptime.
Lyophilization Module	Not needed for PFS; should be dedicated for vials only.

12.7 Conceptual design

12.7.1 Design Objective

Quintex Pharma Ltd. aims to create a Good Manufacturing Practice (GMP)-compliant environment that ensures sterility, efficiency, and regulatory compliance. The facility will support the production of Small Volume Parenterals (SVPs), including vials and prefilled syringes (PFS), while meeting ISO 14644-1 cleanroom classifications and EU and WHO GMP requirements.

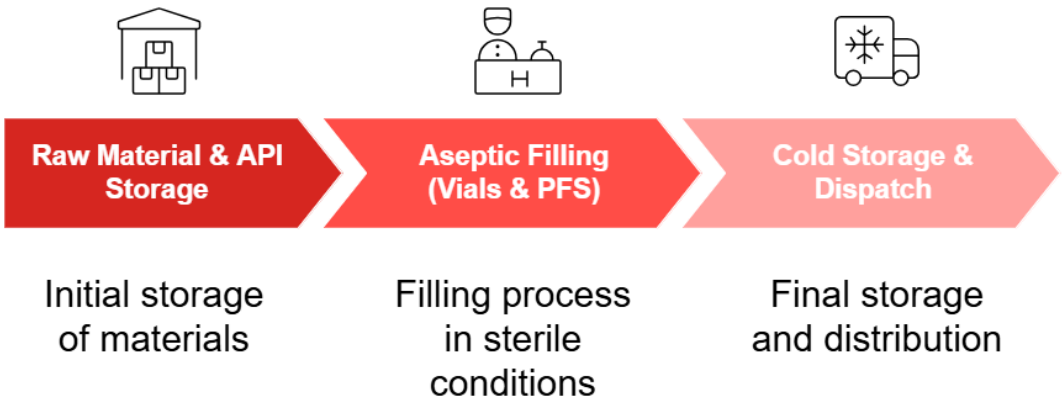
12 Conceptual Design and Equipment Planning

12.7.2 Facility layout considerations

To maintain sterility and maximize efficiency, the layout should follow a unidirectional process flow, ensuring that raw materials and finished products never cross paths. The key steps in the flow can be summarized as follows:

- Raw material & API storage (both room temperature and cold storage)
- Weighing and dispensing
- Solution preparation
- Washing and sterilization of vials
- Aseptic filling of vials and prefilled syringes: there will be two separate dedicated production lines. One for vials and one for prefilled syringes.
- Quality control
- Labelling and packaging: there will also be two dedicated labelling and packaging lines. One for vials and one for prefilled syringes.
- Final product storage (both room temperature and cold storage)

Figure 12.17 Summary of steps involved in the injectables manufacturing plant



12.7.3 Structural and technical requirements

The structural and technical requirements are based on cleanroom classifications and regulatory compliance, ensuring the highest sterility levels.

The following cleanroom classifications are applicable to the facility:

Table 12.5 Cleanroom Classification

Area	Required ISO Classification	EU GMP Grade
Aseptic Filling (Vials & PFS)	ISO 5	Grade A
Background for Filling & Sterile Processing	ISO 7	Grade B
Solution Preparation & Weighing Areas	ISO 7	Grade C
Storage, Packaging & Ancillary Areas	ISO 8	Grade D

226 | Feasibility Studies Report

The following requirements are applicable to the HVAC system:

- High-Efficiency Particulate Air (HEPA) filters ensuring clean airflow in ISO 5 zones.
- Positive air pressure differentials to prevent contamination between classified areas.
- Temperature and humidity control mechanisms to ensure product stability.

The following utility and support systems should be set in place:

- Water for Injection (WFI) generation and distribution system to supply purified water for formulation and cleaning.
- Pure steam generation system for sterilization of equipment and components.
- Compressed air and nitrogen supply to maintain aseptic processing environments and product integrity.
- Cold storage capacity (2-8°C for temperature-sensitive products)

12.7.4 Room list

The following table outlines the designated areas, descriptions and required surface space.

Table 12.6 Room List

Area	Room name	Room description	Room surface (m^2)
Storage areas	Incoming goods area	Storage for raw materials and components awaiting QA release.	120
	Raw material storage	ISO 8 / Grade D. Dedicated storage area for incoming APIs and excipients that passed the quality assurance tests.	30
	Cold storage	ISO 8 / Grade D. Dedicated storage for incoming APIs and excipients that passed the quality assurance tests and require refrigerated storage (2-8˚C).	30
	Final product storage	ISO 8 / Grade D. Warehouse for final products that can be stored at room temperature. Temperature and humidity monitoring is required.	75
	Refrigerated final product storage	ISO 8 / Grade D. Cold storage for final products that require refrigerated storage. This comprises 66% of the final products. Temperature (2-8˚C) and humidity monitoring is required.	150
Ancillary areas	Vial cleaning and washing room	ISO 7 / Grade B. Initial washing, rinsing with WFI and drying and sterilization. Only for vials.	40 (~6.3 x 6.2)
	Vial sterilization room	ISO 5 / Grade A. Dry heat sterilization in depyrogenation tunnel.	52 (~8.5 x 6.1)
	WFI generation and storage room	Water treatment room for making water for injection (WFI), including two storage tanks.	75
	Pure steam generation room	Room that includes a pure steam generator.	15

12 Conceptual Design and Equipment Planning

Area	Room name	Room description	Room surface (m^2)
	Compressed air & nitrogen room	Room that includes an air and nitrogen compressor.	15
Weighing area	Weighing and dispensing room	ISO 7 / Grade C. Room where APIs and excipients are weighed and dispensed.	40
	Mixing room	ISO 7 / Grade C. Room with mixing tanks for stirring APIs and excipients in WFI.	60
Production area - vials	Aseptic filling and sealing	ISO 5 / Grade A. Filling of sterilized vials with the solution under aseptic conditions.	75 (~7.4 x 10.2)
	Labelling and packaging	ISO 8 / Grade D. Vials will get their primary and secondary packaging and a light test will be performed for quality control	95 (~11.2 x 8.46)
Production area – PFS	Asceptic filling and plunger insertion	ISO 5 / Grade A. PFSs will be filled with the solution and the plunger will be inserted and sealed.	28 (~5.5 x 5)
	Labelling and packaging	ISO 8 / Grade D. PFSs will get their primary and secondary packaging and a light test will be performed for quality control.	95 (~11.2 x 8.46)
Quality control area	Laboratory	Laboratory for quality control of APIs and final product.	30
Other areas	Changing rooms	Gowning areas for personnel to change into appropriate cleanroom attire before entering classified areas.	-
	Washrooms	Dedicated washrooms for staff working in the facility, separate from production areas.	-
	Toilets	Restroom facilities for personnel, ensuring hygiene and compliance with workplace standards.	-
	Maintenance workshop	Workshop for equipment repair, maintenance, and spare parts storage.	-
	Office space	Administrative offices, including areas for documentation, meetings, and supervision.	-
	HVAC	Room for the Heating, Ventilation, and Air Conditioning (HVAC) system.	-

228 | Feasibility Studies Report

13 Risk Assesment and Mitigation Plan

13.1 Introduction

The successful establishment of Quintex Pharma's sterile injectable manufacturing facility requires comprehensive risk identification and robust mitigation planning. This chapter outlines the critical risks identified throughout the project lifecycle—from design to operational stages—and presents mitigation strategies that align with global pharmaceutical standards, regulatory requirements, and strategic business objectives.

Each chapter of the present feasibility study elaborates on the risks assessment regarding the section. The present chapter present a brief general overview of all risks mentioned across the document and the corresponding mitigation strategies

13.2 Overview of Risk Categories

Risks associated with the facility's design and layout include potential for cross-contamination, inadequate cleanroom classifications, and improper zoning. These can lead to severe consequences such as regulatory non-compliance, diminished operational efficiency, and possible product recalls. In terms of utilities, failures in critical systems like the Water for Injection (WFI) loops, HVAC, and compressed air lines pose significant threats to product sterility and operational continuity. Furthermore, the complexity of production equipment, particularly the need for reliable changeovers and sterilization processes, introduces risks of downtime, batch contamination, and resource inefficiency.

Operational risks are equally multifaceted. Power outages, inconsistent water quality, and disruptions in the supply chain can halt production or compromise product integrity. Technological risks such as failures in inline water quality sensors or blockchain supply tracking systems further amplify operational vulnerabilities. Non-alignment with WHO GMP, EU GMP Annex 1, and delayed regulatory approvals are key compliance risks that can delay market entry and disrupt export strategies. Personnel-related risks such as limited technical expertise, inadequate aseptic training, and high turnover can lead to increased contamination incidents and loss of institutional knowledge. Financial and market risks, including currency fluctuations and price sensitivity, directly impact profitability. Lastly, external risks such as political instability, climate events, and infrastructure failures introduce systemic threats to long-term business continuity.

13.3 Priority Risk Areas

Among the numerous risks, several have been prioritized due to their potential to critically disrupt operations. The sterilization process is considered the highest threat to both product quality and patient safety. Failures in this area could result in non-sterile product release and serious regulatory

Feasibility Studies Report | 229

13 Risk Assesment and Mitigation Plan

consequences. Utility system reliability, especially with WFI and HVAC infrastructure, is another top priority due to its direct influence on product sterility and cleanroom environment stability. Regulatory non-compliance remains a major risk, particularly the loss of GMP certification or delays in product registration, which would hinder both local and international market access. Additionally, human resource challenges such as inadequate training and high attrition rates increase the likelihood of operational errors. Lastly, vulnerabilities in the supply chain and global logistical disruptions pose a serious threat to consistent production and delivery schedules.

13.4 Expanded Mitigation Strategies

To address facility design-related risks, Quintex will implement a comprehensive unidirectional flow system for both personnel and materials, guided by ISO 14644 standards. Cleanroom classifications will follow modular production design principles, ensuring scalable compliance. The zoning of operations will be regularly audited using facility simulation tools and internal review mechanisms to maintain environmental control and prevent cross-contamination.

In response to utility-related risks, redundancy is key. Multiple WFI loops and HVAC backup systems will ensure resilience. These systems will be monitored using real-time IoT-enabled sensors, supported by predictive analytics to pre-emptively address maintenance issues. Preventive maintenance schedules and HEPA filtration systems will be central to maintaining cleanroom integrity.

To mitigate operational and technological risks, Quintex will deploy smart infrastructure including inline quality sensors, blockchain-based supply tracking with hybrid verification, and climate-responsive warehouse designs. Inventory systems will be designed for flexibility, enabling swift adaptation to demand fluctuations and supply chain interruptions. Predictive analytics will help monitor operational KPIs, flagging anomalies before they impact production.

Regulatory alignment will be ensured through early and continuous engagement with local and international regulatory bodies. GMP audit simulations and compliance benchmarking with WHO and EU GMP standards will prepare the facility for stringent inspections. Accelerated product registration pathways will be pursued through the formation of fast-track compliance teams and liaison officers.

Human capital development is central to the mitigation strategy. Employees will undergo continuous training in GMP, aseptic techniques, and environmental hygiene. Technical staff will benefit from career development pathways and competitive compensation packages designed to boost retention. Onboarding programs will focus on instilling a strong quality culture from the outset.

Market and financial risks will be managed through strategic treasury operations, including interest rate hedging and currency risk management. A dynamic pricing model will be employed, responsive to market trends and input costs. Scenario-based planning and investor engagement frameworks will ensure financial transparency and resilience.

To mitigate external risks, including political instability and climate change, the plant design will emphasize decentralized utility dependencies and modular production units capable of withstanding

230 | Feasibility Studies Report

environmental stress. Business continuity planning will include ESG frameworks, disaster response protocols, and climate-responsive infrastructure.

The table below states the main technical risks involved in the proposed injectables manufacturing plant, including the impact and the mitigation strategy of each risk.

Table 13.1 Risk and Mitigation Plan

Risk Category	Identified Risk	Potential Impact	Mitigation Strategy
Facility Design & Layout	Cross-contamination due to improper facility layout	Risk of microbial contamination and product recalls	Implement unidirectional flow, separate personnel and material pathways, and airlocks
	Insufficient cleanroom classification	Non-compliance with ISO 14644 & EU GMP Annex 1	Design cleanrooms with ISO 5, ISO 7, and ISO 8 zoning and ensure HVAC validation
Utility & Support Systems	Failure of Water for Injection (WFI) system	Contaminated product batches, regulatory non-compliance	Install redundant WFI loops, ensure continuous monitoring and periodic validation
	HVAC system malfunction	Unstable temperature and humidity conditions, sterility risk	Implement HEPA filtration, positive pressure differentials, and automated monitoring
	Compressed air and nitrogen purity issues	Risk of particulate or microbial contamination in filling areas	Use oil-free compressors, sterile filtration, and regular system validation
Production Equipment	Equipment failure or downtime	Delays in production and increased operational costs	Establish preventive maintenance programs, stock critical spare parts
	Inefficient changeover between vial and PFS lines	Reduced production efficiency, downtime	Optimize changeover procedures, use multi-format adaptable machines
	Switching between different vial sizes takes excessive time	Prolonged production downtime, reduced throughput	Limit vial size variations per production run, use quick-changeover tooling, and optimize batch planning
Aseptic Processing & Sterilization	Failure in sterilization (autoclave, SIP, CIP)	Non-sterile product release, high rejection rates	Implement validated sterilization cycles, periodic requalification, and bio-indicator testing
	Particulate contamination during filling	Defective product, risk to patient safety	Use HEPA-filtered laminar airflow, automated particle inspection
Inspection & Quality Control	Failure in automated visual inspection	Release of defective products, regulatory penalties	Regular calibration and validation of visual inspection systems
	Incorrect labelling or serialization	Risk of mislabelling, product recalls	Implement automated vision-based labelling inspection
Cold Storage & Warehousing	Temperature deviations in cold storage	Product degradation, stability loss	Install 24/7 temperature monitoring & alarm systems, validate cold chain logistics
	Poor inventory management	Raw material shortages, expired stock	Implement automated warehouse tracking and FIFO (First-In-First-Out) system
Regulatory Compliance & Validation	Non-compliance with GMP or regulatory audits	Production shutdown, legal penalties	Conduct internal GMP audits, maintain comprehensive documentation
Personnel & Training	Inadequate operator training in aseptic techniques	Increased risk of contamination and human errors	Implement GMP-compliant training programs, conduct regular competency evaluations

14 Financial Modeling

14.1 Introduction

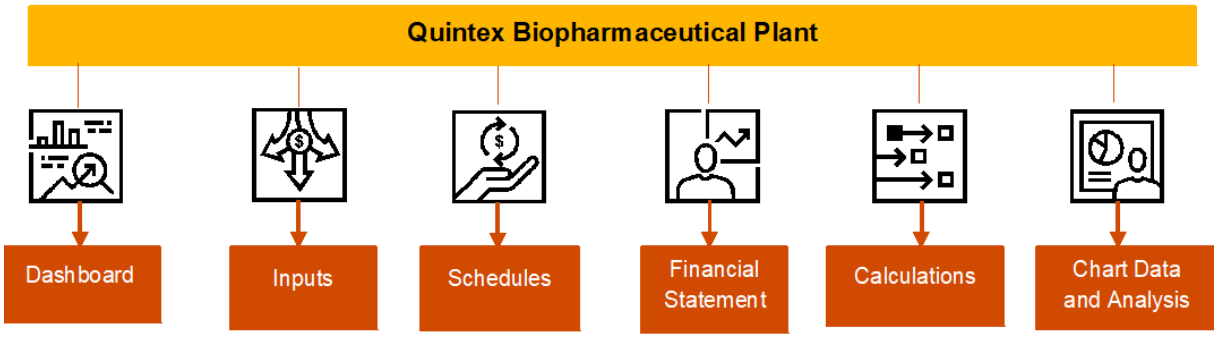
This section of the report assesses financial viability of project based on the cost of the proposed design and development, estimated revenue, estimated operating cost and the relevant financing assumptions for the development and operation of the project. The section will cover the financial viability assessment framework, key financial model assumptions, project evaluation criteria and financial results.

14.2 Approach

A financial model was developed by PwC to assess the financial viability of the project. In the following subsections, the framework of our financial models, key assumptions and schedules are discussed.

The financial model structure is summarised as follows:

Figure 14.1 Financial Model Structure



Source: PwC

The purpose of each element of the financial model is summarised below:

Table 14.1 Elements Purposes

No.	Section	Description
1	Dashboard	The dashboard presents the key results from the financial modelling analysis including the key investment

232 | Feasibility Studies Report

No.	Section	Description
		appraisal output. This includes the following: Project internal rate of return; Equity internal rate of return; Net Present Value (NPV); Average debt service coverage ratio (DSCR); Total Capital Expenditure (CAPEX); Average annual revenue; and Average annual O&M Costs. Beyond the relevant criteria, the dashboard also includes key graphical summaries from the analysis of revenue, costs, financing, production volumes, cash flows, etc. from the Project.
2	Input Sheet	This sheet captures the time based and non-time-based assumptions identified for the Project. It has been structured to facilitate scenario analysis that will help assess the viability of the Project when the various factors (such as product volume, pricing, market areas, capital expenditure [CAPEX], operational and maintenance [O&M] costs, estimated cost of capital etc) are changed. We have highlighted the 4 scenarios that we explored in the next section of this report.
3	Structured Financial Statements	This aspect of the financial model includes a structured statement for the Statement of Profit/Loss and Other Comprehensive Income, Statement of Financial Position and Statement of Cash flows. These financial statements will calculate the line items for revenue, costs, financing, etc. forecasted over the project period.
4	Schedule Sheet	The schedule sheet supported the estimation of key time-based inputs such as annual revenue, annual O&M

14 Financial Modeling

No.	Section	Description
		costs, CAPEX phasing, pricing, depreciation amongst others. The analysis from schedules feed into the financial statement analysis and calculations for the forecasted period of the Project.
5	Calculations Sheet	The calculations sheet focuses on analysing the investment appraisal of the Project. The analysis uses the information from the financial model to compute the return profile and investment criteria elements of the project. This includes the project internal rate of return, equity internal rate of return, net present value, average debt service coverage ratio, etc.

Source: PwC

14.3 Key financial model assumptions

As part of assessing the financial viability of the proposed biopharmaceutical plant, we put in place the following key assumptions:

14.3.1 Time based assumptions

The following time-based assumptions were considered in our financial modelling analysis for the Project.

Table 14.2 Time based assumptions

No.	Assumption	Value
1	Construction start date	01-Jan-2026
2	Construction end date	31-Dec-2027
3	Construction period	2 years
4	Operations start date	31-Dec-2027
5	Operations end date	31-Jan-2036
6	Operations period	8 years
7	Total project period	10 years

Source: PwC

The financial model that we developed for the project has been structured to facilitate a monthly period of assessment in the first year of operation and quarterly thereafter.

234 | Feasibility Studies Report

14.3.2 Key non-time-based assumptions

As part of the development of our financial model and financial analysis. The following selected non-time-based assumptions were considered in the assessment:

- The estimated capital cost for developing the project has been estimated at US$ 55 million. This is information was provided by Quintex.
- Estimated weighted average cost of capital for the Project at approximately 15%.
- Assumed annual dividend payout to equity holders of approximately 12% per annum.
- Cost values and cost structures provided by Quintex to estimate the operations and maintenance costs associated with the running of the pharmaceutical manufacturing facility.
- For debt financing, an assumption that the project will be financed 100% with a single facility with a 2-year moratorium and an 8-year repayment period. The interest structure is linked to a forecast of the 6-month SOFR with an assumed margin of 0.5%. The facility structure also includes the following fees which were accounted for as part of debt financing costs for the project: upfront fees, commitment fees, appraisal fee, administration and supervision fee. Quintex provided some documentation with some indicative terms on these fees to be used as part of the assumptions for this project.
- Computation of revenue was informed by forecasted demand volumes and prices for molecules anticipated to be sold in Ghana, Senegal, Burkina Faso and Cote d'Ivoire. The details on the volumes and pricing are set out in earlier chapters in this report.

It is important to note the following considerations in our work:

- Based on the analysis provided by IQIVIA, the scenario structure is based on a foundation of a base case and Optimistic case (based on projected volumes and pricing). Based on discussions with Quintex, for each of these first level scenarios we have developed a second level of scenarios based on the potential capital structure of the project. This assessment includes assessing a debt-to-equity ratio of 70/30; 60/40; 50/50. Discussion with Quintex indicated that the 50/50 debt to equity ratio was most likely to be structured for the Project. However, we agreed to explore the other 2 capital structures to inform decision making.
- Based on the scenario structure identified, the financial viability analysis for the Project assessed six different scenarios for delivering the Project. Further details on the scenarios are provided in the section below.
- The analysis in this report is based on a financial model that we developed to assess the financial viability of the Project. We have provided tabular summaries on the ley inputs and outputs from our financial model.

14.3.3 Project scenarios analysed

The following six scenarios were analysed using our financial model for the Project:

- **Scenario 1-Base Case 70/30**: In this scenario, we have all the 20 molecules analysed and validated by IQIVIA for Ghana. Additionally, this scenario includes the 5 molecules analysed and validated for Senegal, Cote d'Ivoire and Burkina Faso. The base case indicates the set of molecules for the four countries above, the forecast prices and volumes. Additionally, this scenario explores a 70/30 debt-equity capital structure to finance the Project over the 10-year project period. This base case considers the impact of a relatively high competition from potential local manufacturers and a moderated market share for Quintex over the project period.

14 Financial Modeling

- **Scenario 2- Optimistic Case 70/30**: In this scenario, all the 20 molecules were considered analysed and validated by IQIVIA for Ghana. Additionally, this scenario includes the 5 molecules analysed and validated for Senegal, Cote d'Ivoire and Burkina Faso. This scenario explores a 70/30 debt-equity capital structure to finance the Project over the 10-year project period. However, the optimistic case considers a relatively lower level of competition from potential local manufacturers and a higher market share for Quintex over the project period.
- **Scenario 3- Base Case 60/40**: In this scenario, we have considered all the 20 molecules analysed and validated by IQIVIA for Ghana. This scenario also includes the 5 molecules analysed and validated for Senegal, Cote d'Ivoire and Burkina Faso. Additionally, this scenario explores a 60/40 debt-equity capital structure to finance the Project. This base case considers the impact of a relatively high competition from potential local manufacturers and a moderated market share for Quintex over the project period.
- **Scenario 4: Optimistic Case 60/40**: In this scenario, we have considered all the 20 molecules analysed and validated by IQIVIA for Ghana. The scenario also includes the 5 molecules analysed and validated for Senegal, Cote d'Ivoire and Burkina Faso. Additionally, this scenario explores a 60/40 debt-equity capital structure for financing the Project. This optimistic case considers the impact of a relatively low competition from potential local manufacturers and potentially higher market share for Quintex over the project period.
- **Scenario 5: Base Case 50/50**: In this scenario, we have considered all the 20 molecules analysed and validated by IQIVIA for Ghana. This scenario also includes the 5 molecules analysed and validated for Senegal, Cote d'Ivoire and Burkina Faso. This scenario explores a 50/50 debt-equity capital structure for financing the Project. This base case considers the impact of a relatively high competition from potential local manufacturers and a moderated market share for Quintex over the project period.
- **Scenario 6: Optimistic Case 50/50**: In this scenario, we have considered all the 20 molecules analysed and validated by IQIVIA for Ghana. The scenario also includes the 5 molecules analysed and validated for Senegal, Cote d'Ivoire and Burkina Faso. Additionally, this scenario explores a 50/50 debt-equity capital structure for financing the Project. This optimistic case considers the impact of a relatively low competition from potential local manufacturers and potentially higher market share for Quintex over the project period.

14.4 Preliminary Financial Analysis Output

The following table summarises the output from our financial analysis of the 6 scenarios considered for the preliminary assessment of the Quintex Biopharmaceutical Plant Project.

Table 14.3 :Financial results per scenario

No.	Scenario Name	Investment Appraisal Summary**
1	• Base Case-70/30	• Project IRR: 14.35% • Equity IRR: 10.68% • NPV: US$ 7.86 million • Average DSCR: 2.11 • Payback period (discounted): 15 years • Average Annual Revenue: US$ 23.83 million

236 | Feasibility Studies Report

No.	Scenario Name	Investment Appraisal Summary**
		• Annual Revenue Range (US$ million): 4.37 – 39.74 • Average Annual O&M costs: US$ 6.46 million
• 2	• Optimistic Case-70/30	• Project IRR: 19.21% • Equity IRR: 19.95% • NPV: US$ 20.56 million • Average DSCR: 2.37 • Payback period (discounted): 8 years • Average Annual Revenue: US$ 28.84 million • Annual Revenue Range (US$ million): 5.61 – 50.24 • Average Annual O&M costs: US$ 6.46 million
• 3	• Base Case- 60/40	• Project IRR: 14.29% • Equity IRR: 11.39%` • NPV: US$ 17.21 million • Average DSCR: 2.45 • Payback period (discounted): 9 years • Average Annual Revenue: US$ 23.83 million • Annual Revenue Range (US$ million): 4.37 - 39.74 • Average Annual O&M costs: US$ 6.46 million
• 4	• Optimistic Case-60/40	• Project IRR: 19.15% • Equity IRR: 19.63% • NPV: US$ 32.23 million • Average DSCR: 2.76 • Payback period (discounted): 8 years • Average Annual Revenue: US$ 28.84 million • Annual Revenue Range (US$ million): 5.61 – 50.24 • Average Annual O&M costs: US$ 6.46 million
• 5	• Base Case-50/50	• Project IRR: 14.23% • Equity IRR: 11.97% • NPV: US$ 26.49 million • Average DSCR: 2.93 • Payback period (discounted): 9 years • Average Annual Revenue: US$ 23.83 million • Annual Revenue Range (US$ million): 4.37 – 39.74 • Average Annual O&M costs: US$ 6.46 million
• 6	• Optimistic Case-50/50	• Project IRR: 19.07% • Equity IRR: 19.35% • NPV: US$ 43.10 million • Average DSCR: 3.28 • Payback period (discounted): 8 years • Average Annual Revenue: US$ 28.84 million • Annual Revenue Range (US$ million): 5.61 – 50.24 • Average Annual O&M costs: US$ 6.46 million

Source: PwC

14 Financial Modeling

* These are results from the analysis and the data provided on revenue inputs, operations and maintenance costs, CAPEX and financing for the Project as well as other relevant assumptions. The scenarios are informed by the potential capital structure (debt to equity ratio) of the Project as well as the base versus optimistic case for Ghana, Burkina Faso, Senegal, Cote d'Ivoire and Burkina Faso.

From the table above, we noticed that the optimistic case for the various scenarios (i.e. 70/30; 60/40 and 50/50) indicate the strongest financial viability compared to the base case scenarios.

14.4.1 Sensitivity Analysis

As part of stress testing our assumptions and their potential impact on the viability of the Project. We extended our assessment of the Project to include a sensitivity analysis. Our sensitivity analysis tested decreases (-50%, -40%,…,-10%) and increases (+50%,+40%,…,+10%) in the following parameters and assessed the impact on the viability of the Project:

- Prices of the molecules;
- Volume of the molecules;
- Cost of debt (interest rate);
- Project capital expenditure (CAPEX); and
- Project operations and maintenance (O&M) costs.

The results of the sensitivity analysis across the above parameters are summarised in Annex III of this report. In summary, we made the following key observations:

- Increase in price and volume (holding all other factors constant) for both the base and optimistic cases, increase the strength of the viability parameters for the Project (particularly, equity IRR, NPV and Average DSCR). This indicates that where there may be potential scope, as the project begins operations, Quintex may explore expanding production volumes and increasing prices to enhance the project's viability. It is important to note that the latter must be done strategically to avoid pricing out the molecules produced by Quintex from the market. Periodic market assessments should be used to inform market positioning decisions such as production volume and pricing to help maximise the potential benefit to Quintex and its shareholders;
- The optimistic scenario demonstrated relatively higher annual revenue range compared to the base case scenario. The revenue range for the optimistic case was estimated at a minimum revenue of US$ 5.61 to a maximum of up to US$ 50.24 over the operational period of the Project, holding all other factors constant;
- The analysis indicates that reducing CAPEX further (all other things remaining constant), increases the strength of the project viability in terms of returns and debt coverage. This will involve reviewing the specifications and related considerations for developing the infrastructure by finding relatively cheaper alternatives for example plant, machinery, equipment etc) or phasing out those items further down the operational period; and
- The analysis also indicates that, holding all other factors constant, and reducing the O&M costs, improved the financial viability parameters of the project. This was assessed by reducing line items such as staff costs, maintenance costs, consumables, etc to help strengthen the project's financial viability over the operational period.

238 | Feasibility Studies Report

14.5 Conclusions and suggestions

The financial viability assessment was carried out using data made available by the technical consultants involved in the feasibility study, as well as specific inputs provided by Quintex. The analysis revealed that under the optimistic scenario, all tested capital structures (70/30, 60/40, and 50/50 debt-to-equity ratios) yielded the most favorable outcomes, with strong projected cash flows indicating the project's capacity to comfortably service its debt obligations. This suggests that securing low-cost debt financing could significantly enhance equity returns, provided that other assumptions remain constant. To strengthen the project's viability, it is advisable for Quintex to engage with prospective lenders to obtain draft term sheets, potentially considering a blended financing approach that combines two to four different funding sources. Additionally, establishing a clear benchmark for minimum acceptable equity returns or average Debt Service Coverage Ratio (DSCR) would support decision-making around selecting the most appropriate financing structure..

15 Economic Evaluation

15.1 Introduction

This chapter presents the economic evaluation of Quintex Pharma Limited's proposed development of a biopharmaceutical injectable manufacturing plant in Ghana. The Project forms part of a broader feasibility study designed to assess the financial viability and strategic potential of establishing the facility through a joint venture with an international partner. The economic evaluation provides critical insights into the opportunities and risks associated with the Project, with particular attention to the Ghanaian healthcare market and broader West African region.

As part of Ghana's national agenda to position itself as a pharmaceutical manufacturing hub under the Ministry of Trade and Industry's Ten-Point Industrial Transformation Plan, this Project aligns with initiatives such as the Jobs and Economic Transformation (JET) Programme, supported by the UK Foreign and Commonwealth Development Office (FCDO). The Project seeks to contribute to reducing Ghana's heavy reliance on pharmaceutical imports, enhancing medicine security, fostering technology transfer, and creating skilled employment opportunities.

The economic evaluation assesses the macroeconomic environment, regulatory policies, healthcare market dynamics, and potential demand within Ghana and the ECOWAS sub-region. It identifies key economic drivers, potential barriers, and market prospects that will impact the successful realization of the injectable plant, providing a foundation for informed decision-making regarding project financing and implementation.

15.2 Global Review of Pharmaceutical Industry

The global pharmaceutical market, valued at USD 1,516 billion in 2023, is projected to grow at a compound annual growth rate (CAGR) of 4.9%, reaching USD 1,863 billion by 2028[14]. Over the past five years, global medicine consumption has increased by 14%, with a further 12% growth expected by 2028, bringing annual usage to USD 3.8 trillion defined daily doses[15].
As one of the most vital and rapidly growing industries worldwide, the pharmaceutical sector plays a key role in global health. This was particularly evident in 2021 with the swift development of COVID-19 tests and vaccines. Over the past six decades, the biopharmaceutical industry has significantly improved patient outcomes, contributing to an increase of approximately 20 years in global life expectancy[16]. As medical challenges continue to evolve, ongoing innovations and breakthroughs in biopharmaceuticals are poised to enhance the lives of millions worldwide.

[14] BMI Fitch solutions, "Global-Pharmaceuticals-Report", January 2025: Pg 4.pdf
[15] IQVIA Institute, "The Global Use of Medicines 2024: Outlook to 2028," IQVIA Institute, (2024): https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-global-use-of-medicines-2024-outlook-to-2028
[16] International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), "IFPMA Facts and Figures 2022," IFPMA, (2023): https://www.ifpma.org/wp-content/uploads/2023/01/i2023_IFPMA-Facts-And-Figures-2022.pdf.

240 | Feasibility Studies Report

Key players include Pfizer, Johnson & Johnson, Lily, Novo Nordisk, Roche, Novartis, Merck & Co, AbbVie, Sanofi, AstraZeneca, GlaxoSmithKline (GSK), Bayer, Moderna, Amgen, Vertex, Regeneron which collectively hold the majority of the market share through diversified portfolios and strategic R&D investments[17].

15.2.1 Pharmaceutical Market Projections for 2024

According to Fitch's Global Pharmaceutical Report, the sector has witnessed rapid expansion in recent years and is expected to continue growing at a CAGR of 4.9% over the next decade. Key drivers of this growth include the rising prevalence of chronic diseases, an aging global population, the growing demand for geriatric care, climate change-related health conditions, the emergence of novel viral diseases, and the escalating threat of antimicrobial resistance.

15.2.2 Regional Projections

The table below gives a general overview of the pharmaceutical industry per region as well as factors driving growth in each region.

Table 15.1 Overview of the pharmaceutical industry across regions

No.	Region	Market Value (US$)	Growth Drivers
	North America	517.95 billion	This dominance is attributed to the region's robust healthcare infrastructure, high healthcare spending, and strong emphasis on research and development. The region also boasts major pharmaceutical companies.
	Asia	510.22 billion	Asia's rapid economic growth, increasing healthcare investments, and expanding middle-class population contributed to its substantial market size. China and India are key drivers of innovation and manufacturing in this region.
	Europe	457.75 billion	The region's well-established healthcare systems, strong regulatory frameworks, and significant investments in R&D supported its prominent position in the global market.
	Latin America	88.55 billion	Economic development, improving healthcare infrastructure, and increasing access to healthcare services were key factors driving this growth in this region.
	Middle East and North Africa (MENA)	38.13 billion	The region's market was influenced by factors such as economic diversification, government

[17] GlobalData, "Top 20 Global Biopharmaceutical Companies Report: Market Capitalization Growth to $3.67 Trillion in 2023," GlobalData, (2023): https://www.globaldata.com/media/business-fundamentals/top-20-global-biopharmaceutical-companies-report-1-6-market-capitalization-growth-to-3-67-trillion-in-2023-reveals-globaldata/.

15 Economic Evaluation

No.	Region	Market Value (US$)	Growth Drivers
			initiatives to improve healthcare, and increasing investments in the pharmaceutical sector.

Source: BMI Fitchsolutions, "Global Pharmaceuticals-Report", January 2025

Fitch Solutions report estimates Sub Saharan Africa's market value at US$ 21.09 billion, the smallest among the listed regions for 2024. The economic disparity limited healthcare spending and affected the overall demand for pharmaceutical products. With often less developed Healthcare infrastructure in Sub Saharan Africa, inconsistent regulation across different countries, and Distribution and logistics issues, the region offers great opportunities for pharmaceutical companies who are able to provide tailored solutions and or effectively navigate the regions unique situation.

15.3 Review of the Existing West African Market

This section presents a comprehensive analysis of the economic and healthcare landscapes of selected West African countries, with a focus on the structure, dynamics, and growth prospects of their pharmaceutical industries. Key macroeconomic indicators such as GDP growth trends, population demographics, and government healthcare expenditure are examined to assess factors influencing pharmaceutical demand across the region.

The analysis reviews the regulatory frameworks, trade policies, and infrastructural developments shaping each country's pharmaceutical sector. In addition to evaluating the size and projected growth of the pharmaceutical markets, the competitive landscape is assessed by examining the presence of major market players, prevailing pricing structures, and the extent of reliance on pharmaceutical imports. Particular attention is given to identifying gaps in local manufacturing capabilities and unmet demand for essential medicines, especially injectables.

By systematically evaluating these factors, the assessment aims to determine the market attractiveness of each country and to provide a strategic basis for Quintex Pharma's consideration of West Africa as a viable expansion region. Opportunities and challenges associated with market entry and competition are highlighted to support informed decision-making.

The market potential of 15 West African countries has been assessed, with rankings based on criteria such as dependency on imports, pharmaceutical demand dynamics, and opportunities for local production.

242 | Feasibility Studies Report

Table 15.2 Assessment of the West African Market Potential

No.	Country	Potential Market Attraction	Justification
1	Ghana	High	Ghana presents significant market potential for pharmaceutical manufacturing, with a growing industry valued at US$683 million in 2023 and projected to reach US$836 million by 2028. The country heavily relies on imports, with 70% of its pharmaceuticals being sourced abroad, creating a strong demand for local production. Government-imposed import restrictions on certain drugs like Dexamethasone and Diazepam offer competitive advantages for domestic manufacturers. High demand for sterile injectables, driven by disease burdens such as hypertension, maternal health issues, and cancer, further emphasizes the opportunity. Ghana's role as a regional trade hub and improving infrastructure supports its attractiveness for pharmaceutical manufacturing, particularly with initiatives like the Pharma Enclave and PharmaVax program. However, challenges such as high investment costs, energy supply issues, regulatory compliance, and competition from both local and foreign manufacturers remain. Despite these, strategic focus on restricted drugs, leveraging government support, and expanding regional market access could ensure long-term success in Ghana's pharmaceutical sector.
2	Nigeria	High	Nigeria's pharmaceutical market presents significant demand dynamics, driven by acute shortages of essential injectables, such as antibiotics, vaccines, and biologics. With over 70% of pharmaceutical products imported, the country faces a large import gap, creating substantial opportunities for local manufacturing. Demand is further fuelled by chronic diseases like diabetes, hypertension, and maternal health crises, driving the need for medications like insulin, anticoagulants and oxytocin. Nigeria's population of 223 million, with a median age of 18, further increases the demand for affordable medicines, compounded by the government's push for Universal Health Coverage by 2030. The AfCFTA mutual recognition agreements facilitate faster approvals for Ghana-produced injectables, cutting registration timelines and easing compliance with Nigeria's regulatory standards. However, challenges remain, particularly Nigeria's local content rules requiring 30% domestic input for government contracts. To navigate this, strategic partnerships with Nigerian firms, like Greenlife Pharmaceuticals, could enable compliance while maintaining cost efficiency, positioning firms like Quintex for success in Nigeria's growing pharmaceutical market.

Feasibility Studies Report | 243

15 Economic Evaluation

No.	Country	Potential Market Attraction	Justification
3	Senegal	High	Senegal offers a promising opportunity for pharmaceutical exports, driven by its heavy reliance on imports, with over 90% of medicines and 99% of vaccines being sourced from abroad. The pharmaceutical import market, valued at US$333.94 million in 2023, is dominated by imports from Europe, India, and China, leaving a gap for regional manufacturers like those in Ghana. The country faces significant healthcare challenges, including a shortage of healthcare professionals and high rates of maternal mortality and non-communicable diseases, which increase demand for essential injectables. The government has set ambitious targets to reduce import dependency, aiming to locally produce one-third of its pharmaceutical needs by 2030 and 50% by 2035, with a new manufacturing facility under construction. Despite limited local production capacity, Senegal's pharmaceutical market remains dependent on imports in the medium term. The country's economic growth, improving purchasing power, and strategic position as a trade hub in Francophone West Africa create favorable conditions for market entry. However, potential increases in local production may reduce long-term import demand, making it important for exporters to monitor government initiatives closely.
4	Sierra Leone	High	The Health Sector and Pharmaceutical Industry Analysis analysis reveals a high potential market opportunity for Quintex to enter the pharmaceutical sector in Sierra Leone. The pressing health issues, including significant maternal mortality, widespread hypertension, and the need for effective pain and mental health treatments, create a strong demand for these medications. Quintex can establish a strong presence and drive meaningful impact in the market by addressing these critical healthcare needs.
5	Liberia	High	Liberia offers significant market potential for pharmaceutical companies, driven by a rising demand for essential medicines due to high disease burdens, particularly maternal health issues, cardiovascular diseases, hypertension, and cancer. The pharmaceutical market is heavily reliant on imports, with Liberia receiving a notable increase in pharmaceutical shipments, primarily from India, Ukraine, and Côte d'Ivoire. Despite limited local production, this creates an opportunity for foreign companies to meet the growing demand for key medications like Oxytocin, Furosemide, and Enoxaparin. While challenges such as weak infrastructure, a shortage of skilled healthcare professionals, and underfunding persist, the healthcare sector's ongoing improvement and high need for critical medications make Liberia a promising market for pharmaceutical investment and expansion.

244 | Feasibility Studies Report

No.	Country	Potential Market Attraction	Justification
6	Gambia	High	Quintex's entry into the Gambia pharmaceutical industry provides a unique opportunity to tap into an emerging market with rising healthcare demands. The Gambia has a growing population, which increases the need for medications, particularly for chronic diseases, maternal mortality and infectious diseases, areas where Quintex has a strong portfolio. Moreover, Quintex's innovation would meet the demand for high-standard medications, particularly in a market with limited local production capabilities.
7	Cote D'Ivoire	Medium	Côte d'Ivoire's pharmaceutical market offers substantial opportunities, driven by the increasing prevalence of Non-Communicable Diseases (NCDs) like diabetes and hypertension, which require injectable treatments, many of which Quintex plans to produce. The country heavily relies on imports, particularly from France, for its pharmaceutical needs, and social preferences for French-made drugs pose a challenge for market penetration. However, the pharmaceutical market is lucrative, with the top four distributors generating approximately US$331 million in 2018, accounting for over 80% of the market. Côte d'Ivoire's population of 31 million is expected to grow 79% by 2050, and with strong GDP growth at 6.5% from 2021-2023, the market is expanding. The high demand for sterile injectables, particularly for maternal health and hypertension treatments, further presents opportunities. Local manufacturing currently accounts for only 10% of supply, providing Quintex with a competitive advantage if it can establish production facilities. Despite this, the market faces challenges, including a weak regulatory environment and strong competition from Indian pharmaceutical companies. Nonetheless, these dynamics create a significant market potential for Quintex in Côte d'Ivoire.
8	Cameroon	Medium	Cameroon presents a strong opportunity for pharmaceutical exports, particularly for Quintex's injectables, as the country produces only 5% of its pharmaceutical products, creating a significant gap in supply. The healthcare retail market is expected to grow substantially by 2027, further driving demand for pharmaceuticals. However, Cameroon faces resource deficits, particularly in rural areas where access to healthcare is limited, meaning Quintex may need to explore alternative logistics solutions beyond traditional road transport. Despite issues with counterfeit drugs, the market remains attractive due to the high prevalence of non-communicable diseases, which fuels

15 Economic Evaluation

No.	Country	Potential Market Attraction	Justification
			the demand for essential injectables. This combination of market growth, limited local production, and healthcare challenges creates a favourable environment for pharmaceutical companies like Quintex.
9	Togo	Medium	Togo presents a growing demand for pharmaceuticals, particularly injectables, due to high maternal and infant mortality rates, which drive the need for Oxytocin. The increasing prevalence of Non-Communicable Diseases (NCDs) like diabetes and hypertension further exacerbates healthcare challenges, creating additional demand for injectable treatments, many of which Quintex plans to produce. The Pharmaceuticals in dosage market in Togo reached US$278.59 million in 2023, with a CAGR averaging 2.01%.18 This combination of pressing healthcare needs, rising demand for essential injectables, and a growing market creates a strong opportunity for pharmaceutical companies like Quintex to establish a presence in Togo.
10	Cabo Verde	Medium	Cabo Verde presents a medium market attraction for pharmaceutical products due to its high dependence on imports, limited local production, and significant healthcare improvements. The country's commitment to universal health coverage and improved healthcare infrastructure, including telemedicine, increases the demand for medicines. Despite logistical challenges and a parallel illegal market, these issues highlight the need for affordable, accessible pharmaceuticals. Quintex can leverage these opportunities by establishing reliable distribution networks and complying with regulatory standards, positioning themselves as providers of cost-effective, high-quality medicines.
11	Guinea	Medium	Guinea offers a medium-level market attraction for pharmaceutical products, particularly injectables, due to its heavy reliance on imports and consistent demand for such products. The country faces limited local manufacturing capabilities, but ongoing healthcare projects and international funding are improving healthcare services, driving the need for high-quality medical products. There is a strong demand for maternal, cardiovascular, and mental health injectables. While the regulatory environment poses challenges, including approval processes and counterfeit drug risks, Guinea’s market presents opportunities for companies with local production capabilities. Imports dominate the market, but local manufacturing could provide a competitive edge. Guinea's trade and logistics are favourable, with easy market entry through Ghana and the ECOWAS free trade zone. However, economic and infrastructure challenges, including low affordability and healthcare gaps, pose significant hurdles to market expansion.

[18] ReportLinker, "Dataset Overview," ReportLinker Publications (2025), https://www.reportlinker.com/dataset/c580c6b7093e2f866d5bba3de366162db24e7036.

246 | Feasibility Studies Report

No.	Country	Potential Market Attraction	Justification
12	Benin	Medium	The pharmaceutical market in Guinea shows high demand for injectables, particularly for maternal, cardiovascular, and mental health treatments. Despite this strong demand, the regulatory and business environment presents medium-level challenges due to complex approval processes and risks associated with counterfeit drugs. The competitive landscape is also medium, with imports dominating the market, but local production could provide a strategic advantage. Trade and logistics are favourable, with easy market entry through Ghana and the ECOWAS free trade zone. However, Guinea faces low economic and infrastructure stability, with challenges like low affordability and significant gaps in healthcare infrastructure, which could limit the market's growth potential.
13	Mali	Medium	Mali presents an opportunity for pharmaceutical exports, as it imports over 90% of its pharmaceuticals, valued at US$43.3 million in 2023. The market is heavily reliant on imports from France, India, China, and Morocco, with limited local manufacturing capacity, mostly involving repackaged imports. Key demand drivers include high maternal mortality, hypertension, cardiovascular diseases, cancer, and mental health conditions, all contributing to a strong need for injectables like Oxytocin, Tranexamic Acid, Furosemide, Enoxaparin, and Diazepam. However, Mali faces challenges such as political instability, security threats, counterfeit drugs, weak regulatory systems, and unreliable infrastructure, particularly in electricity and cold storage. While Mali's withdrawal from ECOWAS could complicate trade, the country still benefits from the AfCFTA. The market is largely dominated by foreign firms, but there is a gap in local sterile injectable production, creating opportunities for Ghana-based exporters. Despite these opportunities, monitoring the country's political and regulatory developments will be essential for long-term market success.
14	Burkina Faso	Medium	Burkina Faso heavily depends on pharmaceutical imports, with 99% of its medicines sourced externally, costing around US$208 million annually. The country faces a high demand for affordable injectables, driven by issues such as significant maternal mortality, hypertension, cardiovascular diseases, cancer, and mental health concerns. Key drugs in demand include Oxytocin, Tranexamic Acid, Furosemide, Enoxaparin, Pethidine, and Diazepam. Burkina Faso's trade access is facilitated by its membership in the West African Economic and Monetary Union, though its exit from ECOWAS in 2024 may complicate future trade agreements. Political instability, security risks, and weak infrastructure pose challenges to healthcare delivery, but the government is investing in local manufacturing initiatives, which could reduce dependency

15 Economic Evaluation

No.	Country	Potential Market Attraction	Justification
			on imports. Despite these efforts, weak purchasing power among the population remains a concern. The market offers opportunities for Ghana-based pharmaceutical companies, particularly in low-cost injectables, but the growing local production capacity and political instability present risks that need careful monitoring for long-term market entry.
15	Guinea Bissau	Medium	The market attraction for pharmaceutical products, particularly injectables, in Guinea Bissau is medium. Guinea Bissau's heavy reliance on imports to meet its pharmaceutical needs, coupled with a consistent demand for these products, indicates a stable and growing market. It has a high demand for imported pharmaceuticals and limited local manufacturing capabilities. Also, ongoing healthcare projects and international funding are improving healthcare services, thereby increasing the need for quality medical products.

Source: Primary Reaserch, PwC

248 | Feasibility Studies Report

15.4 Conclusion

15.4.1 Regional Market Potential and Demand for Pharmaceuticals

West Africa presents a compelling opportunity for Ghanaian pharmaceutical manufacturers, with high import dependency, rising disease burdens, and government initiatives to improve healthcare access. Most countries in the region, including Nigeria, Côte d'Ivoire, Senegal, Guinea-Bissau, and Benin, rely on imports for over 70% of their pharmaceutical needs, creating a lucrative market for locally produced medicines. The increasing prevalence of non-communicable diseases (NCDs) such as hypertension (up to 40.5% in Senegal and 36.1% in Nigeria), diabetes, cardiovascular conditions, and cancer has heightened demand for essential injectables, including furosemide, enoxaparin, and pethidine. Maternal health challenges remain critical, with maternal mortality rates exceeding 1,000 deaths per 100,000 live births in some countries, necessitating oxytocin and tranexamic acid for postpartum haemorrhage treatment. Additionally, the African Continental Free Trade Area (AfCFTA) and ECOWAS frameworks provide regulatory advantages by facilitating cross-border trade, reducing tariffs, and expediting drug approvals, enabling Ghanaian manufacturers such as Quintex to enter regional markets with reduced bureaucratic hurdles.

15.4.2 Challenges and Strategic Considerations for Market Entry

Despite the opportunities, several challenges must be addressed to ensure sustainable market penetration. Regulatory barriers, including stringent import controls, extended drug approval processes, and local content requirements in Nigeria and Côte d'Ivoire, may slow market entry. Economic instability, currency depreciation (such as the Nigerian naira losing over 150% of its value in recent years), and high import costs could impact affordability and pricing strategies. Supply chain weaknesses, including poor infrastructure, unreliable power supply, and counterfeit drug proliferation (up to 40% in some markets like Nigeria), pose operational risks. To navigate these challenges, Quintex must adopt a strategic approach focusing on partnerships with established distributors, local pharmaceutical firms, and government procurement agencies to strengthen market access and regulatory compliance. Additionally, investment in robust quality assurance systems, anti-counterfeiting measures, and cost-efficient logistics will be crucial in building market trust and sustaining long-term growth. By leveraging Ghana's competitive advantage in regional pharmaceutical production, Quintex can establish itself as a leader in the West African pharmaceutical landscape, addressing critical healthcare gaps while reducing the region's reliance on external imports.

Feasibility Studies Report | 249

16 Sustainability & Environmental Considerations

16.1 Context of the project

The healthcare sector in Ghana is rapidly evolving, with a rising demand for critical sterile injectables used in surgeries, emergency care, and chronic disease management. Currently, a significant portion of these products is imported, leading to supply chain vulnerabilities and high costs. The Ghanaian government's industrial policy, including the "One District, One Factory" initiative, provides an enabling environment for local pharmaceutical manufacturing. This aligns with both the national goal of self-sufficiency and the African Union's broader vision for essential medicine production.
In response to this opportunity, Quintex Pharma Ltd., a recently established private pharmaceutical company based in Ghana, aims to become a leading manufacturer of both generic and branded medications.

16.2 Background of the Company

Quintex Pharma Ltd. (referred to as QPL) is a limited liability company duly incorporated under the Companies Act, 2019 (Act 992). The Company's registration number and Tax Identification Number is CS1766681122 and C0062315552 respectively.

16.3 Scope of Study

QPL proposes to construct and operate a sterile injectables manufacturing factory at Okwenya-Akuse in the Lower Manya Krobo District of the Eastern Region of Ghana.
The formulation of injectables involves three essential components:

- Active Pharmaceutical Ingredient (API) – The main therapeutic component responsible for therapeutic effect of the medication.
- Excipients – Inactive substances added to support the formulation, ensuring stability, pH balance, tonicity, solubility, and sterility.
- Packaging – The container that maintains sterility and facilitates safe administration

The target product list and corresponding installed production capacity of each product line is attached in Annex I.

16.4 Purpose and Objectives of the ESIA

In accordance with the International Finance Corporation (IFC) Performance Standard 1 and Ghana's Environmental Assessment Regulations, 1999 (LI 1652) , it is required for the assessment and management of Environmental and Social risks/impacts prior to construction and operation of industrial facilities. The Environmental & Social Impact Assessment aims to achieve:

250 | Feasibility Studies Report

7. Compilation of all relevant information on the proposed sterile injectable manufacturing project.
8. Identifying all important receptors and disclosing identified potential environmental impacts of project prior to project being started.
9. Determining the significance of impacts and identifying mitigation measures to alleviate any significant adverse impacts.
10. Ensuring precautionary control alternatives are well considered and incorporated into design.
11. Developing sustainable environmental practices.

This Environmental and Social Impact Assessment (ESIA) will assist management in evaluating the project's feasibility and its potential environmental impacts. It provides a structured opportunity to identify adverse effects and propose appropriate mitigation measures to address them. Additionally, the assessment offers recommendations on implementing the project in an environmentally responsible manner, ensuring minimal harm to the surrounding ecological, social, and economic systems. By adopting sustainable practices, the project can avoid negative consequences while adhering to regulatory requirements. Furthermore, the ESIA facilitates compliance with due procedures, enabling the acquisition of an Environmental Permit necessary for the construction and operation of the proposed project.

16.5 Structure of the ESIA Report

This report is divided into nine (9) chapters. This current chapter presents the Introduction, including background information and introduction to the project, objectives, purpose and methodology for undertaking this EIA study. Chapter 2 presents the Approach & Methodology for the EIA study. Chapter 3 presents a review of Policy, Legislative and Administrative Frameworks applicable/relevant to the project. This is followed by a Project Description in Chapter 4, in which the scope of the project is described. Chapter 5 includes the Identification and Evaluation of Potential Impacts of the project. Chapter 6 describes Public Participation and Stakeholder Engagement. Chapter 7 describes identified Mitigation Measures, followed by the 8 Provisional Environmental Management & Monitoring Plan in Chapter 8 and lastly the Decommissioning Plan and Conclusion in Chapter 9.

17 Approach and Methodology

17.1 Approach & Methodology for EIA Study

17.1.1 Discussions with project management

The project design concept and project objectives as well as the required data and information were discussed with AMPC International Health Consultant, the appointed technical consultants of QPL. Documents obtained from the project owner included the specifications of the products to be manufactured, capacity of the plant to be installed, equipment list, production process and engineering drawings.

17.1.2 Field visits for data collection

As part of the Environmental Impact Assessment (EIA) process, multiple site visits were conducted at QPL's proposed project location in Okwenya-Akuse, commencing in February 2025 and continuing to the present. The primary objective of these visits was to gather essential baseline data and evaluate the existing environmental and social conditions of the site. During the field assessments, the EIA team carried out a thorough inspection of the biophysical environment, documenting key features such as vegetation types, wildlife presence, and overall ecological characteristics. Additionally, the team recorded critical infrastructure-related factors, including site accessibility, proximity to power supply sources, and other logistical considerations that may influence project implementation.

Beyond the biophysical assessment, the team also conducted observations of the social setting within the project area. This included interactions with local communities, noting demographic patterns, land use activities, and potential socio-economic impacts that the project may introduce. The findings from these site visits will inform the development of mitigation strategies and ensure that the project is designed and executed in a sustainable and socially responsible manner.

17.1.3 Review of relevant literature

The literature review for this assessment included a comprehensive analysis of relevant project documents and the World Bank's Environmental and Social Safeguard Policies to ensure alignment with international best practices. Additionally, Environmental and Social Impact Assessment (ESIA) reports from other pharmaceutical manufacturing facilities were examined to draw comparative insights, identify potential risks, and apply lessons learned to the current project. This review helped establish a robust framework for evaluating impacts and developing appropriate mitigation measures.

252 | Feasibility Studies Report

17.1.4 Consultations with stakeholders

As part of the stakeholder engagement process, key institutions were formally notified about the proposed project to ensure regulatory compliance and gather critical input. These included the Lower Manya Krobo Municipal Assembly's Physical Planning Department and Environmental Health and Sanitation Department, responsible for land use and environmental oversight. Additionally, regulatory bodies such as the Ghana Standards Authority (GSA) and the Food and Drugs Authority (FDA) were consulted to address product quality and safety standards. The Ghana National Fire Service (GNFS) was engaged to assess fire safety requirements, while utility providers—Ghana Water Company Limited (GWCL) and the Electricity Company of Ghana (ECG)—were contacted to evaluate infrastructure and service provisions for the project. This inclusive approach ensures alignment with legal, safety, and operational guidelines.

18 Policy, legislative and administrative frameworks

This chapter explains the relevant policy, legislative and administrative requirements applicable to the project under the constitution of Ghana. It also highlights some international laws and standards that intend to optimize best industry standards and practices in relation to the project.

18.1 National Policy and Regulation Guidelines

18.1.1 Applicable Acts

The following acts are applicable:

- Environmental Protection Act, 2025 (Act 1124)
- The Local Governance Act, 2016 (Act 936)
- Factories, Offices and Shops Act, 1970 (Act 328)
- Ghana National Fire Service Act, 1997 (Act 537)
- The Labour Act, 2003 (Act 651)
- Workmen's Compensation Act, 1987 (PNDCL 187)
- Land Use and Spatial Planning Act, 2016 (Act 925)
- Weights and Measures Act, 1975 (NRCD 326)
- Ghana Standard Authority Act, 2022 (Act 1078)
- Persons with Disability Act, 2006 (Act 715)
- Public Health Act, 2012 (Act 851)
- Fees and Charges (Miscellaneous Provision) Act, 2022 (Act 1080)
- The Children's Act, 1998 (Act 560)

The table below further summarizes the content of each act as well as the application and relevance to project, highlighting the actions expected from Quintex Pharma Ltd.

Table 18.1 List of applicable Acts

Act	Summary of Act	Applicability/Relevance to the Project
Environmental Protection Act, 2025 (Act 1124)	The new Environmental Protection Act, 2025 (Act 1124) serves as the primary legislation for Environmental Protection; Pesticides Control and Management; The Control and Management of Hazardous Wastes and Other Wastes.	It is required for the proponent to register the project with the EPA

254 | Feasibility Studies Report

Act	Summary of Act	Applicability/Relevance to the Project
	Additionally, it serves The Control and Management of Electrical and Electronic Waste; The Coordination of Climate Change Responses.	
The Local Governance Act, 2016 (Act 936)	The Act empowers the Assemblies to establish Waste Management Departments to be responsible for the development and management of waste disposal sites within the areas of jurisdiction.	QPL is required to involve the local Environmental Health and Sanitation Departments in Lower Manya Krobo Municipal Assembly for the safe disposal of wastes to be generated by project activities; and for the Assembly to also review and grant the building permit
Factories, Offices and Shops Act, 1970 (Act 328)	The Factories, Offices and Shops Act of 1970, Act 328 requires all proponents to register every factory with the Chief Inspector of Factories Inspectorate Department.	QPL must ensure it registers its facility with the Department of Factories Inspectorate
The Children's Act, 1998 (Act 560)	This Act is intended for the protection of children by giving directive that the minimum age for admission of employment is 15 years. And the minimum age for engagement of a person for hazardous work is 18 years.	It is expected for management to disallow engagement of children for any directly and indirectly for any work activity at the QPL plant
Ghana National Fire Service Act, 1977 (Act 537)	This Act establishes the GNFS as the company to provide management for undesired fires.	QPL must involve the GNFS in planning fire prevention and firefighting systems to be used by the company
The New Labour Act, 2003 (Act 651)	The New Labor Act, 2003 (Act 651) stipulates that it is the duty of an employer to ensure that every worker employed works under satisfactory, safe and healthy conditions. Act 651 contains a number of specific provisions relating to an employer's duty of care to its workers. These include providing and maintaining "at the workplace, plant and system of work that are safe and without risk to health" and taking "steps to prevent contamination of the workplaces by,	It is required for QPL to act in its capacity as an employer to ensure the welfare and protection of workers from dangers at the workplace.

18 Policy, legislative and administrative frameworks

Act	Summary of Act	Applicability/Relevance to the Project
	and protect the workers from, toxic gases, noxious substances, vapors, dust, fumes, mists and other substances or materials likely to cause risk to safety or health". A worker is required to report situations that he believes may pose "an imminent and serious danger to his or her life, safety or health". It is required for QPL to act in its capacity as an employer to ensure the welfare and protection from dangers at the workplace.	
Workmen's Compensation Act, 1987 (PNDCL 187)	This Act highlights an employee's accessibility to rightful compensation.	QPL will ensure proper and appropriate payment is made for work done by its employees by abiding with the minimum wage
Land Use and Spatial Planning Act, 2016 (Act 925)	This Act assigns the Town and Country Planning Department the role of planning land use and ensuring compliance with zoning.	QPL must ensure it consults with the LMKMA Physical Planning Department to ensure the project is consistent with the land use plan.
Weights and Measures Act, 1975 (NRCD 326	The Ghana Standards Authority is mandated by the Weights and Measures Decree, NRCD 326 of 1975 to ensure fair trading practices through the verification of weights and measures. It also organizes trading seminars annually for stakeholders to build their capacity on measurements and related subjects.	QPL has to incorporate these standards to ensure fair admission of weights.
Ghana Standard Authority Act, 2022 (Act 1078)	This Act establishes GSA as the authority responsible for the establishment and promulgation of standards, enforcement of conformity assessment and Metrology	QPL will ensure it registers its project and product with the GSA to ensure conformity.

256 | Feasibility Studies Report

Act	Summary of Act	Applicability/Relevance to the Project
	framework in Ghana in line with best practices.	
Persons with Disability Act, 2006, (Act 715)	AN ACT to provide for persons with disability, to establish a National Council on Persons with Disability and to provide for related matters.	The management of QPL will ensure its facility is built to be disability friendly and must actively ensure it is not bias against disabled persons.
Public Health Act , 2012 (Act 851)	This act states that "A person who manufactures, labels, packages, sells or advertises a food in a manner that is false, misleading, deceptive or misbranded as regards its character, nature, value additives, substance, quality, quantity, composition, merit or safety commits an offence"	Management will comply with stipulated systems for manufacturing, labelling, packaging and sales/advertisement of its products.

18.1.2 Applicable Policy Guidelines

The following Policy Guidelines are applicable:

- National Environmental Policy, 2012
- National Environmental Action Plan, 2014
- National Workplace HIV/AIDS Policy, 2012
- Climate Change Policy, 2012
- National Energy Policy, 2010

The table below outlines the applicable policies The table below further summarizes the content of each policy as well as the application and relevance to project, highlighting the actions expected from Quintex Pharma Ltd.

Table 18.2 List of applicable Policies

Policy	Summary of Policy	Applicability/Relevance to the Project
National Environmental Policy, 2012	The main objective of the NEP is to improve the environment, living conditions and quality of life for all Ghana's citizens. It aims to reconcile economic development with conservation and seeks to promote the sustainable use and maintenance of Ghana's natural resources. The policy seeks to maintain ecosystem and ecological processes, ensure sound management of natural	The policy objectives are clearly in line with the project undertaking. The project has an impact on the general environment and natural resource; thus loss of biodiversity (flora and fauna) arising from land clearing. The proposed project should aim to promote sustainable development by

18 Policy, legislative and administrative frameworks

Policy	Summary of Policy	Applicability/Relevance to the Project
	resources and the environment, adequately protect against harmful impacts and destructive practices and preserve biological diversity. It also aims to integrate environmental considerations into sectoral, structural and socio-economic planning at the national, regional, district and grassroots levels and to seek common solutions to environmental problems in West Africa, as well as in the African continent and world as a whole.	including economic, social and environmental considerations.
National Environmental Action Plan, 2014	The policy aims at sound management of resources and environment, and the reconciliation between economic planning and environmental resource utilization for sustainable national development.	The proposed project is required to address all potential environmental impacts to promote sustainable use of natural resources and to ensure the sustainability of the project.
National Workplace HIV/AIDS Policy, 2012	The general objectives of the Policy among others are to provide protection from discrimination in the workplace to people living with HIV and AIDS; prevent HIV and AIDS spread amongst workers and provide care, support and counselling for those infected and affected. Involvement of persons from different backgrounds in performing various project related activities as a workforce indicate the relevance of this Policy to the intended project.	QPL shall ensure the non-discrimination against persons with HIV/AIDS and providing them opportunity for employment when they are qualified for the role.
The Climate Change Policy, 2012	The National Climate Change Policy is Ghana's integrated response to climate change. It has been prepared and designed within the context of national sustainable development priorities; it provides a clearly defined pathway for dealing with the challenges of climate change within the current socio-economic context of	Management shall ensure it operates its facility in accordance with the climate change policy objectives

258 | Feasibility Studies Report

Policy	Summary of Policy	Applicability/Relevance to the Project
	Ghana, and looks ahead to the opportunities and benefits of a green economy.	

18.1.3 Applicable Regulations

The following regulations are applicable:

- Environmental Assessment Regulations, 1999, LI 1652
- Fire Precaution (Premises) Regulations 2003, LI 1724
- Hazardous, Electronic and Other Wastes (Classification) Control and Management Regulations 2016, LI 2250
- Management of Ozone Depleting Substances and Products Regulations, 2005 (LI 1812)

The following table will explain each act and the expected actions expected from QPL on each regulation.

Table 18.3 List of Applicable Regulations

Regulation	Summary of Regulation	Applicability to the Project
Environmental Assessment Regulations 1999, LI 1652	The Environmental Assessment Regulations LI 1652, 1999 enjoins any proponent or person to register an undertaking with the Agency and obtain an Environmental permit prior to commencement of the project.	It is required for proponent to register the project with the EPA by conducting the assessment in accordance with EPA procedures
The Fire Precaution (Premises) Regulations 2003, LI 1724	The Fire Precaution (Premises) Regulations LI 1724, 2003 requires all premises intended for use as workplaces to have Fire Certificates.	It is required for proponent to obtain a Fire Permit.
Hazardous, Electronic and other Wastes (Classification) Control and Management Regulations 2016, LI 2250	This legal framework set the background for a new and innovative strategy towards a sustainable management of e-waste in Ghana.	QPL shall comply by following measures to properly dispose all e-waste it generates in accordance with this regulation.
Management of Ozone Depleting Substances and Products Regulations, 2005 (LI 1812)	The Ozone-Depleting Substances Regulations 2005 were enacted to protect the Earth's ozone layer by controlling the production, use, import, and export of substances known as ozone-depleting substances (ODS). The regulations aim to fulfil commitments under the Montreal Protocol, an international treaty addressing ozone layer depletion.	QPL shall ensure it limits or totally avoids use of ozone depleting substances in its operations especially for cold storage and logistics of its finished products.

18 Policy, legislative and administrative frameworks

Regulation	Summary of Regulation	Applicability to the Project
	The purpose of these regulations is to minimize the release of ODS into the atmosphere, as they contribute to the depletion of the ozone layer. By doing so, the regulations help mitigate the adverse effects of harmful ultraviolet (UV) radiation on human health and the environment.	

18.1.4 Applicable National Environmental Quality Standards

The following national environmental quality standards are applicable:

- Ghana Standard for Health Protection Requirements for Ambient Noise Control (GS 1222, 2018)
- Ghana Standard for Environmental Protection Requirement for effluent discharge (GS 1212, 2019)
- Ghana Standard for Environmental and Health Protection Requirement for Ambient Air Quality and Point Source/Stack Emissions (GS 1236, 2019)
- Ghana Standards for Environmental and Health Protection - Requirement for Motor Vehicles Emissions (GS 1219, 2019)

In the table below a summary of the standards as well as their applicability in the project is given.

Table 18.4 List of applicable National Environmental Quality Standards

Ghana Standard	Summary of Regulation	Applicability to the Project
Ghana Standard for Environment and Health Protection - Requirements for Ambient Air Quality and Point Source/Stack Emissions (GS 1236:2019)	This stipulates the standard for the acceptable level for ambient air quality and point source emissions. The standards also provides the test methods and frequency of monitoring for assessing the levels of emissions and	QPL is supposed to comply with these standards for its air emissions.
Ghana Standard for Environment and Health Protection - Requirements for Effluent Discharge (GS 1212: 2019)	This stipulates the standards for the quality of effluent discharge for specific industries and commercial facilities. The stipulated test methods are stated in the standards.	QPL must comply with these discharge standards
Ghana Standard for Health Protection - Requirements for Ambient Noise Control (GS 1222:2018)	This provides standards for level of ambient noise generation for industries, commercial zones, and residential areas. The test methods are stated in the standards	QPL must comply with these noise levels

260 | Feasibility Studies Report

Ghana Standard	Summary of Regulation	Applicability to the Project
Ghana Standards for Environmental and Health Protection - Requirement for Motor Vehicles Emissions (GS 1219, 2019)	This standards stipulate standards for exhaust emission of motor vehicles. The test methods are stated in the standards	QPL will ensure all vehicles it uses are regularly serviced to ensure good emissions.

18.2 Regional and International Conventions

18.2.1 Convention on the Conservation of Migratory Species of Wild Animals

The Convention on the Conservation of Migratory Species of Wild Animals (CMS), ratified by Ghana in 1983, establishes a legal framework for the protection of endangered migratory species. Under this agreement, species classified as "endangered"—including mammals, birds, and reptiles—receive special conservation attention. The primary objective of the convention is to ensure the long-term survival of migratory species by promoting international cooperation, as many of these animals cross national boundaries during their life cycles. By implementing coordinated protection measures, the CMS seeks to mitigate threats such as habitat loss and overexploitation, thereby preventing the extinction of vulnerable migratory wildlife.

18.2.2 African Convention on the Conservation of Nature & Natural Resources

The African Convention on the Conservation of Nature and Natural Resources serves as a foundational framework for environmental protection across the continent. Its primary objectives include establishing comprehensive guidelines to enhance environmental conservation, promote the sustainable use of natural resources, and harmonize policies in these critical areas. By recognizing the ecological and socio-economic value of the natural environment, the convention seeks to strengthen legal and regulatory measures that safeguard ecosystems and biodiversity.

In alignment with this convention, the current Environmental and Social Impact Assessment (ESIA) has been conducted as a proactive measure to identify, assess, and mitigate potential environmental and social risks associated with the proposed cassava plantation. This assessment ensures compliance with regional conservation standards while fostering responsible and sustainable development practices.

18.2.3 Convention Concerning the Protection of the World Cultural and Natural Heritage

The convention acknowledges the ongoing degradation of the world's cultural and natural heritage, emphasizing the need for their preservation. Cultural heritage encompasses the traditions, history, beliefs, and artifacts of indigenous and historical communities—such as Native Americans, Aboriginal peoples, and the Māori. While this aspect of the convention does not directly pertain to the investors' proposed development, natural heritage—including geological formations, ecologically significant landscapes, and sites of historical importance—remains relevant to the project's potential environmental impact.

Under this convention, participating nations commit to safeguarding both cultural and natural heritage as a legacy for future generations, ensuring that these irreplaceable assets endure as a testament to their land and people. Given this obligation, the investors must assess and mitigate any risks their activities may pose to natural heritage sites, aligning with global conservation standards and national regulatory frameworks.

18 Policy, legislative and administrative frameworks

18.2.4 Convention on Biodiversity, 1993

The Convention on Biological Diversity (CBD), which entered into force on 29 December 1993, establishes three fundamental objectives:

12. Conservation of biological diversity – protecting ecosystems, species, and genetic variability;
13. Sustainable use of its components – ensuring that natural resources are utilized in a way that maintains ecological balance; and
14. Fair and equitable sharing of benefits derived from genetic resources – promoting ethical and inclusive practices in biotechnology and traditional knowledge applications.

As a legally binding international agreement, the CBD provides a framework for nations to balance environmental protection with sustainable development, ensuring long-term ecological integrity and equitable resource governance.

18.2.5 Nationally Determined Contributions

Nationally Determined Contributions (NDCs) form the cornerstone of the Paris Agreement, serving as the primary mechanism for achieving its long-term climate goals. Under the agreement (Article 4, Paragraph 2), each participating country is required to develop, communicate, and regularly update its NDCs, outlining national efforts to reduce greenhouse gas emissions and enhance climate resilience. These commitments reflect individualized yet collective action, with nations expected to implement domestic mitigation measures to meet their declared targets. By fostering accountability and progressive ambition, NDCs enable a unified global response to climate change while respecting diverse national circumstances and capabilities.

18.3 International Finance Corporation (IFC) Performance Standards

The eight (8) Performance Standards from IFC provide a robust framework for assessing and managing the Environmental Impacts and Social Risks associated with activities or operation of businesses. The applicability or otherwise of the 8 Performance Standards in relation to the activities of QPL is provided in a tabular form below.

Table 18.5 IFC Performance Standards

Performance Standard (PS)	Applicability	Purpose/Reason
PS 1: Assessment and Management of Environmental and Social Impacts and Risks	Applicable	The activities of QPL would have environmental and social aspects that may pose potential environmental impacts and social risks. Best practice suggests that, all businesses, as long as environment and social aspects exist, should have systems in place for assessing and managing the potential risks and impacts resulting from such aspects. Therefore, PS 1 is applicable to activities of QPL

262 | Feasibility Studies Report

Performance Standard (PS)	Applicability	Purpose/Reason
PS 2: Labour and Working Conditions	Applicable	QPL currently has workforce requirement of over 20 persons. The number is expected to increase when the company expands its operations. It is necessary to maintain appropriate labour and working conditions for these workers. Therefore, PS 2 is applicable to activities of QPL
PS 3: Resource Efficiency and Pollution Prevention	Applicable	This PS is synonymous to cleaner production of which raw materials, water, energy are the targets. PS 3 is applicable to QPL's activities.
PS 4: Community Health, Safety and Security	Applicable	The fundamental requirements of PS 4 include – fire drills, certification of potable fire extinguishers, life and fire safety audits, emergency preparedness and response actions and security and these are all applicable to the activities of QPL
PS 5: Land Acquisition and Involuntary Resettlement	Not Applicable	Not applicable to activities of QPL
PS 6: Biodiversity Conservation and Sustainable Management of Living Natural Resources	Applicable	Applicable for the land concession owned by QPL
PS 7: Indigenous Peoples	Not Applicable	There are no known indigenous People (as defined by IFC) within the location proposed for the factory facility
PS 8: Cultural Heritage	Not Applicable	No Cultural Heritage features or resources have been identified in close proximity to the project site.

19 Project Description

19.1 Overview of the project

Quality Pharmaceuticals Limited (QPL) is proposing to develop a modern sterile injectables manufacturing facility in Akuse, located within Ghana's Lower Manya Krobo District of the Eastern Region. This strategic initiative aims to establish a world-class pharmaceutical production plant that will manufacture critical medications requiring sterile administration. The facility will be designed and operated in compliance with international Good Manufacturing Practices (GMP) and relevant Ghanaian regulatory standards to ensure the production of safe, effective, and high-quality injectable medicines for both domestic use and regional distribution.

19.1.1 Understanding Injectable Manufacturing

The proposed facility will specialize in parenteral drug production - a term originating from the Greek words "para" (beside) and "enteron" (intestine), referring to medications administered outside the digestive system. These sterile dosage forms include various injection types (intravenous, intramuscular, subcutaneous), topical applications, and inhalation products. Parenteral administration is particularly crucial for medications that require precise dosing, rapid therapeutic action, or for compounds that would be degraded if taken orally, such as many biologic drugs and chemotherapy agents.

19.1.2 Significance of Injectable Medications

Injectable pharmaceuticals play an increasingly vital role in modern healthcare, especially with the advancement of biotechnological medicines. Many life-saving treatments, including insulin, vaccines, monoclonal antibodies, and specialized chemotherapy drugs, can only be administered through injection. The growing global demand for these products, coupled with Ghana's need to strengthen its pharmaceutical independence, makes this project both timely and strategically important for the nation's healthcare system.

19.1.3 Core Manufacturing Components

The production of sterile injectables involves three fundamental elements working in harmony. First, the Active Pharmaceutical Ingredients (APIs) form the therapeutic foundation of each medication, delivering the intended medical benefits. Second, carefully selected excipients serve crucial supporting roles, maintaining product stability, ensuring proper pH levels, adjusting tonicity, enhancing solubility, and preserving sterility throughout the product's shelf life. Third, specialized packaging systems provide secure containment that protects the medication's integrity while enabling safe and convenient administration by healthcare professionals.

19.1.4 Quality Assurance and Safety

The facility will implement rigorous quality control measures at every production stage, from raw material inspection to final product release. Advanced sterilization techniques, environmental

264 | Feasibility Studies Report

monitoring systems, and comprehensive staff training programs will ensure consistent production of sterile, pyrogen-free medications. The plant design will incorporate cleanroom technology and isolation barriers to maintain the stringent aseptic conditions required for injectable manufacturing.

19.1.5 National Healthcare Impact

This project represents a significant step forward in Ghana's pharmaceutical manufacturing capabilities. By establishing local production of essential injectable medications, QPL will contribute to healthcare security, reduce dependence on imports, create skilled employment opportunities, and support the nation's broader industrialization agenda. The facility's output will help address critical medication needs in Ghana while potentially serving neighbouring countries in the West African region.

19.2 Location and Access

19.2.1 Project Site Location and Description

The proposed project site is situated in Okwenya-Akuse, within the Lower Manya Krobo Municipality of Ghana’s Eastern Region. The parcel occupies 0.74 acres of undeveloped land, bordered by:

- North, West, and South: Vacant, undeveloped lands
- East: Unpaved access roads leading to the site

19.2.2 Accessibility

The site is reachable via the Akuse Road, with GPS coordinates 6°06'31.7"N 0°05'08.1"E. The nearest notable landmark, Manaaw Courts, lies approximately 3 km south of the location.

19.2.3 Current Site Conditions

The terrain consists primarily of grassland with scattered shrub patches, with no residential structures within a 200-meter radius. The absence of existing development minimizes immediate land-use conflicts and facilitates project implementation.
The conceptual plan is provided in Annex II.

19 Project Description

Figure 19.1 Satellite Image showing location of the site

Source: Google maps

19.3 Project Design and Components

19.3.1 Project Design Criteria

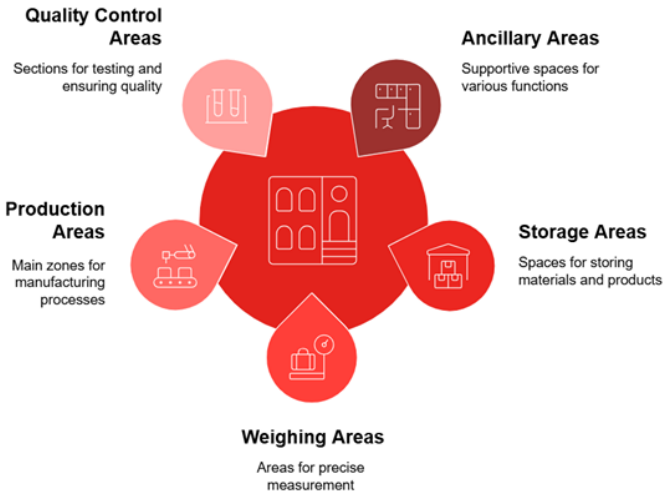
The facility layout of an injectable manufacturing plant represents one of the most crucial design elements, directly impacting product sterility, operational efficiency, and regulatory compliance. The architectural plan must incorporate:

- Unidirectional Workflow - Ensuring logical product flow from raw materials to finished goods
- Contamination Control - Implementing physical barriers and procedural controls to prevent cross-contamination
- Cleanroom Compliance - Maintaining designated ISO 14644-1 classifications throughout all critical zones

As illustrated in the figure below, the production area for fluid manufacturing comprises distinct functional sections, including:

266 | Feasibility Studies Report

Figure 19.2 Proposed integrated components of the plant



The strategic segregation of these operational zones ensures proper material and personnel flow while maintaining the stringent environmental controls required for parenteral manufacturing. Each section's design incorporates appropriate air handling systems, pressure differentials, and material transfer mechanisms to preserve product integrity throughout the manufacturing process.

19.3.2 Ancillary Areas

Ancillary areas are non-production spaces that support pharmaceutical manufacturing operations. These include rest and refreshment rooms, which must be separate from manufacturing and control areas to prevent contamination. Changing rooms, washrooms, and toilets should be easily accessible and maintained in a hygienic condition, ensuring they do not have direct access to production or storage areas. Maintenance workshops should ideally be located separately from production zones to avoid any risk of contamination; if tools or parts must be stored within production, they should be placed in dedicated rooms or lockers.

19.3.3 Storage Areas

Storage areas are critical for organizing and maintaining the quality of raw materials, packaging components, intermediates, and finished products. These spaces must be large enough to allow clear separation between different categories of materials, including quarantined, released, rejected, and recalled products. The environmental conditions within these storage areas should be closely controlled and monitored, ensuring that temperature, humidity, and cleanliness do not compromise material integrity. Receiving and dispatch bays should be distinctly separated from other operations to prevent contamination during the movement of goods. Additionally, certain materials, such as narcotics, hazardous chemicals, flammable substances, and radioactive materials, must be stored in secure, dedicated sections with restricted access to ensure compliance with safety regulations.

19.3.4 Weighing Areas

Weighing areas are designated spaces where raw materials are carefully measured and prepared before being introduced into the production process. These areas must be separate from general storage and production zones to avoid cross-contamination. They should also be equipped with appropriate dust control systems to minimize the risk of airborne contamination, particularly when

19 Project Description

handling fine powders or active pharmaceutical ingredients (APIs). Proper environmental conditions, including ventilation and air filtration, must be maintained to ensure precision and prevent contamination of materials.

19.3.5 Production Areas

Production areas are the core zones where pharmaceutical formulations are manufactured, requiring strict environmental control to ensure product safety and compliance with regulatory standards. The layout of these areas must follow a logical sequence to minimize processing errors and prevent contamination. Walls, floors, and ceilings should be smooth, non-porous, and easy to clean, reducing the risk of microbial or particulate contamination. Air-handling systems, including HEPA filtration and humidity control, are essential in maintaining sterility and preventing cross-contamination between different manufacturing stages. For high-risk products, such as antibiotics, hormones, cytotoxic drugs, and live biological preparations, dedicated production facilities are necessary to prevent contamination with other pharmaceutical products. In cases where complete separation is not feasible, validated cleaning and decontamination procedures must be implemented.

19.3.6 Quality Control Areas

Quality Control (QC) areas play a crucial role in ensuring that raw materials, intermediates, and finished products meet required specifications before being approved for release. These areas must be physically separated from production environments to prevent interference and cross contamination. QC laboratories should be designed with specialized sections for microbiological, chemical, and radiological testing, each maintaining specific environmental conditions appropriate for the testing procedures. Storage space should be available for reference samples, which need to be kept under controlled conditions to ensure long-term stability and reproducibility of test results. Additionally, QC areas must have independent air-handling and ventilation systems to prevent contamination from external sources or production activities.

19.4 Proposed Infrastructures and Ancillary Facilities

The project will incorporate purpose-built infrastructure designed to support efficient pharmaceutical manufacturing operations while meeting regulatory requirements. The production floor will serve as the core manufacturing space, equipped with cleanroom environments and specialized equipment for sterile injectable production. Adjacent to this, a dedicated raw materials area will provide secure, climate-controlled storage for active pharmaceutical ingredients and excipients, ensuring proper material handling and inventory control. For finished products, a finished goods warehouse will feature temperature-monitored storage systems to maintain product stability until distribution.

Supporting facilities include a staff changing room with graded access to maintain cleanroom protocols, administrative office spaces for operational management, and a parking area to accommodate employees and visitors. Environmental protection measures will be implemented through an on-site wastewater treatment plant, which will process pharmaceutical effluent to meet discharge standards before safe disposal. The layout will follow current Good Manufacturing Practices (cGMP) principles, with segregated zones to prevent cross-contamination and optimized workflows for manufacturing efficiency. All facilities will be designed with appropriate utilities,

268 | Feasibility Studies Report

including HVAC systems, purified water supply, and emergency power backups to ensure uninterrupted operations.

19.5 Utility Requirement

During the construction phase, the project will utilize a dual power supply system comprising grid electricity from the Electricity Company of Ghana (ECG) and backup support from a diesel generator. The estimated monthly electricity consumption during this phase is 1,280 kWh. For water supply, the company will source from the Ghana Water Company Limited (GWCL), with an anticipated usage of 80 cubic meters per month to support construction activities.

Upon transitioning to the operational phase, the facility's power demand will increase significantly to approximately 30,000 kWh per month, sourced primarily from ECG. Water requirements will also rise to an estimated 600 cubic meters per month, supplied by GWCL to support manufacturing processes, sanitation, and other operational needs. These projections have been calculated based on production scale, equipment specifications, and industry benchmarks to ensure reliable utility planning. Contingency measures, including backup power solutions and water storage systems, will be implemented to mitigate potential supply disruptions. The company will adhere to sustainable consumption practices and explore efficiency improvements where feasible.

19.6 Raw Material Requirement

Injectable medications require three fundamental elements to ensure therapeutic efficacy, stability, and patient safety:

15. Active Pharmaceutical Ingredient (API) – The primary biologically active compound that delivers the intended pharmacological effect. The API is carefully selected and purified to meet stringent pharmacopeial standards for potency and purity in parenteral products.
16. Excipients – Pharmacologically inactive ingredients that perform vital auxiliary functions. These include:
    a. Stabilizers to prevent API degradation
    b. Buffers to maintain physiological pH
    c. Tonicity adjusters (e.g., sodium chloride) to achieve iso-osmotic conditions
    d. Solubilizers for poorly soluble APIs
    e. Antimicrobial preservatives (in multi-dose vials)

Each excipient is qualified to ensure compatibility and safety for intravenous/intramuscular administration.

17. Primary Packaging System – A sterile containment solution (typically vials, ampoules, or pre-filled syringes) that:
    a. Maintains product sterility through hermetic sealing
    b. Prevents chemical interaction via appropriate material selection (Type I glass/polymer)
    c. Incorporates administration features (e.g., breakable ampoule necks, syringe plungers)
    d. Complies with USP<1> and EP 3.2.1 standards for parenteral packaging

The formulation process requires strict aseptic handling and quality control at each stage to meet compendial requirements for particulate matter, endotoxins, and sterility (USP <71>, EP 2.6.1). This tri-component system ensures the final product delivers the API safely while maintaining stability throughout its shelf life.

19 Project Description

19.7 Labour/Manpower Requirement

The successful execution of the project will require skilled personnel across both construction and operational phases, with distinct staffing needs for each stage.

19.7.1 Construction Phase Workforce

The project will employ a diverse team of technical specialists to execute civil works and facility development, including:

- Construction Supervision: Foremen, project managers, civil engineers, and architects
- Skilled Trades: Masons, carpenters, plumbers, and electricians
- Support Staff: Forklift operators and security personnel

19.7.2 Operational Phase Workforce

During routine manufacturing operations, the staffing structure will comprise:

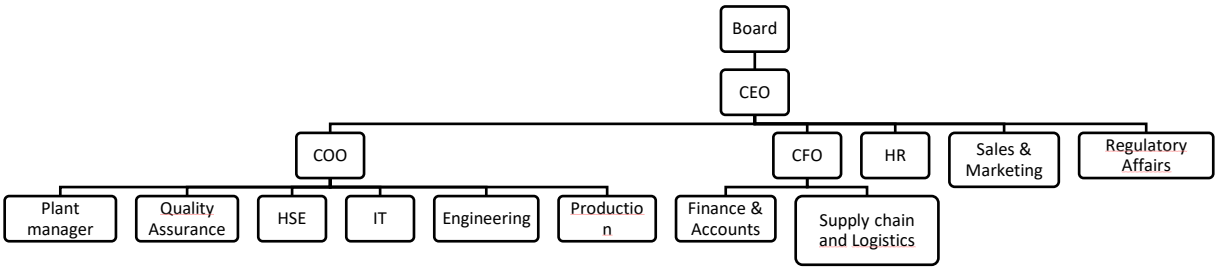
- Local Talent: Ghanaian professionals and technicians across production, quality control, and administration
- Expatriate Specialists: International experts providing technical leadership in pharmaceutical manufacturing and engineering

The phased staffing approach ensures appropriate expertise is available during:

- Facility development (construction specialists)
- Ongoing production (manufacturing and quality professionals)

Workforce planning incorporates knowledge transfer programs between expatriate and local staff to enhance domestic technical capabilities. All positions will be filled in compliance with Ghanaian labour regulations and industry best practices for pharmaceutical manufacturing. The proposed organogram for the factory operations has been given in the figure below.

Figure 19.3 Proposed Organogram



19.8 Pre-Development, Construction and Operational Phase Activities.

The proposed works consists of the following stages:

270 | Feasibility Studies Report

19.8.1 The Pre-development

The Pre-Development activities involves the acquisition of land, conduction of feasibility studies, application for required permits and licenses. Architects and civil engineers would also make site visits to profile the site to enhance the designing /drawing of the layout.

19.8.2 Construction phase

This would involve civil works such as shoring, dewatering, drilling, excavation, digging, backfilling, concrete works, structural formations & fabrications, surface levelling, and haulage of items such as sand, stone, wood. There will be a high dependence on heavy-duty equipment and manual methods for the performance of these activities. The heavy-duty equipment will include excavators, compaction rollers, tipper trucks and concrete mixers which will be used for soil excavations, compacting the surface, carrying sand and stones and making of concrete respectively. Manual methods will include digging of trenches with pickaxes and shovels, casting of mortar, and haulage of items with wheelbarrows. Carpentry works such as nailing, fixing of roofs and doors will also be performed during the construction phase. There will also be electrical engineering works such as installation of electrical cables; transformers, lighting, air conditioners, fire alarms, etc.
The construction phase will take a period of 15 months and would require a workforce of approximately forty (40) people.

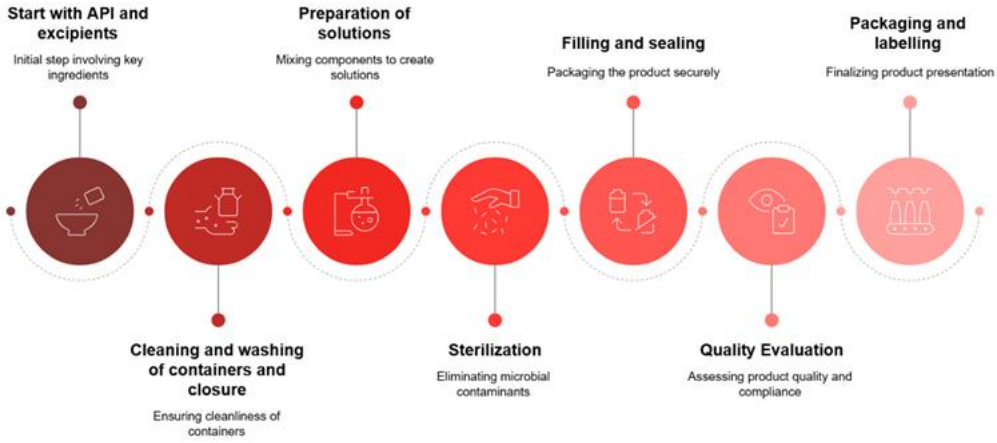
19.8.3 Operational Phase

The production process will involve the production process will involve sterile injectables manufacturing. There will also be maintenance works
The operational phase will require about thirty-seven (37) persons.

19.8.4 Production Process

The production process involves multiple stages, from cleaning the containers to final quality control and distribution. Below is an overview of the key steps involved in the manufacturing process of injectables

Figure 19.4 Injectables manufacturing process



19 Project Description

19.8.4.1 Start with API and excipients

The manufacturing process begins with the Active Pharmaceutical Ingredient (API) and excipients, which are carefully measured, mixed, and processed according to the required formulation. Once the sterile solution is prepared, it must be filled into appropriate containers under aseptic conditions. At this stage, there is a choice to either purchase ready-to-use (RTU) containers or produce them in-house, depending on the supply chain strategy and production capabilities.

19.8.4.2 Cleaning and washing of containers and closure

Containers, closures, and equipment used in injectables production undergo a thorough cleaning process to eliminate contaminants. This involves:

- Initial washing with detergent to remove residues.
- Multiple rinses with distilled water to remove detergent traces.
- A final rinse with Water for Injection (WFI) to ensure sterility before use in production.
- Drying and sterilization of cleaned components before filling

19.8.4.3 Preparation of solutions

The preparation of solutions requires precise weighing, mixing, and control under aseptic conditions. This stage includes:

- Weighing and dissolving the required active pharmaceutical ingredients (APIs) and excipients
- in WFI.
- Use of mixing tanks with controlled temperature and stirring speed to ensure uniformity.
- pH and osmolarity adjustments to meet physiological requirements.
- Filtration of the solution through 0.22-micron filters to remove particulate matter before
- sterilization.

19.8.4.4 Sterilization

Sterilization is a critical step in ensuring the safety and efficacy of injectables.
There are two primary sterilization methods:

- Terminal Sterilization: This is the preferred method, where the product is sterilized in its final container using heat (autoclaving at 121°C for 15-20 minutes). It is the most reliable method for microbial inactivation.
- Aseptic Processing: Used when terminal sterilization is not feasible due to heat sensitivity of the product. This method involves:
    - Sterile filtration (through 0.22-micron filters) to remove microorganisms.
    - Aseptic filling and sealing inside ISO 5 (Grade A) cleanrooms.
    - Media fill tests to validate sterility assurance levels.

19.8.4.5 Filling and sealing

After sterilization, the solution is transferred into final pre-sterilized containers under aseptic conditions. The process includes:

- Filling of the solution into ampoules, vials, and transfusion bottles in an ISO 5 (Grade A) clean
- environment.
- Ensuring accurate filling volume using automated filling machines.
- Immediate sealing of containers to prevent contamination and evaporation.

272 | Feasibility Studies Report

- Sealing methods such as fusion sealing for ampoules or rubber stopper crimping for vials.

19.8.5 Quality Evaluation

The finished parenteral products undergo extensive quality testing to ensure compliance with pharmacopeial standards. The main tests include:

1. Sterility Test: Confirms that no microbial contamination is present.
2. Clarity Test: Ensures the absence of particulate matter.
3. Leakage Test: Detects any defects in container closure integrity.
4. Pyrogen Test: Determines the presence of endotoxins that could cause fever in patients.
5. pH and Osmolarity Tests: Ensures the solution matches physiological requirements for safe
6. administration.
7. Particulate Matter Testing: Conducted using light obscuration or microscopy.

19.8.6 Packaging and labelling

Approved products are labelled and packaged for storage or distribution. The packaging process includes:

- Selection of appropriate packaging material based on stability and compatibility.
- Filling and assembling containers in secondary packaging to prevent contamination.
- Sterilization in the final container, if applicable.
- Labelling with batch numbers, expiry dates, and barcodes to ensure traceability
- Storage in temperature-controlled warehouses before distribution.

20 Identification and Evaluation of Potential Impacts

This chapter provides details of the potential environmental and socio-economic impacts that were identified and would require further assessment and analysis during the Impact Assessment study. It constitutes the potential positive and negative impacts of the proposed project throughout its entire life cycle.

20.1 Impacts

An environmental or social impact refers to any measurable change—whether positive or negative, partial or complete—that occurs in the physical surroundings, ecological systems, or community structures as a direct or indirect consequence of the project's implementation. These changes may stem from construction activities, operational processes, or the project's end products and services. The assessment considers all potential modifications to air quality, water resources, soil composition, biodiversity, employment patterns, cultural heritage, and public health that could reasonably be linked to project execution.

20.1.1 Methodology for Impact Identification

The process of identifying potential impacts began with a thorough examination of baseline environmental and social conditions in the project area. Special attention was given to three critical dimensions: first, the natural environment including soil characteristics, surface and groundwater systems, and vegetative cover; second, the human environment encompassing land ownership patterns, population density, local governance structures, and existing community infrastructure; and third, socioeconomic factors such as livelihood sources, income levels, and overall community wellbeing. This tripartite approach ensures comprehensive coverage of all parameters that might influence or be influenced by project activities.

20.1.1.1 Environmental Risk Impact Matrix

The Environmental Risk Impact Matrix evaluates risks based on their Frequency and Severity of Environmental Impact. This matrix helps in pinpointing activities that could harm the environment. It guides organisations in prioritizing actions to mitigate adverse environmental effects, reflecting the growing emphasis on sustainability and environmental stewardship.

The risk impact matrix has been categorized into three broad areas, namely likelihood, consequence and overall risk level.

274 | Feasibility Studies Report

The table below provides the likelihood score rating which is a qualitative assessment that explains how likely a Risk will occur.

Table 20.1 Likelihood Score Rating

Likelihood Rating	Description
Almost Certain	Is expected to occur in most circumstances (>85% chance of occuring)
Likely	Will probably occur in most circumstances (55% to 85% chance of occuring)
Possible	Could occur (30% to 55% chance of occuring)
Unlikely	Could occur but not expected (5% to 30% chance of occuring)
Rare	Occurs but only in exceptonal cicumstances (<5% chance of occuring)

The table below presents the Risk Consequence Score Rating which depicts the level of impact if an event occurs.

Table 20.2 Consequence Score Rating

Consequence rating	Description – impact	Description – opportunity
Extreme	Permanent pollution damage or other environmental damage	Demonstrate environmental innovation likely to lead to changes in international standards
Severe	Significant and widespread pollution or other environmental/socioeconomic damage, with long-term effects	Demonstrate environmental innovation likely to lead to changes in national standards
Moderate	Pollution or other environmental/socioeconomic damage at a localized level, with medium-term effects. There are measurable changes in the environment or society	Demonstrate a number of enhancements to environmental and socioeconomic best practice
Minor	Minimum pollution or other environmental/socioeconomic damage. Short-term effects only	Demonstrate industry leading application of environmental and socioeconomic best practice
Insignificant	Small scale pollution or other environmental/socioeconomic damage is localized with no resultant effects. Contained locally	Demonstrates compliance with environmental and socioeconomic practice

20 Identification and Evaluation of Potential Impacts

Table 20.3 Risk ranking and evaluation criteria

	Evaluation Criteria			
Ranking	Duration	Extent	Importance/Resilience of Receptor/Resource	Number of elements involved
Low	Less than 1 year / Temporary	Local scale: the proposed operating site and its immediate environs	Low value/sensitivity of receptors or resources, table to recover or adapt to the change without interventions	Affecting small number of individuals, households, individual enterprises and/or small number of species
Medium	Between 1 and 5 years	Regional Scale: as determined by country's administrative boundaries	Moderate value/sensitivity of receptors or resources, able to adapt with some difficulty and which may require interventions	Affecting small number of individuals, communities or administrative and or higher number of species and habitats
High	Between 5 and 10 years	National Scale: Entire country	High value/sensitivity of receptors or resources, poorly able to adapt to changes with strong interventions	Affecting great number of individuals households and/or medium/large enterprises and/or habitats and ecosystems
Critical	Over 10 years/irreversible	International scale: transboundary	Extreme value/sensitivity of receptors or resources, resulting in permanent changes	Affecting huge number of individuals, households and/or large enterprises and/or habitats structure and ecosystems functions

Table 20.4 Colour coded Impact Rating

	Insignificant	**Minor**	**Moderate**	**Severe**	**Extreme**
Almost Certain	Low	Medium	High	Critical	Critical
Likely	Low	Medium	High	Critical	Critical

276 | Feasibility Studies Report

	Insignificant	Minor	Moderate	Severe	Extreme
Posssible	Low	Medium	Medium	High	Critical
Unlikely	Low	Low	Medium	Medium	High
Rare	Low	Low	Low	Low	High

Note: **Impact Raking Score:**

Low: 4 - 6

Medium: 7 - 9

High: 10 - 12

Critical: 13 - 16

20.1.2 Framework for Assessing Impact Significance

The evaluation of each identified impact's importance followed a systematic approach examining four key aspects: the fundamental character of the change (whether it represents an enhancement or degradation); the degree of alteration from baseline conditions; the spatial distribution across the project area and surrounding regions; and the temporal profile including duration, recurrence patterns, and potential for restoration to original conditions. This multidimensional assessment allows for balanced consideration of both immediate and long-term consequences across different geographic scales.

20.1.3 Phase-Based Impact Occurrence

Project-related impacts manifest differently across three distinct temporal phases: the preparatory pre-construction stage, the active construction period, and the long-term operational phase. Each stage generates unique interactions with the surrounding environment and communities, requiring tailored monitoring and mitigation approaches. The temporal distribution of impacts ranges from transient effects during early development to potentially permanent changes during sustained operations.

20.2 Pre-Construction Phase Impact Analysis

Pre-construction activities include site visits for feasibility studies, surveying and land acquisition procedures. Other activities would include architectural planning, cost estimation, award of construction contracts, purchase of building materials etc. The likely impacts envisaged to occur include:

- Employment and Business Opportunities
- Occupational Health and Safety Issues
- Land Litigation and Compensation Issues
- Ground disturbance and associated impacts on flora and fauna

20.2.1 Employment and Business Opportunities

The pre-development phase will serve as a significant catalyst for local economic growth and professional employment opportunities. This initial stage will create direct, high-value jobs for skilled professionals including architects (responsible for facility design and layout), land surveyors

20 Identification and Evaluation of Potential Impacts

(conducting topographic assessments and boundary demarcation), planning engineers (developing technical specifications), and various consultants (providing specialized expertise in environmental, legal, and regulatory matters). These positions typically offer competitive remuneration and often require advanced technical qualifications, contributing to the development of specialized human capital within the region.

Concurrently, the preparatory activities will stimulate commercial activity across multiple supply chains. Local building material suppliers, hardware merchants, and construction equipment vendors will experience increased demand for their products, generating substantial revenue streams. This economic multiplier effect may extend to transportation services for material delivery, printing services for technical documentation, and temporary accommodation for visiting professionals. The cumulative impact will enhance liquidity in the local economy, potentially leading to secondary benefits such as improved business viability, expanded tax revenues for municipal authorities, and possible reinvestment in community development initiatives by benefiting enterprises.

Furthermore, this phase often establishes important professional networks and business relationships that can endure throughout subsequent project phases. Local firms participating in these early activities frequently gain valuable experience that improves their competitiveness for future projects, creating a lasting positive impact on the regional business ecosystem. The knowledge transfer occurring during this phase, particularly when international consultants collaborate with domestic professionals, may also elevate local technical standards and operational practices in the construction and engineering sectors.

These economic benefits will be carefully monitored to ensure equitable distribution across demographic groups and geographic areas within the project's sphere of influence, with particular attention to opportunities for local workforce participation and small business development. The project proponents will implement measures to maximize local content while maintaining the necessary quality standards for this technically demanding phase of development.

20.2.2 Occupational Health and Safety Issues

The pre-development phase, while critical for project planning and setup, presents several occupational hazards that require proactive risk management. Site assessment activities—including topographic surveys, soil testing, and boundary demarcation—expose personnel to potential injuries from uneven terrain, falling objects, or contact with sharp vegetation. Similarly, the handling of heavy equipment and construction materials during loading, transportation, and offloading operations creates additional risks such as:

- Impact injuries from falling or shifting loads
- Musculoskeletal strains due to improper lifting techniques
- Lacerations and puncture wounds from sharp-edged materials
- Vehicle-related accidents during material transport

These hazards are compounded by typical site conditions during preliminary works, which often lack the structured safety controls of established construction sites. The absence of paved access routes, temporary storage areas, and proper material handling equipment further elevates the risk potential.

278 | Feasibility Studies Report

20.2.3 Land Litigation and Compensation Issues

The potential for land-related legal disputes represents a significant risk factor that could substantially impede project timelines if not properly managed. Failure by project management to conduct thorough due diligence in identifying all legitimate landowners and custodians, or deviations from established land acquisition protocols, may result in several consequential issues:

20.2.3.1 Legal Challenges

Dissatisfied landholders may pursue judicial recourse through the court system, initiating protracted litigation processes. Such legal actions typically involve injunctions that could suspend all development activities pending resolution, potentially for extended periods.

20.2.3.2 Community Relations Breakdown

Improper acquisition procedures often create deep-seated grievances among affected families and traditional land custodians. These stakeholders may adopt uncompromising positions, transforming what should be routine negotiations into intractable conflicts requiring third-party mediation.

20.2.3.3 Financial and Scheduling Impacts

Litigation-related delays directly translate into cost escalations through idle equipment, extended consultant contracts, and lost opportunity costs. Project timelines may require complete restructuring as court processes often operate on schedules incompatible with construction planning.

20.2.3.4 Reputational Consequences

Protracted land disputes frequently attract media attention and regulatory scrutiny, potentially damaging the company's social license to operate and complicating future expansion plans in the region.

20.2.4 Ground Disturbance and Associated Impacts on Flora and Fauna

The movement of survey teams and their equipment across the site during pre-development activities inevitably affects existing ground vegetation. As personnel repeatedly traverse the area to take measurements and establish reference points, their foot traffic compacts the soil and damages low-lying plants. The operation of survey vehicles creates temporary tracks that crush vegetation and disrupt root systems, particularly for delicate native species. These disturbances, while localized, can lead to small-scale erosion where plant cover is reduced, potentially affecting the micro-ecosystems that depend on this vegetation. The cumulative effect of multiple survey visits may create visible pathways that persist until natural regrowth occurs, especially in areas with sensitive or slow-growing plant species.

20.2.4.1 Alterations to Soil Characteristics During Survey Work

The physical process of conducting site surveys has measurable effects on soil structure and composition. The weight of survey vehicles and equipment alters soil porosity, potentially affecting water infiltration rates and drainage patterns in the immediate vicinity of survey points. When survey markers are installed, the digging process mixes different soil layers, temporarily disrupting the natural stratification that affects nutrient distribution. In areas where topsoil is thin or fragile, even limited ground disturbance can expose less fertile subsoil, creating patches where vegetation may

20 Identification and Evaluation of Potential Impacts

struggle to regrow. These changes, while typically confined to small areas around survey points, represent the first anthropogenic modifications to the site's natural soil profile.

20.2.4.2 Effects of Survey Operations on Local Wildlife

The presence of survey teams and their equipment creates temporary disruptions to wildlife patterns in the project area. The noise and activity associated with surveying may cause small mammals and ground-nesting birds to temporarily vacate their habitats, potentially affecting feeding and breeding behaviours. More subtle impacts include the possible destruction of inconspicuous ground nests or burrows that survey crews might inadvertently disturb. The linear paths created by repeated survey routes can act as temporary barriers to small animal movement, fragmenting habitats until vegetation recovers. These effects are generally short-term but may be more significant in areas supporting sensitive or endangered species that are particularly vulnerable to human disturbance.

Table 20.5 Potential Negative Pre-Development Impact Rating

Pre-Development Phase Impact	Overall Risk Rating		
	Likelihood	**Consequence**	**Risk Level**
Occupational Health and Safety Issues	Likely	Minor	Low
Land Litigation and Compensation Issues	Likely	Moderate	Medium
Ground Disturbances and Associated Impacts on Flora and Fauna	Likely	Minor	Low

20.3 Construction Phase Impacts

The construction phase of the project will involve the site clearance, civil works, installation of steel frame structures, setting up of containerized site offices where engineers will work from, etc. The impacts that will be associated with this phase are:

- Generation of Employment and Business Opportunities
- Impact on Air Quality
- Generation of Noise and Vibration
- Wastewater generation
- Solid waste generation
- Resource Consumption
- Impact on ecosystem
- Traffic Impact
- Occupational Health and Safety Risks
- Public Health and Safety Issues
- Visual Impact
- Soil Erosion
- Soil and land pollution from oil spillages from equipment

280 | Feasibility Studies Report

- Fire Outbreak
- Climate Change Issues

20.3.1 Generation of Employment and Business Opportunities

The construction phase will create substantial employment opportunities across multiple skill levels, providing both short-term economic benefits and long-term professional development for local workers. At the operational level, the project will employ numerous casual labourers for general construction support, including site preparation, material handling, and assistant roles to skilled tradespeople. These positions offer vital entry points into the construction industry for local community members, often requiring minimal prior experience but providing on-the-job training.

For skilled trades, the project will engage various artisans including carpenters (for formwork and structural framing), masons (for blockwork and concrete finishing), and metal fabrication specialists (for structural steel and reinforcement work). These positions typically require vocational training or apprenticeships and provide higher wage potential. The project will prioritize hiring locally available skilled workers while arranging specialized training where specific technical competencies are needed.

At the professional level, employment opportunities will include:

- Civil engineers overseeing earthworks and infrastructure development
- Structural engineers ensuring building integrity and design compliance
- Project managers coordinating timelines, budgets, and subcontractors
- Surveyors maintaining construction layout accuracy
- Mechanical engineers handling equipment and utility installations
- HSE practitioners implementing safety protocols and environmental controls

The project will create a workforce composition of approximately 60% local hires, 30% regional workers, and 10% specialized expatriates where specific technical expertise is unavailable locally. A structured mentorship program will pair junior professionals with experienced personnel to facilitate knowledge transfer, while vocational partnerships with technical institutes will enhance local capacity building.

20.3.1.1 Economic Multiplier Effects

- Direct wages injecting capital into local economies
- Secondary employment in supporting service industries
- Development of permanent skills within the regional workforce
- Stimulus for local businesses providing construction materials and equipment

The project will implement targeted recruitment initiatives to ensure equitable access to employment opportunities across demographic groups, with particular attention to gender inclusion in non-traditional construction roles. All positions will adhere to Ghanaian labor laws regarding wages, working conditions, and occupational safety standards, with third-party monitoring to ensure compliance. This impact is high, local and temporal.

20 Identification and Evaluation of Potential Impacts

20.3.2 Impact on Air Quality

The construction process will generate substantial airborne particulate matter through multiple pathways. Earthmoving operations, including excavation, grading, and backfilling, will disturb surface soils and release fine dust particles into the atmosphere. The continuous movement of heavy equipment and trucks along unpaved access routes will create additional dust plumes, particularly during dry weather conditions. Stockpiled construction materials such as sand, gravel, and crushed aggregate will be vulnerable to wind erosion unless properly contained. These dust emissions will primarily consist of larger PM10 particles that can travel significant distances from their source, potentially affecting air quality throughout the immediate project area and surrounding vicinity. The problem will be most acute during peak construction periods when multiple dust-generating activities occur simultaneously.

20.3.2.1 Combustion-Related Air Pollutants from Equipment Operation

The operation of diesel-powered construction machinery will contribute various gaseous and particulate emissions to the local air environment. Heavy equipment such as excavators, bulldozers, and loaders will emit nitrogen oxides (NOx) and particulate matter through their exhaust systems, with older or poorly maintained equipment being particularly problematic. Backup generators required for power supply will produce additional emissions, including sulphur dioxide (SO_2) and carbon monoxide (CO), especially during extended operation. These combustion byproducts will mix with construction dust to form a complex mixture of airborne contaminants. The concentration of these pollutants will be highest in immediate work zones where equipment operates continuously, creating potential exposure hotspots across the construction site.

20.3.2.2 Vulnerable Groups and Exposure Risks

Construction workers face the most significant exposure risks due to their prolonged presence in high-activity zones where both dust and equipment emissions concentrate. Without proper controls, these workers could experience respiratory irritation and reduced visibility during their shifts. Employees at nearby businesses may encounter intermittent exposure depending on prevailing wind patterns and their facility's proximity to active work areas. Pedestrians and motorists using adjacent roads may experience temporary nuisance-level exposure when passing near the site during peak construction activities. The cumulative effect creates a tiered exposure risk profile that decreases with distance from the construction zone but remains a consideration for all regular users of the immediate area.

20.3.2.3 Temporal and Spatial Characteristics of Air Quality Impacts

The air quality impacts will demonstrate distinct temporal and spatial patterns throughout the construction period. Particulate levels will spike during dry, windy conditions when dust generation and dispersion are maximized, particularly during major earthworks phases. Geographically, the impacts will radiate outward from active work zones with intensity diminishing proportionally to distance from source areas. The most severe effects will remain localized within approximately 500 meters of construction activities, though occasional dust plumes may travel farther under ideal atmospheric conditions. These impacts will be temporary in nature, correlating directly with active construction phases and subsiding completely upon project completion and site stabilization. This impact is high, local and temporal.

282 | Feasibility Studies Report

20.3.3 6.2.3 Generation of noise

The construction phase will generate significant noise pollution through multiple activities and equipment operations, creating temporary but potentially disruptive sound emissions in the project vicinity. The primary noise sources can be categorized as follows:

20.3.3.1 Heavy Equipment Operation

The use of earthmoving machinery such as bulldozers, excavators, and loaders will produce continuous low-frequency noise during grading and excavation work. Concrete mixers, cranes, and dump trucks will contribute additional operational noise through engine rumble, hydraulic systems, and material loading/unloading activities. These mobile noise sources will create fluctuating sound levels as equipment moves across the site.

20.3.3.2 Construction Processes and Activities

Impact tools including pile drivers, jackhammers, and pneumatic drills will generate high-decibel, impulsive noise during foundation work and structural installation. Metal fabrication activities like cutting, grinding, and welding will add intermittent high-frequency noise components. General construction noise from hammering, material handling, and site preparation will contribute to the cumulative noise environment.

20.3.3.3 Support Equipment Operation

Generator sets, compressors, and other power sources will produce constant background noise throughout work shifts. Vehicle movements including delivery trucks and worker transportation will generate traffic noise at site access points. Temporary workshop areas with power tools will create localized high-noise zones.

20.3.4 Wastewater Generation

Civil works will result in the release of watery slurry residues. Another impact is the liquid waste from urine of construction workers.

This impact will be local in nature and limited to the project site and its immediate periphery.

20.3.5 Solid Waste Generation

The construction process will generate multiple categories of solid waste requiring different handling approaches. Construction and demolition debris will form the largest volume, including concrete fragments, brick pieces, and masonry waste from structural work. Wooden materials such as pallets, formwork, and timber offcuts will constitute another significant portion, along with various metal scraps from steel reinforcements, pipe cuttings, and packaging materials. Additionally, the project will accumulate drywall pieces, insulation scraps, and roofing materials as building construction progresses. These materials vary widely in their potential for reuse, recycling, or required disposal methods, necessitating a comprehensive sorting and management system.

20.3.5.1 Packaging and Consumables Waste Generation

Material deliveries and daily operations will produce substantial packaging waste throughout the construction period. Cardboard boxes, plastic wrapping films, and protective padding materials will accumulate from equipment and material shipments. Various containers including empty paint cans,

20 Identification and Evaluation of Potential Impacts

used solvent tins, and exhausted adhesive tubes will require special handling as potential hazardous waste. The construction of mechanical and electrical systems will generate discarded tubing segments, wiring offcuts, and obsolete electrical components. While some of these materials have recycling potential, others may contain residual substances requiring controlled disposal, making proper segregation essential at the point of generation.

20.3.5.2 Operational and Support Waste Production

Beyond construction materials, daily site operations will generate routine waste streams similar to commercial activities. Food containers, beverage bottles, and organic leftovers from worker meals will require regular collection and proper disposal. Office operations will yield typical administrative waste such as paper documents, used writing instruments, and printer consumables. The mandatory use of personal protective equipment will result in disposable gloves, masks, and other safety gear entering the waste stream. While these items generally represent smaller volumes compared to construction debris, their continuous generation throughout the project duration requires established collection systems and responsible disposal protocols.

20.3.5.3 Environmental Consequences of Waste Mismanagement

Improper handling of construction waste carries multiple environmental risks that the project must mitigate. Soil and groundwater contamination may occur from leaching of paint residues or chemicals if containers are not properly disposed. Accumulated waste piles create visual pollution and may become breeding grounds for pests if not regularly cleared. Food waste improperly stored can attract wildlife and stray animals, potentially creating nuisance situations. Perhaps most significantly, uncontrolled waste disposal increases pressure on local landfill capacity and represents lost opportunities for material recovery. These potential impacts necessitate rigorous waste management protocols to prevent environmental degradation during the construction phase.

20.3.5.4 Systematic Waste Management Approach

The project will implement a multi-tiered waste management strategy following international best practices. Source reduction forms the first priority, achieved through careful material ordering and handling to minimize excess. Where waste generation is unavoidable, maximum emphasis will be placed on reuse opportunities, such as repurposing excavated earth for on-site grading. A comprehensive recycling program will target metals, wood, paper, and plastics through dedicated sorting stations. Only materials without recovery potential will proceed to licensed disposal facilities, with particular attention to proper handling of any hazardous items. This structured approach aims to significantly reduce the project's environmental footprint while complying with all regulatory requirements for construction waste management.

20.3.5.5 Specialized Waste Handling Requirements

Certain waste categories demand particular handling protocols due to their composition or potential hazards. Paint-related waste, solvents, and chemical containers will be collected separately as hazardous materials for processing by licensed treatment facilities. Organic waste from food services will be either composted or provided as animal feed where safe and appropriate. Electronic waste components will be processed through certified e-waste recyclers to recover valuable materials and ensure proper disposal of hazardous elements. Fluorescent tubes, batteries, and other special waste

284 | Feasibility Studies Report

items will be handled according to their specific regulatory requirements, with complete documentation maintained for all specialized waste streams.

20.3.6 Resource Consumption

The project's implementation will require substantial quantities of water and construction materials, including sand, quarry stones, cement, and other essential building components, necessitating a robust and environmentally responsible procurement and management strategy. Water supply will be primarily sourced through a carefully planned dual approach involving the development of an on-site borehole, subject to thorough hydrogeological assessments to ensure sustainable extraction rates that do not compromise local groundwater resources, supplemented by regulated private water suppliers to meet peak demand periods. This water will be strategically allocated across critical construction activities including concrete production and curing, dust suppression measures to maintain air quality standards, sanitation facilities for workforce welfare, and equipment maintenance procedures. Recognizing the potential strain on local water resources, the project will implement water conservation measures such as closed-loop recycling systems for non-potable applications, rainwater collection infrastructure during seasonal rainfall, and continuous monitoring of aquifer levels to prevent over-extraction.

For construction materials, the project will exclusively source high-quality aggregates and cement from Environmental Protection Agency (EPA)-permitted facilities, including established industry leaders such as Eastern Quarries Limited, Atlantic Quarries and Concrete Limited, CIMAF Ghana Limited, and Dangote Cement (Ghana) Limited, all of which operate under stringent environmental compliance standards. The procurement process will emphasize sustainable practices through bulk purchasing to minimize packaging waste, just-in-time delivery schedules to reduce on-site storage requirements, and preferential selection of suppliers with certified environmental management systems. The anticipated surge in demand for quarry products will be carefully managed through advance planning and coordination with suppliers to ensure stable supply chains while monitoring the environmental rehabilitation progress of extraction sites.

Concurrently, the project's operational activities will lead to increased consumption of fossil fuels, predominantly diesel, to power transportation networks, construction machinery, and support vehicles. This non-renewable resource demand will be systematically addressed through a multi-faceted efficiency program incorporating regular equipment maintenance to optimize performance, strategic fleet management prioritizing fuel-efficient vehicles, and advanced route planning for material transport to minimize unnecessary consumption.

20.3.7 Impacts on Ecosystem

The site clearance process will inevitably alter the existing ecosystem through the removal of vegetation and disturbance of terrestrial habitats, resulting in temporary but measurable biodiversity impacts. The project area currently supports various grass species including Brachiaria decumbens (Signal grass) and Hyparrhenia rufa (Jaragua grass), which serve important ecological functions as ground cover and soil stabilizers. Herbaceous plants such as Alternanthera philoxeroides (Alligator weed) in moist areas and Cyperus rotundus (Nutgrass) in drier zones will also be affected, along with their associated invertebrate communities. The clearance operations will particularly impact arthropod populations including Caelifera (grasshoppers) and several ant species (Formicinae and Tetraponera), which play crucial roles in nutrient cycling and local food webs. While none of these

20 Identification and Evaluation of Potential Impacts

species are classified as endangered, their removal represents a reduction in local biodiversity that requires careful management.

20.3.8 Traffic Impacts

The construction activities will generate significant traffic-related impacts that require careful management to minimize disruptions to the local road network and ensure public safety. The primary anticipated effects include substantial pressure on existing road infrastructure due to intensified vehicle movements associated with the transportation of construction materials, equipment, and workforce. Heavy-duty vehicles such as trucks delivering aggregates, cement, and structural components will make frequent trips along access routes, potentially accelerating pavement deterioration through increased axle loading and wear. This concentrated commercial vehicle activity may compromise road surface integrity, particularly on secondary roads not originally designed for such intensive use.

Concurrent with material deliveries, the regular movement of construction vehicles including excavators, bulldozers, and concrete mixers between the project site and support facilities will contribute to elevated traffic volumes. The potential breakdown of these specialized vehicles on public roads presents additional congestion risks, potentially creating bottlenecks that disrupt normal traffic flow patterns. These operational factors combine to create temporary but substantial changes to baseline traffic conditions in the project vicinity.

Of particular concern are safety risks arising from construction-related traffic, including potential non-compliance with traffic regulations by project vehicles, inadequate signage at access points, and increased accident potential due to the mixing of heavy construction equipment with regular commuter traffic. The introduction of large vehicles with limited manoeuvrability into existing traffic streams may create hazardous interactions with vulnerable road users such as pedestrians and cyclists. Nighttime deliveries or work under low-visibility conditions could further exacerbate these risks without proper mitigation measures.

20.3.9 Occupational Health and Safety Risks

The construction phase presents significant workplace hazards that require rigorous safety management to protect workers from potential injuries. The nature of construction operations—including roofing installation, metal fabrication, concrete placement, structural steel erection, and welding activities—creates multiple exposure risks that must be systematically controlled.

Workers face fall hazards when working at elevation during roof construction and steel assembly, where improper fall protection could lead to serious injuries. Equipment-related dangers emerge from power tools, cutting machinery, and material handling devices that may cause lacerations, crush injuries, or amputations if improperly used. Material handling risks are particularly acute when working with sharp-edged metal sheets, rebar, and other construction components that can produce severe cuts or puncture wounds.

The welding and grinding processes introduce additional hazards including:

- Eye injuries from flying metal particles

286 | Feasibility Studies Report

- Burns from hot materials or sparks
- Respiratory risks from metal fumes

This impact is high and temporal.

20.3.10 Public Health and Safety Risks

The project's construction activities may temporarily affect surrounding communities through several channels that require careful management, including increased traffic risks from construction vehicles operating near residential areas, potential exposure to dust and emissions from site operations, and socio-cultural interactions between project workers and local residents. To address these concerns, the project will implement a comprehensive mitigation framework featuring designated truck routes with traffic calming measures, daily air quality monitoring with dust suppression systems, and cultural awareness training for all personnel. While these impacts will be most noticeable during peak construction periods, the project has established protocols to minimize disruptions, including community liaison officers to facilitate communication, strict enforcement of noise and emission controls during sensitive hours, and workforce policies promoting respectful engagement with local residents.

20.3.11 Visual Impact

The clearing of the already existing vegetation and associated earthworks will alter the aesthetic quality the project site. The green nature of the site will be replaced with scenes of cleared bare land, parked construction equipment, heaped sand and suspended dust. This impact is expected to be local in nature and temporal.

20.3.12 Soil Erosion

Construction will require removal of vegetation which will expose the soil to wind and rain action that can wash away the topsoil and deposit it into natural drainage pathways located in the site and cause silting.

20.3.12.1 Soil and land pollution from oil spillages from equipment

There is potential for oil spillages from heavy diesel fuelled equipment (being used for construction activities) to seep into the soil and cause pollution to the land.

20.3.12.2 Fire Outbreak

Use of equipment and electrical devices can cause fire outbreak when they sometimes malfunction.

20.3.12.3 Climate Change Issues

Climate issues can arise from the following:

- Vegetation clearance which reduces absorption of carbon dioxide from the atmosphere
- Greenhouse gas Emissions from construction equipment being used on site
- Use of high carbon construction materials

20 Identification and Evaluation of Potential Impacts

Table 20.6 Potential Negative Construction Phase Impact Rating

	Overall Risk Rating		
Impact	**Likelihood**	**Consequence**	**Risk Level**
Impact on Air Quality	Almost Certain	Moderate	High
Generation of noise and vibration	Almost Certain	Moderate	High
Wastewater Generation	Possible	Minor	Medium
Solid Waste Generation	Almost Certain	Moderate	High
Resource Consumption	Likely	Minor	Medium
Impact on Ecosystem	Likely	Minor	Medium
Traffic Impact	Possible	Insignificant	Low
Occupational Health and Safety Risks	Almost Certain	Moderate	High
Public Health and Safety Issues	Possible	Minor	Medium
Visual Impact	Unlikely	Insignificant	Low
Soil Erosion	Likely	Minor	Medium
Soil and land pollution from oil spillage	Possible	Minor	Medium
Fire Outbreak	Possible	Minor	Medium
Climate Change Issues	Possible	Moderate	Medium

20.4 Operational Phase Impacts

The anticipated impacts include:

- Solid Waste generation
- Dust and Gaseous emissions
- Noise Generation
- Liquid waste Generation
- Sanitation and hygiene impacts
- Waste Oil Generation
- Occupational Health and Safety Hazards
- Fire & Explosion Hazards
- Public Health and Safety Issues
- Generation of Employment, Business Opportunities and Tax Revenues

20.4.1 Generation of Employment and Revenue

The project is expected to create thirty-seven (37) direct job opportunities for local persons. This will provide income for these persons and their families who are dependent on them. The operation of

288 | Feasibility Studies Report

the factory will also boost income of logistics , vehicle maintenance and accommodation service providers in the project area. This impact will lead to the generation of tax for government. This impact is high, regional and permanent in nature.

20.4.2 Increased Pressure on Utility Supply

The project will require approximately 30000 kWh of electricity per month and 600 m3 of water per month. Thus will directly have an impact on the energy and water demand in the project area. This impact is medium, local and permanent in nature.

20.4.3 Dust and Gaseous Emissions

The sources and types of emissions are as follows:

- Dust (TSP and PM10) and exhaust gases (SO2 and NO2) from the use of generators and diesel powered forklifts
- Air-blown dust from movement of vehicles around the site
- Green House Gases from use of air-conditioning units for the offices
- Particulate matter from powdery raw material spillages

This impact is low, local and permanent in nature.

20.4.4 Noise Generation

The operation of the forklifts, conveyors, and factory machinery will lead to the generation of noise. The machines are fitted with motors and engines which rev and make roaring noises when being operated at high capacities. This impact is of medium scale, local and permanent in nature

20.4.5 Solid Waste Generation

The anticipated solid wastes envisaged includes packaging material, raw material spillages, obsolete and expired chemicals, wooden pallets during maintenance works, office wastes and worn-out clothing. It is estimated that approximately 650 Kg of solid waste will be generated per annum. This impact is high, local and permanent in nature.

20.4.6 Wastewater Generation

Liquid wastes will be of three (3) in nature, namely:

- Process wastewater from washing of mixing tanks
- Greywater from the washroom sinks, showers and sinks
- Blackwater from the washroom toilet facilities

20.4.7 Waste Oil Generation

The potential sources of waste oil are:

- Leakages and spills from the diesel tanks and forklifts
- Spills from forklift and other equipment servicing
- Spills during fuelling of the generator

20.4.8 Hygiene and Sanitation Impacts

It is important to always keep the workplace tidy to avoid unhygienic and unsanitary conditions such as growing of mould, yeast and fungi in certain places of the factory such as the washroom and gutters. The presence of mould, yeast and fungi can pose health risks to staff and visitors.

20 Identification and Evaluation of Potential Impacts

20.4.9 Occupational Health and Safety Hazards

Examples of occupational hazards that can affect workers include heat stress, burns, scalds, severe injuries from accidents, irritability from exposure to noise, fatigue, etc.

20.4.10 Fire and Explosion Hazards

The presence of fuel and electrical cables poses a fire and explosion risk. The electrical cable installations must be properly installed in a manner that ensures they are at reasonable distances from each other.

20.4.11 Public Health and Safety Risks

Persons located close to the project will be exposed to a myriad of impacts such as noise, gaseous emissions, traffic jams and at worst incidences of fire and explosion.

20.4.12 Generation of Heat on the Factory Floor

The production process can lead to the generation of heat on the production floor.

20.4.13 Potential Spillage of Raw Materials and Products

There is potential spills of reagents, solvents, additives, etc which can pollute/contaminate the environment upon exposure to soil.

20.4.14 Climate Change Issues

Key climate change issues can arise from:

- Use of certain types of refrigerants for air-conditioning systems which may have ozone depleting and global warming potential
- Use of heating systems which may generate greenhouse gas emissions
- Emissions from transportation systems
- Reliance on energy grid that emits higher carbon footprints
- Use of low-energy efficient equipment for production

20.4.15 Potential Generation of Obsolete chemicals

There is potential for generation of obsolete or expired chemicals .
This can pose major environmental and public health issues if exposed to the public.

Table 20.7 Potential Negative Operational Phase Impact Rating

	Overall Risk Rating		
Operational Phase Impacts	**Likelihood**	**Consequence**	**Risk Level**
Increased pressure on utility supply	Unlikely	Insignificant	Low
Dust and Gaseous Emissions	Almost Certain	Moderate	High

290 | Feasibility Studies Report

	Overall Risk Rating		
Operational Phase Impacts	**Likelihood**	**Consequence**	**Risk Level**
Noise Generation	Almost Certain	Moderate	High
Solid Waste Generation	Almost Certain	Moderate	High
Wastewater Generation	Almost Certain	Moderate	High
Waste Oil Generation	Possible	Minor	Medium
Hygiene and Sanitation Issues	Possible	Minor	Medium
Traffic Impact	Possible	Moderate	Medium
Occupational Health and Safety Risks	Almost Certain	Moderate	High
Public Health and Safety Issues	Possible	Minor	Medium
Potential Spillage of Raw Materials and Products	Unlikely	Insignificant	Low
Potential Generation of Obsolete Chemicals	Likely	Minor	Medium
Generation of Heat	Possible	Minor	Medium
Fire and Explosion Hazards	Possible	Minor	Medium
Climate Change Issues	Likely	Moderate	High

21 Public Participation/ Stakeholder Engagement

21.1 Introduction

As part of the Environmental Impact Assessment, consultations must be held with key public institutions and immediate neighbours to provide them information of the project as it allows them the opportunity to voice their candid opinions about the project. This can be achieved via all stakeholder-inclusive approach. An all-stakeholder inclusive approach is the involvement of all parties who potentially have a regulatory control over the proposed facility or may be affected by it. The principal objective of public participation in an Environmental Impact Assessment (EIA) process is to inform and enrich decision-making. Dialogues were held with all identified key stakeholders during the process of data collection, impact identification and development of mitigation measures. This approach sought to promote consensus building and general acceptance of the project by the stakeholders.

21.2 Stakeholder Identification and Mapping

The stakeholder identification and assessment process was carried out via stakeholder mapping to pinpoint likely project affected persons, businesses and institutions. This was done based on assessing activities in close proximity to the project and identifying persons, businesses and institutions that will be likely affected by the project or whose activities could also affect the project. An overview of institutions was done to identify public institutions that have an oversight responsibility to regulate projects of such nature.

21.3 Stakeholder Engagement Procedures

To date, ten (10) stakeholder groups have been contacted and provided with information on the proposed plastics and used tires recycling project and briefed about the EIA process. In order to achieve the objectives of the stakeholder consultation, the field trip activities included the following:

8. Stakeholder identification and assessment;
9. Notifications of key stakeholders; and
10. Dialogues with public institutions and potential project affected persons/businesses.

21.4 Stakeholder Consultation Activities

21.4.1 Notification of Regulatory Authorities

The following institutions have been notified of the proposed project:

- Environmental Protection Authority
- Ghana National Fire Service
- Food and Drugs Authority
- Ghana Standards Authority

292 | Feasibility Studies Report

21.4.2 Consultation of Other Governmental Institutions

Other governmental institutions consulted included the:

- Physical Planning Department of Lower Manya Krobo Municipal Assembly
- Environmental Health and Sanitation Department of Lower Manya Krobo Municipal Assembly
- Ghana Water Company
- Electricity Company of Ghana

21.4.3 Community and Neighbourhood stakeholder consultations

Some of the local community and neighbours consulted included:

- Traditional Council of Okwenya-Akuse Traditional Area
- The Assemblyman and Unit Committee members

21.5 Mode of Consultations

The success of stakeholder consultations relies on the best approach of communicating with the identified stakeholders to notify them and provide them with opportunity to respond effectively. Two modes of stakeholder consultation, namely official correspondence and in-person meetings was chosen based on prior enquiries and operational strategy of the identified stakeholders.
Both modes of stakeholder engagements were adopted for some of the identified stakeholders whilst others were engaged via either one of the modes

21.5.1 Consultation via official Correspondence

Letters were shared with the under listed institutions to seek their concerns and recommendations however they are yet to respond. Follow-ups are being done to obtain the official responses.

- Food and Drugs Authority
- Ghana Standards Authority
- Ghana Water Company Limited
- Electricity Company of Ghana
- Physical Planning Department and Works Department of Lower Manya Krobo Municipal Assembly
- Environmental Health and Sanitation Department of Lower Manya Krobo Municipal Assembly

21.5.2 5.4.2 In-Person Meetings

The in-person meetings provided opportunity for detailed discussions of the project to enhance consensus building amongst participants. This strategy helps to develop alignment with the project's needs and to enhance community support and regulatory input for the project.
In-person meetings were done with the following stakeholders:

- Physical Planning Department and Works Department of Lower Manya Krobo Municipal Assembly
- Environmental Health and Sanitation Department of Lower Manya Krobo Municipal Assembly
- Environmental Protection Authority
- Ghana National Fire Service

21 Public Participation/ Stakeholder Engagement

- Ghana Water Company Limited
- Electricity Company of Ghana
- Traditional Council of Okwenya-Akuse Traditional Area
- The Assemblyman and Unit committee members of Okwenya-Akuse Community

21.6 Register of Stakeholder Consultations

The table below provides details of stakeholders who have been engaged and provided responses so far.

Table 21.1 Register of Consulted Stakeholders

S/N	Names	Contact	Designation	Institution/Area
1	Nene Per-Teye Osei Kwashie II	0241479755	Chief	Okwenya - Akuse Traditional Area
2	Bright Gbedze	0247264018	Deputy Director	Environmental Health and Sanitation Department, LMKMA
3	Shirley Sowah	0207248104	Head of Department	Physical Planning Department, LMKMA
4	DO1 Stanley Lamptey	0243959111	Officer-In-Charge	Ghana National Fire Service
5	STNO II Eric Larbi	0244644519	Safety	
6	Gerdaline Sedem Gidiglo	0247494885	Liaison Officer	Environmental Protection Agency
7	Tovor Stephen Mawuli	541943044	Commercial Relations Officer	Ghana Water Company Limited, Kpong
8	Ing. Christopher Apawu	501616351	Branch Manager	Electricity Company of Ghana
9	Hon. Mensah Robert Senyo	0243457293	Assemblyman	Okwenya community
10	Nene Akwetey Narh		Opinion leader	Okwenya community
11	Enoch Akwetey Narh		PTA chairman	Okwenya community
12	Vincent Amanor		Unit Committee member	Okwenya community
13	Richard Akwetey		Unit committee Member	Okwenya community
14	Godwin Alipue		Unit committee Member	Okwenya community

294 | Feasibility Studies Report

21 Public Participation/ Stakeholder Engagement

21.7 Outcome of consultations

21.7.1 Outcome of consultation with the Chief of Okwenya-Akuse Traditional Area

On the 12th of March, the traditional council of Akuse Junction Area was engaged to notify them of the proposed construction and operation of a pharmaceutical facility.
The chief of Akuse Junction Area, Nene Per-Teye Osei Kwashie was present and was engaged via an in-person meeting. The chief welcomed the project since both the construction and operational phases would create employment for his community members and Ghanaians.

He raised some concerns which are listed below:

1. Check the registration of the acquired land to ensure it is litigation free.
2. The traditional council of Akuse junction area must be engaged again when the construction phase commences.

Figure 21.1 Evidence of consultation with the Chief of Okwenya-Akuse Traditional Area (seated left), Nene Per-Teye Osei Kwashie II

21.7.2 Consultation with the Assemblyman and Unit Committee Members

The Assemblyman and Unit committee members are part of the decentralized process by which the local district, municipal and metropolitan assemblies operate. They are the direct representatives of the community and are involved in helping achieve developmental targets within their community.

Feasibility Studies Report| 295

21 Public Participation/ Stakeholder Engagement

The assemblyman, unit committee members and opinion leaders were consulted to notify them of the project to enhance community acceptance of the project. The following comments were made at the meeting with the Assemblyman and Unit Committee members:

- The Assemblyman and unit committee members lauded the project and hoped it commences very soon.
- The assemblyman asked about what aid the community could offer the project to make it successful.
- The Assemblyman queried how the community could benefit from the project;
- The unit committee members stated that business opportunities should be given to some of the skilled persons.

Figure 21.2 Consultation with Assemblyman (middle) and unit committee members (1s, 2nd, 3rd, 5th and 6th from the left)

21.7.3 Outcome of consultation with the LMKMA Physical Planning Department

1. The department notified the team that the company commenced a building permit acquisition process in 2023 with a Geotechnical Report for another project within the same site.
2. The secretary mentioned that a chieftaincy dispute concerning the acquired land for the project. She advised that the management of QPL must engage all stakeholders to ensure smooth land acquisition is done.

296 | Feasibility Studies Report

3. A response from the department stating the requirement was given to Quintex Pharma with recommendation and an ultimatum which ended February 2025. The report is attached for your necessary action.

Figure 21.3 Evidence of consultation with Madam Shirley Sowah (right), Director for the LMKMA Physical Planning Department

21.7.4 Outcome of consultation with the LMKMA Environmental Health and Sanitation Department

The department made the following recommendations:

1. The company must obtain a Food and Drugs Authority license for its operations.
2. QPL must submit the required documentations for issuance of its building permit
3. Officials of EHSD will inspect the site for the proposed project before and during construction phase.
4. ESHD officers will inspect the site after construction and issue a Suitability certificate.
5. The company must acquire a Business Operating Permit from the LMKMA during operational phase.
6. The company must obtain a Fire permit and install a fire extinguisher from Ghana National Fire Service.

21 Public Participation/ Stakeholder Engagement

21.7.5 Ghana Water Company Limited, Kpong

Ghana Water Ltd. (GWL) is the sole government owned water utility company. It is responsible for the production, transmission and distribution of water in urban areas in Ghana.
The Kpong Old Water Works is responsible for distribution of water within the project area.
The Commercial Relations Officer of GWCL's Kpone Old Works outlined certain requirement to ensure distribution of access to pipe-borne water to the project site;

- Submission of a copy of the Site Plan
- Submission of an application letter addressed to the 'GWCL District Manager-Kpong'
- After this submission, an application form must be completed followed by a site inspection by the Water Distribution Department of the GWCL to ascertain material costs for purposes of invoicing.

21.7.6 Electricity Company Ghana, Somanya Branch Office

The Electricity Company of Ghana (ECG) is responsible for power distribution within the Southern sector of Ghana. The ECG operates by offtaking power from GRIDCo and takes the power through a number of step down sequences to enable distribution to homes and industries.
The Somanya ECG branch has jurisdiction over the Yilo Krobo, Lower Manya Municipal and Asuogyaman District areas. The branch manager outlined the following application requirements for connectivity of the proposed factory to the national grid:

- Submission of a Site Plan, accompanied with a copy of the Ghana Card of the company's chosen representative.
- Completion of an Energy Commission form to facilitate a site inspection by the Energy Commission and Electricity Company of Ghana. This will help to determine feeder distribution systems appropriate for the facility.

21.7.7 Environmental Protection Authority (EPA), Asuogyaman Office

The Lower Manya Krobo Municipality does not have any substantive EPA office but all EPA related issues are under the purview of the Asuogyaman EPA Liaison office.
The Asuogyaman EPA Liaison officer stated that an official application must be done via the EPA's Eastern Regional office or Head office by completion of the necessary application Environmental Assessment forms with attachment of the following documents:

- A structural design for the proposed project.
- A signed Site Plan and Block Plan
- A license from Food and Drugs Authority (FDA)

She further stated that an Environmental Impact Assessment Report will be requested for further review and consideration for the permit.

21.7.8 Ghana National Fire Service - Kpong (Lower Manya Korbo Municipal Fire Station)

The Ghana National Fire Service is mandated to ensure fire safety of the entire country by ensuring appropriate steps are taken to prevent and manage fire outbreaks.
One of the activities of the department is to review applications and issue fire permits for facilities based on fire preventive measures.

298 | Feasibility Studies Report

The GNFS was consulted for regulatory recommendations and indicated that the company must acquire a Fire permit before construction phase commences.
The application must have the following attachments for review and approval:

- A structural plan
- Certificate of Incorporation

The company must acquire Fire Certificate during operational phase.

Figure 21.4 Evidence of consultation with the Lower Manaya Krobo Municipal Fire Station of the Ghana National Fire Service

21 Public Participation/ Stakeholder Engagement

Figure 21.5 Consultation of consultation with the Lower Manaya Krobo Municipal Fire Station of the Ghana National Fire Service

300 | Feasibility Studies Report

22 Mitigation Measures

22.1 Introduction

The mitigation measures provide management guidelines for ensuring the impacts of the proposed project are minimized. The mitigation measures are intended to ensure construction and operation in a manner that prevents adverse environmental impacts.

The general rules followed in designing these measures are:
a) Minor impacts occur where effects are experienced, but the impact magnitudes are sufficiently small and well within accepted standards, and/or the receptors are of low sensitivity/value.
b) Reduction of major and moderate impacts: moderate impacts are impacts within accepted limits and standards. Moderate impacts may cover a broad range, from a threshold below which the impact is minor, up to a level that might be just short of breaching an established (legal) limit.
c) Avoidance of major impacts: major impacts are impacts where an accepted limit or standard may be exceeded, or large magnitude impacts occur to highly valued/sensitive resources/receptors.

The proposed mitigation measures have been taken into consideration based on costs, feasibility and ease of implementation. The mitigation measures have been designed specifically to remedy the negative impacts during the pre-development, construction and operational phases.

22.2 General Mitigation Measures

An objective of the impact assessment process is to reduce the negative effects and enhance the benefits associated with Project activities. Once potential impacts are identified and evaluated, mitigations are applied to avoid or reduce the effects according to the following hierarchy:

Table 22.1 Mitigation Hierarchy for Planned Project Activities

Hierarchy Strategy	Details
Avoid at Source; Reduce at Source	Avoiding or reducing at source is essentially 'designing' the project so that a feature causing an impact is designed out (or altered Often called minimisation). Example e.g. re-routing a pipeline, relocating facilities, etc.
Reduction on Site	This involves adding design control system to the basic design to abate the impact - pollution controls fall within this category. Often called "end of pipe". Example wastewater treatment, NOx reduction technology
Reduce off site	If an impact cannot be abated on-site then measures can be implemented off-site. Example soundproof equipment at a nearby residences, visual screening by planting of hedges.

Feasibility Studies Report | 301

22 Mitigation Measures

Hierarchy Strategy	Details
Repair or Remedy	Some impacts involve unavoidable damage to a resource, e.g. vegetation disturbance. Repair essentially involves restoration and reinstatement type measures.
Compensate in kind	Where other mitigation approaches are not possible or fully effective, then compensation, in some measure, for loss, damage and general intrusion might be appropriate. Example is a like-for-like biological offset attaining ecological no net loss.
Net Positive Outcomes	Make a positive contribution to Biodiversity conservation and/or improvement of Ecosystem Services and communities' development.

22.3 Mitigation Measures For Negative Pre-Development Phase Impacts

22.3.1 Management of Occupational Health and Safety Issues

The management of QPL will actively ensure there is limited exposure to occupational hazards during site survey and project feasibility phase by ensuring that personnel visiting the site wear the basic personal protective clothing such as safety boots, thick clothing and reflectors.

22.3.2 Mitigation Against Land Litigation

Management followed due procedures for identifying land owners and regulatory stakeholders for a smooth land acquisition and registration process. This ensured that the company transacted business with the right land owners so as to avert litigation issues.

22.3.3 Mitigation Against Ground Disturbance and Impacts on Flora and Fauna

The management of the company will ensure that there is well-planned work plan to ensure there are limited visits to the site during pre-development phase to ensure there is reduced disturbance to the ground, flora and fauna.

22.4 Mitigation for Negative Construction Phase Impacts

22.4.1 Management of Ambient Air Quality Impacts

Some measures to be applied will include water dowsing of surfaces to reduce suspension of dust; servicing and tuning of engines of construction vehicles to ensure proper combustion so the exhaust is not laden with high levels of noxious gases; and provision of nose-masks for workers.

22.4.2 Management of Noise Impacts

Noise will be managed by ensuring the equipment is operated at their capacities. The work plan for the construction will be designed to prevent concurrent performance of tasks which can attribute to loud noises at the same time. Work will be limited to daytime hours of 6:30 am and 5:30 pm.

22.4.3 Wastewater Management

Slurry material will stored and reused for concrete mixing. There would also be planning to ensure that the materials are estimated properly to prevent wastage.

302 | Feasibility Studies Report

22.4.4 Solid Waste Generation

Wooden pallets and metal scraps would be separated and packed nicely. Some of the aluminium scraps would be reserved and used as raw material for the factory operations. Wooden pallets would be carted off site and sold to local carpenters. Excavated earth would be used for re-stabilizing areas demarcated for lawns.
There will be provision of skips for the collection of wastes that will go to the landfill.

22.4.5 Resource Consumption Management

Proper estimation of all raw materials will be done to ensure efficient utilization of resources. Construction staff will be educated to make judicious use of raw materials.

22.4.6 Impact on Ecosystem

The clearance of vegetation will be limited to the areas required. Excavated top soils during earthworks will be reserved and reused for re-filling areas demarcated for lawns. The topsoil will be used as surface layer during re-filling to ensure that the lawns to be developed have access to nutrients. This action will also allow for the re-creation of a habitat for soil microorganisms.

22.4.7 Traffic Impact Management

Noting the risks associated with transportation of project materials and equipment to the site, management has made provisional plans to ensure that the proposed routes are checked to ascertain their suitability prior to the movement of the project materials. Obstacles will be cleared to ensure that the smooth transportation of items to the site. Management will also ensure it employs or contracts professional drivers with valid driving licenses. The trucks to be used for the transportation will be checked to ensure they are in good condition before they are put on the road. There will be regular compaction of the access routes created to connect the site to ensure they are in good condition.

22.4.8 Management of Occupational Hazards

It will be a strict requirement for workers to appropriately use the basic personal protective equipment while on site. Workers will be given basic training to enable them adhere to the highest safety standards. Regular medical check-ups must be done for the workers throughout the construction phase.

22.4.9 Management Public Health and Safety Issues

The site is walled to prevent unauthorized access to the site. Items such as quarry aggregates being conveyed to the site in trucks will be covered to prevent material spillage. Construction workers will be given education on issues such as hygiene, HIV/AIDS, and the conducts that are legally admissible in the project area. This is to help workers avoid practices/vices that can pose health risks and or unpleasant situations. Issues of racism and ethnocentrism will be discussed to ensure workers identify as people of equal rights and opportunities.

22.4.10 Management of Visual Impacts

There will be spraying of the ground prior to earthworks to ensure that there is limited suspension of dust in the atmosphere. Trucks and equipment will be neatly packed within the project site to keep the place tidy.

22 Mitigation Measures

22.4.11 Erosion Prevention and Management

Exposed land surfaces shall be compacted and stabilized to prevent erosion impacts. Vegetation removal shall be limited to only areas required to limit the extent of which top soil is washed away. Site drainage with receptacles shall be engineered to prevent washing away of soil sediments into watercourses.

22.4.12 Prevention and Management of Soil/Land Pollution Resulting from oil Spillages from Equipment

Management shall put in place the following provisions to prevent/manage soil/land pollution resulting from oil spillages from Equipment:

- Ensuring that all heavy duty equipment working on site are in good shape and do not have leaking. Any equipment that show signs of leakages shall be prevented from working on the site.
- Fuelling, servicing, maintenance and oil changes on all equipment will be done off-site to prevent oil spills from being encountered on site.
- Provision of drip pans on-site to immediately collect any drips/leaks from equipment and storing the oils in metallic drums placed on an impermeable surface.
- Regular inspection of equipment for signs of leaks and taking appropriate action of taking them off site.
- Checking for equipment maintenance records and history before allowing them to be used on site.

22.4.13 Fire Prevention/Management

Some fire preventive/management procedures on site include:

- Checking for faulty electrical problems on equipment and ensuring they are fixed.
- Ensuring there is a actively working fire extinguisher on site at all times.
- Ensuring all workers on site are trained on how to raise alarms during fire outbreaks and effectively use fire extinguishers.

22.4.14 Management of Climate Change Issues

Some of the measures to counter climate change issues during the construction phase are:

- Limiting vegetation clearance to only areas required and replanting trees with high leaf density.
- Use of construction vehicles that use alternative fuels or powered by electric, or ensuring emissions are good.
- Use of low carbon construction materials

22.5 Mitigation for Operational & Maintenance Phase Impacts

22.5.1 Management of Increased Pressure on Utilities

It would be required for machines to be operated at their installed capacities. Capacitors and Transformers will be installed on site. Equipment will be turned off when they are not in use. Management will ensure equipment are regularly serviced to ensure their output is efficient to avoid the potential for drawing more energy than required. Water taps with automatic shut-off valves and low pressures shall be installed to help prevent water wastage.

304 | Feasibility Studies Report

22.5.2 Management of Dust and Gaseous Emissions

Gaseous emissions will be controlled with a myriad of measures to ensure noxious emissions and fugitive particulate emissions are effectively controlled.

Table 22.2 Proposed Mitigation for Dust and Gaseous Emissions

Emission	Proposed control Measures
Particulate emissions	· A dedusting air filter shall be installed on factory floor to collect particulate matter generated on the factory floor. · The car park and internal access routes will be paved with concrete blocks to reduce the resuspension of dust in the ambient environment A speed limit of 10km/hr will be enforced on site.
GHG Emissions from air-conditioning units	The company will ensure it purchases and installs air-conditioning units that only use zero ozone depleting and global warming potential
Gaseous emissions from forklifts	Purchasing good efficient fuel from EPA permitted OMCs for forklifts and generators because emission is based on fuel combustion thus a fuel which is low in sulphur will release very little sulphur dioxide into the atmosphere. Another mitigative measure is using alternative fuels or electric forklifts and trucks

22.5.3 Solid Waste Generation

Proactive measures will be adopted to ensure proper management of all solid wastes.
Wooden pallets from maintenance activities would be carted off site and sold to local carpenters.
Office wastes, worn-out clothing, food leftovers, packaging materials, etc. would be disposed into bins and skips for disposal at an approved landfill site.

Management of QPL will contract a competent solid waste management company for timely collection and safe disposal of all its wastes. Management shall engage FDA and LMKMA's EHSD for guidance on handling and disposal of all obsolete and expired chemicals.
Zoompak Company Limited shall be engaged for the timely collection and treatment of chemical wastes and their packaging.
A trail document shall be developed to update the management of the company on the final destinations of its wastes.

22.5.4 Wastewater Management

The following management systems shall be applied:

- Process wastewater shall be treated with a recirculation sand filter before being discharged into the external drains.
- Blackwater will be channelled into septic tanks and septic management companies shall be contracted to collect and dispose it safely.
- Greywater will be channelled into the drainage and discharged into the external drainage.

22 Mitigation Measures

22.5.5 Waste Oil Management

To ensure effective waste oil management, several key measures will be implemented, including regular inspections to detect and address leaks or spills, with spill kits readily available in the generator area for prompt cleanup. Drip pans will be placed beneath forklifts and other machinery during servicing to capture waste oil, which will then be safely transferred into sealed containers to prevent leaks and environmental contamination. The collected oil will be responsibly disposed of through sale to Greenwich Industries Limited, a certified waste oil recycling company based in Prampram, ensuring proper recycling and regulatory compliance. Additionally, proper funnels and containment measures will be used during generator refuelling to minimize spills and maintain a clean, safe workspace. These steps collectively enhance environmental protection, operational safety, and sustainable waste handling practices.

22.5.6 Sanitation and Hygiene Management

GSA approved disinfectants and detergents will be used for weekly cleaning, mopping and scrubbing of the washroom and offices to ensure the workplace is hygienic at all times. Proper raw material containment, handling and transportation systems shall be implemented on site to prevent toxic substances from entering the environment. The Management shall ensure the raw materials have appropriate MSDS and duly follow guidelines provided for handling all these chemicals. Workers shall be trained to understand the use of MSDS for handling chemicals. Only authorized workers will be granted access to handle chemical substances to ensure they are not introduced into any environmental media.

22.5.7 Management of Heat Impact

To maintain a comfortable and safe working environment, the factory should be equipped with sizable ventilation ducts and efficient heat extraction systems designed to regulate indoor temperatures and keep the factory floor at atmospheric room temperature.

22.5.8 Occupational Health and Safety Management System

22.5.8.1 Regulatory Compliance & Expert Guidance

The company will maintain consistent communication with the Factories Inspectorate Department and Ghana National Fire Service to obtain expert advice on critical safety protocols. This ongoing collaboration will ensure all operations adhere to national safety regulations while implementing the most current and effective protective measures for the workforce and facility.

22.5.8.2 Worker Health Management System

A comprehensive health program will be implemented, beginning with mandatory medical examinations for all prospective employees prior to employment. Continuous health monitoring will be conducted to identify and address any occupational health concerns at their earliest stages. Additionally, management will guarantee all staff members are covered under a comprehensive health insurance plan to ensure access to necessary medical care.

22.5.8.3 Personal Protective Equipment Protocol

All personnel will be supplied with complete personal protective equipment, including respiratory masks, safety helmets, protective gloves, heat-resistant garments, high-visibility reflectors, and eye

306 | Feasibility Studies Report

protection goggles. The company will enforce a strict PPE policy requiring proper usage at all times during factory operations to maximize worker safety.

22.5.8.4 First Aid Preparedness Initiative

Strategically located first aid stations equipped with fully stocked medical kits will be established throughout the facility. All employees will participate in regular first aid training sessions to ensure proper response capabilities for minor injuries and medical emergencies that may occur during work hours.

22.5.8.5 Workplace Environment Optimization

The facility will incorporate advanced ventilation and heat dissipation systems to maintain optimal working temperatures. To further safeguard employee well-being, the company will implement structured work shifts with scheduled rest periods to prevent fatigue and maintain high productivity levels.

22.5.8.6 Emergency Response Framework

A comprehensive emergency action plan will be developed, featuring clearly marked evacuation routes, prominently displayed emergency contact information, and audible alarm systems. Regular safety drills and instructional toolbox meetings will be conducted to reinforce proper emergency procedures and maintain a culture of safety awareness among all staff members.

22.5.9 Managing Fire and Explosion Hazards

To ensure comprehensive fire safety compliance, the facility will be formally registered with the Ghana National Fire Service (GNFS) to facilitate regular regulatory inspections and oversight. This registration will enable professional guidance for the strategic placement of appropriate firefighting equipment throughout the premises, including fire extinguishers, hydrants, and smoke detectors in all critical areas. The company will employ trained fire safety personnel who will be specifically designated to manage fire emergencies, conduct routine equipment checks, and lead evacuation procedures when necessary. A strict materials management protocol will be implemented to segregate and properly store all flammable substances like fuels and chemicals in dedicated, well-ventilated storage areas located at safe distances from potential ignition sources and combustible materials. These integrated measures will create a robust fire prevention and response system that meets national safety standards while protecting both personnel and assets from fire-related hazards. Regular fire drills and staff training sessions will complement these physical safeguards to maintain a high level of preparedness across the organization.

22.5.10 Managing Public Health and Safety Risks

The factory premises will include sufficient designated parking areas to accommodate all employee and visitor vehicles, eliminating the need for roadside parking and ensuring smooth traffic flow around the facility. Trained traffic wardens will be stationed at key points to direct vehicles, facilitate safe entry and exit, and maintain orderly parking. To foster positive community relations and regulatory compliance, the company will appoint the HSE Officer as the dedicated liaison to promptly address and resolve any concerns raised by neighbours or regulatory bodies. Additionally, a secure perimeter fence wall will enclose the entire site, serving as a physical barrier to prevent unauthorized access while enhancing overall site security and safety. These measures collectively promote efficient operations, community goodwill, and a protected work environment.

22 Mitigation Measures

22.5.11 Odour Management

To maintain a clean and odour-free work environment, the facility will implement comprehensive waste management measures including sealed containment systems for all waste collection areas to effectively trap unpleasant odours. All accumulated waste will be promptly removed from the site by licensed waste management providers to prevent any lingering smells or pest attraction. For chemical storage, a dedicated, well-ventilated warehouse with proper air circulation systems will be maintained to prevent the buildup of strong chemical odours. The management will enforce strict inventory control protocols, including a first-expired-first-out system and regular stock audits, to ensure no expired products are purchased or stored on the premises. These proactive measures will ensure proper hygiene standards, employee comfort, and regulatory compliance throughout the facility.

22.5.12 Management of Climate Change Issues

To demonstrate its commitment to environmental sustainability and climate change adaptation, the company will implement a comprehensive green initiative program. All air-conditioning systems will utilize advanced refrigerants with zero ozone depletion potential (ODP) and zero global warming potential (GWP) to minimize environmental impact. The energy infrastructure will be enhanced through the integration of solar power generation, creating a diversified and renewable energy mix. For material handling operations, the facility will transition to electric-powered forklifts and trucks, eliminating fossil fuel emissions from internal logistics. Equipment procurement will prioritize high-efficiency models that meet international energy performance standards, while the building architecture will incorporate strategic sky lighting designs and energy-conserving materials to maximize natural illumination and reduce electricity consumption. These measures collectively form an integrated approach to reducing the company's carbon footprint while maintaining operational efficiency in alignment with global climate action goals.

22.5.13 Management of spills

The company will implement a robust spill prevention and containment system by utilizing specially designed containers featuring high-integrity secondary containment systems to effectively prevent leaks and spills of hazardous materials. Strategically placed spill response kits, equipped with absorbents, neutralizing agents, and protective gear, will be readily available throughout the facility to enable immediate cleanup of any accidental releases. Dedicated, clearly labelled spill waste containers will be positioned in all critical areas to ensure proper segregation and temporary storage of contaminated materials pending proper disposal. These measures will be complemented by regular employee training programs on spill response procedures and periodic integrity testing of all containment systems to maintain optimal performance and regulatory compliance.

22.5.14 Obsolete and Expired Chemicals Management

22.5.14.1 Chemical Procurement and Documentation Requirements

Management will enforce strict procurement protocols requiring all chemical purchases to include up-to-date Material Safety Data Sheets (MSDS/SDS) detailing proper handling, hazards, and emergency measures. Additionally, specialized transport vehicles meeting hazardous material safety standards will be exclusively used for chemical deliveries to maintain safety during transit.

308 | Feasibility Studies Report

22.5.14.2 Chemical Storage and Spill Containment Systems

The facility will implement robust chemical storage solutions featuring secondary containment structures such as bunded areas and spill pallets to prevent environmental contamination. Strategically placed spill response kits and designated waste containers will enable immediate containment and cleanup of any accidental chemical releases.

22.5.14.3 Workforce Training and Protective Measures

All employees handling chemicals will receive comprehensive training on MSDS protocols, safe handling procedures, and emergency response actions. The company will provide complete personal protective equipment including gloves, eye protection, and respirators to ensure worker safety during chemical operations.

22.5.14.4 Inventory Management and Chemical Rotation

A rigorous First-In-First-Out (FIFO) inventory system will be maintained to prevent chemical obsolescence, with strict monitoring of expiration dates during both procurement and storage processes. This systematic approach ensures only viable chemicals remain in stock.

22.5.14.5 Obsolete Chemical Handling and Disposal Procedures

Expired or unused chemicals will be immediately segregated into clearly marked, leak-proof containers designed for hazardous waste. These materials will be processed exclusively through EPA-approved waste management partners, ensuring full compliance with national chemical disposal regulations and environmental protection standards.

23 Provisional Environmental Management & Monitoring Plan

23.1 Development of an Environmental Management System

Some of the institutional arrangements that will be considered in guiding long-term environmental sustainability and compliance with environmental regulations will include:

1. Adoption and use of an environmental policy and system
2. Identification of Environmental Aspects
3. Creation of Environmental Quality Targets
4. Employee training
5. Use of Employee and Management Manuals
6. Environmental Quality and Performance Monitoring
7. Environmental Action Plans/Programs
8. Environmental Audits and Reporting

23.1.1 Adoption and Use of an Environmental Policy and System

23.1.1.1 Corporate Environmental Management Policy and Implementation Framework

To demonstrate our unwavering commitment to environmental stewardship, the company will establish a formal Environmental Management Policy that outlines our corporate dedication to sustainable operations. This policy will serve as the foundation for a comprehensive Environmental Management System (EMS) designed to systematically address both social and ecological impacts. Our EMS framework will adopt the internationally recognized Plan-Do-Check-Act (PDCA) cycle, ensuring continuous improvement through five key elements: (1) development of a clear environmental policy, (2) strategic planning, (3) operational implementation and control measures, (4) rigorous monitoring and evaluation processes, and (5) periodic management reviews for system optimization.

While institutionalizing the EMS, we recognize the potential risk of environmental responsibilities becoming siloed within a specialized team. Although this approach may optimize resources, it could inadvertently limit broader employee engagement and innovation in environmental initiatives. To prevent such stagnation, we will cultivate a dynamic learning culture that encourages all staff members to actively contribute to environmental improvements. This inclusive approach will be particularly emphasized during new employee onboarding, where orientation programs will move beyond basic compliance training to foster genuine understanding of our environmental ethos. These sessions will highlight our collaborative problem-solving culture while actively seeking to integrate

310 | Feasibility Studies Report

the fresh perspectives and specialized expertise that new hires bring to our sustainability efforts. By maintaining this balance between structured systems and organic participation, we ensure our environmental program remains both professionally managed and continuously evolving through collective input.

23.1.1.2 Continuous Improvement and Knowledge Integration Strategy

The implementation of our EMS will incorporate mechanisms to capture and utilize the diverse expertise of our workforce. We will implement structured knowledge-sharing platforms that enable experienced employees to mentor colleagues while remaining open to innovative ideas from all levels of the organization. Special emphasis will be placed on creating cross-functional environmental teams that bring together tenured staff and new hires to evaluate processes through multiple perspectives. This approach not only sustains engagement with our environmental objectives but also leverages the unique advantage that newcomers offer - the ability to identify improvement opportunities that may have become invisible to long-term employees through routine exposure. Regular "environmental innovation" forums will be conducted to harvest these fresh insights, ensuring our management system remains dynamic and responsive to emerging sustainability challenges and opportunities. Through this dual focus on systematic management and inclusive participation, we will maintain an environmental program that achieves both compliance excellence and continuous performance enhancement.

23.1.2 Identification of Environmental Aspects

A critical component of our environmental management strategy involves systematically identifying and evaluating all operational activities that may directly impact the immediate surroundings. The company will implement formalized procedures—governed by our Environmental Management System (EMS) and Identification of Environmental Aspects protocols—to assess and prioritize risks associated with factory operations. Using a structured, risk-based methodology, we will classify and rank environmental aspects based on their potential severity, ensuring that the most significant risks (termed Significant Environmental Aspects) receive targeted attention through dedicated Environmental Action Plans.

To comprehensively evaluate these aspects, we will examine all operational and administrative activities within the EMS scope, including:

- Resource consumption (land, water, fuel, energy, and natural resources)
- Air emissions (gaseous and particulate releases)
- Water discharges (surface and groundwater contamination risks)
- Land contamination (soil pollution from spills or waste disposal)
- Waste generation (solid and liquid waste streams)
- Nuisance factors (noise, odour, and visual impacts)
- Ecological effects (biodiversity loss or habitat disruption)
- Stakeholder concerns (community complaints or regulatory expectations)

Our assessment will account for past incidents, current operations, and future plans, as well as routine, non-routine (e.g., maintenance), and emergency scenarios (e.g., spills, accidents). To maintain accuracy and relevance, the Environmental Aspects Register will undergo periodic reviews, ensuring all potential impacts are documented, monitored, and mitigated through measurable objectives and corrective actions. This proactive approach ensures continuous environmental

performance improvement while aligning with regulatory requirements and sustainability best practices.

23.1.3 Creation of Environmental Quality Targets

As part of QPL's commitment to continuous environmental enhancement, QPL will establish a structured framework for setting measurable environmental objectives and targets, ensuring systematic progress tracking and accountability. These targets will be developed collaboratively between QPL's HSE Manager and Departmental Heads, with a focus on addressing significant environmental aspects identified through QPL's risk assessment process.

Each target will be supported by a detailed Environmental Action Plan, outlining:

- Specific tasks/projects required to achieve the goal
- Assigned responsibilities (individuals/teams accountable)
- Clear timelines for implementation and review
- Resource allocation (budget, technology, personnel)

When establishing environmental targets, QPL will base its decisions on multiple critical factors:

1. Policy and Regulatory Compliance:
    a. Alignment with QPL's established Environmental Policy
    b. Conformity with national environmental laws and regulatory standards
2. Performance and Compliance History:
    a. Analysis of previous environmental incidents and non-compliance issues
    b. Findings from both internal and external Environmental Management System audits
3. Operational and Business Considerations:
    a. Current operational needs, limitations, and physical constraints
    b. Core business objectives and strategic priorities
    c. Financial viability and budget allocations
4. Innovation and Stakeholder Engagement:
    a. Available and emerging technological solutions
    b. Input and concerns from external stakeholders and community groups

This comprehensive approach ensures that QPL's environmental targets are:

- Realistic and achievable within operational contexts
- Compliant with all regulatory requirements
- Financially sustainable
- Technologically feasible
- Responsive to stakeholder concerns

23.1.4 Employee Training

QPL management recognizes that achieving meaningful sustainability outcomes requires company-wide participation, with every employee understanding and adhering to established environmental standards. To cultivate this shared responsibility, management will implement comprehensive awareness programs to educate all personnel about their environmental obligations, ensuring

312 | Feasibility Studies Report

protection of ecosystems becomes an integral part of daily operations and decision-making processes across all organizational levels.

23.1.4.1 Interactive Training Methodology

The company will deliver engaging, thought-provoking training sessions designed to actively examine and potentially reshape participants' environmental perspectives while exploring their specific roles in minimizing ecological impacts. These interactive programs will respect existing viewpoints while demonstrating how individual job functions, production processes, and operational decisions collectively influence environmental performance, with all perspectives receiving serious consideration to maintain participant engagement and commitment.

23.1.4.2 Comprehensive Employee Development Program

QPL will implement mandatory environmental, health and safety education for all personnel categories - including permanent staff, temporary workers and contractors - delivered through regular toolbox meetings, specialized workshops and ongoing training initiatives. Environmental specialists will receive additional professional development opportunities to ensure their expertise remains current with evolving best practices and regulatory requirements in sustainability and workplace safety.

23.1.4.3 Continuous Workforce Engagement Strategy

The HSE committee will oversee systematic orientation for new hires while conducting annual competency evaluations for all staff regarding health and safety responsibilities. This structured approach ensures continuous reinforcement of optimal environmental practices and occupational safety standards throughout the workforce, maintaining high levels of awareness and compliance across all company operations.

23.1.4.4 Organizational Benefits

This comprehensive environmental education and engagement framework delivers multiple advantages including unified sustainability consciousness across all employee levels, sustained adherence to environmental best practices, and an empowered workforce capable of driving ongoing improvements in ecological performance and workplace safety standards.

23.1.5 Use of Employee Manuals

To ensure full adherence to environmental and safety standards, QPL will implement a comprehensive documentation system detailing all production processes and emergency response protocols. These materials will be distributed to all relevant personnel, equipping them with the necessary knowledge to maintain compliance with regulatory and operational requirements.

To maximize comprehension and retention, the documentation will incorporate high-visibility graphic aids, including:

- Process flow diagrams illustrating key production stages
- Safety infographics highlighting hazard zones and protective measures
- Emergency response charts with clear visual instructions

This visual strategy will enhance information accessibility for employees of all literacy levels, strengthen retention of vital safety protocols through impactful imagery, and ensure consistent

implementation of operational best practices throughout all workforce teams. Regular audits will verify the effective implementation of these documented procedures, ensuring continuous alignment with evolving industry standards.

23.1.6 Environmental Quality and Performance Monitoring

In full compliance with the monitoring requirements stipulated in the Environmental Permit Schedule, QPL will implement a rigorous environmental monitoring program to verify the efficacy of all implemented control measures and demonstrate regulatory due diligence. This comprehensive monitoring initiative will systematically track and assess:

1. Ecological impacts - Evaluating effects on local biodiversity and ecosystems
2. Noise pollution levels - Measuring operational sound emissions against permissible limits
3. Air quality parameters - Monitoring both particulate matter and gaseous emissions

The program will employ standardized measurement protocols, calibrated equipment, and periodic reporting to ensure:

- Continuous compliance with permit conditions
- Early detection of any deviations from environmental standards
- Data-driven optimization of pollution control measures

All findings will be documented in quarterly environmental performance reports, providing transparent verification of QPL's operational compliance and commitment to sustainable practices.

23.1.7 Environmental Action Plans

QPL will implement structured Environmental Action Programs (EAPs) to systematically organize, delegate, and oversee all initiatives and resources necessary to meet established environmental objectives within specified timelines. These programs will:

- Clearly define implementation strategies and key performance indicators
- Assign specific responsibilities to designated personnel/departments
- Establish coordinated execution frameworks with measurable milestones
- Incorporate control mechanisms to ensure timely progress

The company will conduct regular progress evaluations through:

1. Quarterly Performance Reviews: Tracking quantitative metrics against targets
2. Management Review Meetings: Featuring detailed progress reports from responsible parties
3. Corrective Action Processes: Addressing any implementation delays or deviations

This systematic approach ensures accountability, maintains operational alignment with sustainability goals, and enables data-driven decision making for continuous environmental performance improvement.

23.1.8 Environmental Audits and Reporting

Management will establish a standardized independent compliance auditing system to rigorously evaluate the effectiveness of this PEMP as an operational document, conducting comprehensive assessments in full alignment with applicable national and international environmental laws, standards, and policies. These audits will serve dual purposes of internal performance monitoring

314 | Feasibility Studies Report

and external regulatory reporting, systematically reviewing implementation status, regulatory compliance, and operational effectiveness while identifying areas requiring corrective action. The auditing framework will incorporate the Provisional Environmental Management Plan outlined in the accompanying table, which details key environmental aspects, corresponding control measures, assigned responsibilities, implementation timelines, and performance indicators, thereby ensuring structured evaluation, transparent reporting, and continuous environmental performance improvement across all project activities. The table below present the monitoring parameters.

Table 23.1 Environmental Quality Parameters and Standards for Monitoring

Issues	Parameters	Standards
Ambient Air Quality	PM_{10}	· PM_{10}: 70 ug/m^3 in 24 hours
	$PM_{2.5}$	· $PM_{2.5}$: 35 ug/m^3 in 24 hours
	SO_2	· SO_2: 150 ug/m^3 in 24 hours
	NO_2	· NO_2: 150 ug/m^3 in 24 hours
	CO	· CO : 10 mg/m^3 in 24 hours
Point Source Emission (from generator set emissions)	TPM	· TPM: 20 mg/m^3
	CO	· CO : 100 mg/Nm^3
	SO_2	· SO_2: 100 mg/Nm^3
	NO_2	· NO_2: 320 mg/Nm^3
Noise	Ambient Noise	· 70 dB (A)
	Occupational Noise	· 80 dB (A)
Treated Effluent	Temperature	· ≤3^0 C above ambient
	Alkalinity (mg/l)	· 150
	Colour(TCU)	· 200
	COD(mg/l)	· 250
	BOD_5(mg/l)	· 50
	Oil & Grease(mg/l)	· 5
	Conductivity(µS/Cm)	· 1500
	pH	· 6-9
	TDS(mg/l)	· 1000
	Total phosphorus(mg/l)	· 2
	TSS(mg/l)	· 50
	Turbidity(N.T.U)	· 75
	Nitrate as total Nitrogen (mg/l)	· 50
	Total Coliforms (MPN/100ml)	· 400

The provisional Environmental Management Plan has been provided in the tables below.

Table 23.2 Provisional Environmental Management Plan

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
Pre-development phase							
Environmental Issues							
Ecosystem Impacts	Limit number of visits to the site	Screen requests for site visits to ensure they are important and ensure such visits will not lead to activities that will disturb flora and fauna. Prevent unauthorized access to the site.	To prevent ecological disturbances prior to the EIA	Maintain ecological quality of the site		Prior to construction phase	Project Manager
Occupational Health and Safety Issues							
Occupational Health and safety issues	Use of PPEs	Ensuring personnel are trained on safety issues and ensuring they use PPEs for site visits	To prevent injury on site	Complete protection from occupational hazards	4,000.00	Prior to construction	Project Manager
Construction Phase							
Environmental Issues							
Impact on Air Quality	Dust suppression	Water Dowsing. Use of efficient fuels in heavy duty equipment	Reduce dust emissions and noxious gas releases	< 35 ug/m^3 for $PM_{2.5}$ < 70 ug/m^3 for PM_{10} < 50 ug/m^3 for SO_2 < 150 ug/m^3 for NO_2	3,000.00	During Construction	Site HSE Officer of Contractor

316 | Feasibility Studies Report

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		Servicing of construction equipment which use fuel to run engines		< 150 ug/m³ for TSP over a 24-hour monitoring period			
Generation of Noise and Vibration	Identifying noise generation sources and efficiently conducting operations to ensure noise is at low levels	Servicing construction equipment Operating machineries at their installed capacities and selecting machineries with low noise levels Limiting construction work to daytime hours of 6:30am to 5:30pm	Reduce loud noises on site	< 70 dB for both night and daytime hours	2,000.00	During Construction	Site HSE officer of Contractor
Wastewater Generation	Providing washrooms on site and containers for construction slurry	Ensuring presence of washrooms for construction staff Estimation of materials to ensure there aren't left overs Provision of sizable containers for collection of construction slurry	Prevent irresponsible disposal of wastewater generated during the construction phase	Collection and safe disposal of of bodily wastes.	4,000.00	During Construction	Site HSE Officer of Contractor

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		to be reused in concrete mixing					
Solid Waste Generation	Reuse and disposal of unwanted items	Engaging an efficient waste management company and introducing waste management system that enhances segregation on site. Provision of sizable bins for collection of wastes. Selling wooden pallets to carpenters All other wastes will be collected in skips and transferred to the Kpone landfill site for safe disposal	Ensuring proper waste management practices are adopted on site	Carting wooden pallets off-site to carpenters Safe disposal of all other types of waste Saving scraps to be reused in the operation phase, and selling off the rest to scrap dealers.	3,000.00	During Construction	Site HSE Officer of Contractor
Resource Consumption	Avoiding wastage	Estimations of right quantities of all materials and ensuring the quantities are supplied based on	Utilizing resources efficiently	Using 100% of every material delivered to the construction site		During Construction	QA/QC of Contractor

318 | Feasibility Studies Report

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		exact quantities needed					
Traffic Impact	Avoiding Traffic Irregularities	Training drivers to adhere to traffic regulations. Regularly servicing vehicles to ensure they are always in good condition.	Avoiding traffic irregularities	zero incidence of vehicular related accidents and irregularities	5,000.00	During construction	Site HSE Officer of Contractor
Visual Impact	Preventing unsavory scenes emanating from the site	Building a perimeter wall to screen off unsavory sites Water dowsing the site and sand/aggregate stockpiles to prevent suspension of dust from the site.	Limiting impact on visual amenity	Zero complaints about unsavory nature of the site	1,000	During Construction	Site HSE Officer of Contractor
Waste Oil Generation	Preventing waste oil spills and initiating clean up procedures in the event of a spill	Servicing machinery and vehicles off-site. Regularly checking the fuel tanks of machinery and vehicles to ensure they aren't leaking. In the event of a spill, sand will be used to clean up	Containment and clean up of spills	Ensuring the site is not contaminated with oil spills	4,500.00	During Construction	Site HSE Officer of Contractor

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		and the sand will be collected in containers. Bidi Group will be contracted to safely dispose the contents.					
Erosion	Prevent Erosion and silting of drains	Compaction of uncovered soil surfaces	Avoid silting of drains and washing away of topsoil's	Ensuring all types of erosion are avoided	4,000.00	During Construction	Site HSE Officer of Contractor
Occupational Health and Safety Issues							
Public Health and Safety Issues	Limiting and eradicating any negative impact of construction on the nearby neighbors and community	Building a perimeter wall to avoid unauthorized access Signages will also be installed to notify the general public of ongoing construction works Properly transporting project materials through the town to avoid accidents.	Prevent complaints from the community on issues related to their public health and safety due to the project.	Zero public complaints about nuisance caused by the construction		During Construction	Site HSE Officer and Project Manager of Contractor
Work Camp Impacts	Sensitization	Educating construction workers on issues such as hygiene,	Create awareness for health and human right issues	Cohesion among workforce and healthiness of the construction team	800.00	During Construction	Project Manager of Contractor

320 | Feasibility Studies Report

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		communicable and transmitted diseases, equal rights, etc.					
Occupational Health and Safety Issues	Preventive and control measures	Provision of required PPEs, First Aid Kits, Emergency Response Systems, safety signages for all construction activities Ensuring workforce are given safety training. Enforcing usage of PPEs and compliance to safety procedures for work.	Create a safe working environment	Zero accidents	13,000.000	During Construction	Site HSE Officer of Contractor
Occupational Health and Safety Issues	Preventive and control measures	Provision of required PPEs, First Aid Kits, Emergency Response Systems, safety signages for all construction activities Ensuring workforce are given safety training.	Create a safe working environment	Zero accidents	13,000.000	During Construction	Site HSE Officer of Contractor

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		Enforcing usage of PPEs and compliance to safety procedures for work.					
Environmental Issues							
Increased Pressure on Utility Supply	Efficient utilization of utilities	Turning off equipments that are not in use to conserve electricity. Reuse of treated water in the wet scrubber	To reduce costs for resource consumption	Specific Consumption must be within the benchmark	1,000 per month	During Operational phase	HSE Officer
Dust and Noxious gas emissions	Treatment of emissions prior to release and use of dust control measures	· Installation fo de-dusting air filter · The car park and internal access routes will be paved with concrete blocks to reduce the resuspension of dust in the ambient environment. · Use of efficient fuels in the generator sets A speed limit of 10km/hr will be enforced on site.	Ensure emissions meet regulatory standards/guidelines	***Ambient Air Quality*** < 35 ug/m^3 for $PM_{2.5}$ < 70 ug/m^3 for PM_{10} < 50 ug/m^3 for SO_2 < 150 ug/m^3 for NO_2 < 150 ug/m^3 for TSP over a 24-hour monitoring period at all baseline monitoring points	350,000	During Operational Phase	Plant Manager and HSE Officer

322 | Feasibility Studies Report

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
Odour	Reduce/eliminate foul odour	Prompt disposal of expired and obsolete chemicals	Avoid Foul odour	Ensure there is no choking smell at the factory premises	1,000 Per month	During Operational Phase	Plant Manager and HSE Officer
Sanitation and Hygiene Impacts	Cleaning the workplace regularly	Approved disinfectants and detergents will be used for regular cleaning and scrubbing of the washroom, gutters, factory floor and offices to ensure the workplace is hygienic at all times.	A safe, clean and healthy working environment devoid of diseases such as cholera, diarrhoea	No penalties from regulatory authorities due to poor sanitary conditions	8,000 per year	During Operation	HSE Manager
Operational Phase							
Environmental Issues							
Solid Waste Generation	Waste segregation, reuse and safe disposal	· Engage Zoompak for safe disposal of chemical wastes Wooden pallets from maintenance activities would be carted off site and sold to local carpenters. Office wastes, worn-out clothing, food leftovers, packaging materials, etc. would be disposed into bins and skips	Segregate waste to prevent everything from going to the landfill	Reuse and recycle about 30% of wastes generated	5,000 per month	During Operational Phase	HSE Officer

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		for disposal at closest approved dumpsite by an EPA permitted waste management contractor.					
Wastewater Generation	Channelling wastewater into appropriate handling and carriage systems	The following management systems shall be applied: · Greywater from washrooms and sinks will be channeled into the drainage and discharged into the external drainage. · Blackwater will be channeled into septic tanks and septic management companies shall be contracted to collect and dispose it safely. Process wastewater from the wet scrubber will be treated in an Effluent Treatment plant before it is discharged	Prevent polluted wastewater from being discharged into the environment	Treated process wastewater to be discharged will be required to meet the stipulated GS 1212, 2019 standard as indicated in Table 13.	10,000 per year	During operational phase	HSE Manager

324 | Feasibility Studies Report

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
Waste Oil Generation	Avoid waste oil spillage to the bare ground	Measures to be adopted for waste oil management include: · Checking for leakages and spills and making provisions for spill kits to clean up spills. Providing proper funneling to assist in generator re-fueling.	Containment of waste oil spills	Zero waste oil spills to ground	500 per month	During Operational Phase	HSE Manager
Occupational Health and Safety Issues							
Fire and Explosion Hazards	Ensuring fire and explosion risks are eradicated completely	There will be provision of fire fighting equipment and a trained personnel to handle fire emergencies. The facility would be registered with the Ghana National Fire Service to ensure regular surveillance by the regulator. This would also help in the installation of firefighting equipment at the appropriate places.	Provide safe working environment	Zero fire and explosion incidents	40,000 per year	During operation	HSE Manager

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
Occupational Health and Safety Risks	Introduction of a well-coordinated Occupational Health and Safety Management Program	· Medical assessment will be conducted for workers prior to engaging them. Health surveillance will be done to continuously diagnose early symptoms for treatment. Management will also ensure all workers are · Provision of PPEs such as nose masks, helmets, gloves, heat protective clothing, reflectors and goggles for workers. Management will adopt the strict usage for factory operations. · Proper ventilation will be provided to enhance quick displacement of heat on the factory floor. Workers must limit their working hours near high	Provide a safe work place for employees and visitors	Zero accidents	45,000 per year	During operations	Production Manager and HSE Manager

326 | Feasibility Studies Report

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		heat sources and be provided with heat protective clothing. · Provision of a well-stocked First Aid Kit. · Ensuring there are emergency response measures such as response steps, contact numbers, alarms and signages displayed boldly to enhance quick handling of emergencies. Regular liaison with Factories Inspectorate Department and Ghana National Fire Service for guidance on key safety measures to adopt.					
Public Health and Safety Risks	Prevention of negative impacts on neighbours and the community	There will be adequate parking space within the factory premises to prevent parking of vehicles on the fringes of the road. There will also be traffic wardens to	Avoid litigation with neighbours over negative impacts	No complaints from neighbours	8,000.00 per year	During operations	Plant Manager and HSE Officer

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		assist vehicles entering and leaving the facility. The company shall be receptive to its neighbors and regulators by designating a liaison role to the HSE Officer to allow for quick response and addressing of complaints.					
Heat Generation	Rapid emission of heat from factory floor	Management will ensure proper ventilation is provided by creating sizable vents and installation of heat extractors to enhance quick displacement of heat on the factory floor.	Reduce or at best eliminate any potential for heat stress	< 33^0 C	9,000.00 per year	During operations	HSE Manager and Production Manger
Traffic Impact	Provide adequate parking and traffic attenuation protocols on site	Management shall ensure adequate parking space is available for all vehicles. Additionally, traffic control systems and wardens shall be used to ensure traffic is duly	Avoid traffic congestions within and around the site	Avoid traffic irregularities	2,000 per month	Daily	HSE Manager and Logistics Manager

328 | Feasibility Studies Report

Impact	Identified mitigation action	Actual action	Objective	Target	Budget (GHS)	Time frame	Responsibility
		regulated. Schedules for delivery of raw materials and dispatch of finished products shall be developed to prevent heavy traffic around the site is prevented. Provision of parking space, walkways and driveways within the facility.					

23.2 Environmental Monitoring Plan

23.2.1 Purpose of Environmental Monitoring

Environmental monitoring serves as a critical mechanism for tracking and analysing the environmental changes induced by both the construction and operational phases of the factory. This systematic approach enables the company to: (1) identify and quantify its environmental impacts, (2) evaluate compliance status against regulatory requirements, and (3) formulate targeted corrective measures when necessary. As an essential component of QPL's environmental management system, monitoring provides verifiable data to assess the effectiveness of current practices while driving continuous improvement in environmental performance. All monitoring activities will be rigorously conducted using approved Ghana Standards testing methodologies to ensure accuracy, reliability, and full compliance with national environmental regulations. This evidence-based approach not only safeguards environmental quality but also supports informed decision-making for sustainable operations.

23.2.2 Proposed Monitoring Schedule, Budget and Responsibility

The table below provides the issues and parameters of concern and the phases to look out for these issues.

330 | Feasibility Studies Report

Table 23.3 Environmental Monitoring Plan for Construction Phase

What to Monitor	When to Monitor	How to Monitor	Who Monitors	Budget/Month (GHS)
Ambient Air Quality (TSP, PM_{10}, SO_x, NO_x, CO, VOCs)	Monthly	Outdoor Ambient Air Quality Monitors such as Minivol Sampler, Aeroqual, etc.	Site Safety Officer of Contractor	2,000.00
Raw Material Consumption	Weekly	Comparing Procurement sheets with project deliverables	Procurement Manager of Contractor	300.00
Solid Waste Management	Daily	Visual inspection of site and waste trail documents	Site Safety Officer of Contractor	350.00
Liquid Waste Management (Greywater exiting the facility)	Daily	Visual inspection of site and temporary washrooms and containers for carrying construction slurry	Site Safety Officer of Contractor	350.00
Noise	Monthly	Noise Meters such as Casella	Site Safety Officer of Contractor	400.00
Utilities	Monthly	Review of utility bills	Project Manager of Contractor	200.00
Occupational and Public Health & Safety Issues including Traffic Impacts	Daily	· Observations Review of incident records and complaint records	Site Safety Officer of Contractor	3,000.00
TOTAL				**6,600.00**

Feasibility Studies Report | 331

Table 23.4 Environmental Monitoring Plan for Operational Phase

Aspect	How To Monitor	Objective	Proposed Schedule	Responsible Personnel	Estimated Budget/Year (GHS)
Ambient Air Quality (TSP, PM_{10}, SO_x, $PM_{2.5}$, NO_x, CO)	Outdoor Ambient Air Quality Monitors which operate in accordance with the Test methods approved by GSA	Ensure ambient air quality levels meet regulatory standards	Monthly	Factory Manager	45,500.00
Point source Emissions	Using equipment that follow test methods approved in the GS 1236, 2019	Ensure point source emissions meet the standards	Monthly	Factory Manager	20,000.00
Noise Level (dB)	Class 1 noise meters	Ensure ambient noise levels meet regulatory standards	Bi-annually	Factory Manager	6,500
Wastewater	Sampling and analysis of pH, Temperature, BOD, COD, TSS, TDS, Nitrate, Ammonia, E. Coli	To analyse if the wastewater being discharged meets the standards	Monthly	Factory Manager	14,000.00
Heat	Indoor Thermometers	Ensure heat and discomfort levels are checked	Monthly	Factory Manager	2,000.00
Medical	Professional Medical Diagnosis of employees	Ensure the workforce is healthy	Once per Year	Factory Manager	5,000.00
Waste Management, sanitation and housekeeping	Using waste trail documents to determine efficiency of waste management practices	Ensure proper handling of all wastes	Daily	Production Supervisor	1,000.00

332 | Feasibility Studies Report

Aspect	How To Monitor	Objective	Proposed Schedule	Responsible Personnel	Estimated Budget/Year (GHS)
Raw Material Usage	Assessment of productivity against raw material consumption	Ensuring efficiency and high productivity	Monthly	Production Supervisor	1,200.00
Utility consumption	Assessment of utility consumption against productivity	Ensuring efficiency and high productivity	Monthly	Production Supervisor	1,200.00
Public Health and Safety	Continuous consultation to assess stakeholder concerns and solutions provided	Avoid negative impacts on neighbours and creation of good rapport between neighbours	Daily	Factory Manager	1,000.00
TOTAL					**97,400.00**

23.3 Provisional Emergency Preparedness and Response Plans

Environmental incidents and natural hazards constitute urgent threats to ecological systems, human health, and physical assets, collectively termed "emergency situations" within QPL's operational context. These scenarios are characterized by their sudden onset and potential for severe environmental degradation, necessitating immediate intervention to mitigate impacts. The proposed emergency preparedness plan has been prepared to cater for the following types of emergencies:

- Medical Injury including serious illnesses (heat stroke, heart attack)
- Fire
- Incidental spills
- Motor accidents
- Natural disasters (floods, etc.)

QPL's Emergency Response Plan implements a comprehensive framework of proactive measures and response protocols designed to ensure organizational preparedness for potential extreme events that may threaten environmental integrity or disrupt project operations. The plan's primary objectives focus on minimizing adverse impacts through timely interventions that safeguard human health, protect physical infrastructure, and preserve operational continuity, with a dual strategic emphasis on (1) preventive measures to reduce incident likelihood through systematic risk identification and mitigation, and (2) effective containment protocols to neutralize any occurring incidents through rapid, coordinated response actions. This structured approach ensures all potential emergencies are addressed through a continuum of prevention, preparedness, and response measures that collectively maintain QPL's commitment to environmental stewardship and operational resilience. The priorities for protection in an emergency situation are the following:

- Human life and health;
- The environment;
- Assets belonging to QPL
- Maintenance of normal operations on site.

23.3.1 Key emergency response systems

Some of the key systems to be instituted to enhance emergency response include:

23.3.1.1 Emergency Communication System

In the event of an emergency, communications shall be via the use of UHF radio, mobile phones, and shouting. A siren should be available to alert staff. A list of emergency contact numbers will be provided and will be posted on site notice boards. The appropriate emergency service shall be notified immediately in the event of an emergency. Some of the key emergency service contacts will include the nearest Ghana National Fire Service station, Ghana Police Service station, National Disaster Management Organization (NADMO) office, Hospital, and ambulance service.

23.3.1.2 Site Register

The company shall ensure it keeps an active register of workers, subcontractors, and visitors who report to the site. It will be a key requirement prior to entering the site. This register shall be used to ascertain numbers of persons present on site during roll calls for evacuation procedures.

334 | Feasibility Studies Report

23.3.1.3 Assembly Point

The company shall choose a primary assembly point in a location that is deemed safe should an emergency occur. This earmarked location shall be boldly signposted with the green Assembly Point sign. In the event that this assembly point is not appropriate then the HSE Manager shall nominate a second assembly point. The location of these assembly points shall be communicated to all workers and visitors during the site induction. For site work, the work group leader of each work group shall nominate the local assembly point and inform the HSE Officer and members of the work group.

23.3.1.4 First Aid Facilities

First aid facilities shall be located in every work vehicle and in the site office(s). First aid kits shall be easily accessible and left unlocked at all times. First aid kit locations and trained first aiders and contact numbers shall be displayed on site notice boards. First aid kits shall be kept clean and checked and restocked as necessary.

23.3.1.5 Fire Equipment

Firefighting equipment shall be located in every work vehicle and in the site office(s). Firefighting equipment shall be easily accessible at all times. Firefighting equipment locations and trained fire personnel and contact numbers shall be displayed on site noticeboards. Firefighting equipment shall be tested and tagged by a competent person every six months. Used fire extinguishers shall be promptly removed from service and replaced immediately with a full replacement.

23.3.2 Emergency Response Team And Responsibilities

The management of QPL shall set up an Emergency Response Team (ERT). The management will appoint qualified personnel to be members of the team. The management will also make provision for the necessary administrative and logistics support to enhance the effectiveness of the Emergency Response Team.

23.3.2.1 Formation of the Emergency Response Team

The ERT shall consist of the HSE Manager; Head of Production, Quality Control Supervisor and the Head of the Mechanical Department. The Emergency Response Team will be required to meet regularly and subject the Provisional Emergency Response Plan to review and update their knowledge of emergency responses.

Table 23.5 Roles and Responsibilities of Emergency Response Team

Emergency Response Team		
Position	**Delegation**	**Responsibilities**
Managing Director, General Manager	Management	· Hire a consultant to develop a Provisional Emergency Response Plan · Provide adequate resources to support the developed plan · Appoint qualified personnel to be part of the Emergency Response

Emergency Response Team

Position	Delegation	Responsibilities
		Team to effectively implement and update this plan.
Head of Production	Emergency Response Team Leader	· Lead the review and update the plan, at least annually · Establish relationship and open communication line with the nearest Ghana National Fire Service station, Ghana Police Service station, National Disaster Management Organization (NADMO) office, Hospital, and ambulance service, as well as calling for their assistance when required. · If available, lead the roll out of emergency response actions. · Ensure regular training for the Emergency Response Team and workers on topics such as Emergency Responses, First Aid, Raising Alarm, Emergency Communication, Fire fighting · Keep records of incidents and accidents. · Lead investigation of all incidents and accidents · Perform Emergency Drills and ensure emergency systems are functional · Receive suggestions for updating emergency response plan and making recommendations to management · Display emergency contacts at vantage points.
· Head of Engineering Department · Quality Control Supervisor	Emergency Response Team Members (Head of Production as Assistant Team Leader)	· Serve as principal contact persons for emergency actions · Performing out emergency response actions · Assist in emergency-related data collection as well as helping review

336 | Feasibility Studies Report

Emergency Response Team		
Position	**Delegation**	**Responsibilities**
		and update the emergency response plan · Assist in investigation and reporting to external authorities · Assist the Emergency Response Team Leader to perform tasks assigned to the Team. · Ensure emergency signage and equipment are functional
All Workers	Staff	· Quickly reporting all incidents/accidents to the ERT · Follow laid down procedures in the event of an emergency · Attend training programmes

23.3.3 Emergency Response Actions

23.3.3.1 Fire Emergency

23.3.3.1.1 Small fires

The following steps and process shall strictly be adhered to and carried out in the event of an emergency to put out a small fire:

1. Immediate Alert and Alarm Activation: Upon discovering a fire, the first responder must immediately raise the alarm by shouting "FIRE! FIRE! FIRE!" loudly and clearly to alert nearby personnel. Simultaneously, if the fire alarm system is within reach, it should be activated without delay to trigger the facility-wide emergency response procedures and ensure all occupants are aware of the danger.
2. Emergency Response Team Notification and Initial Action: The individual who spotted the fire must promptly locate and inform the nearest Emergency Response Team member or any person trained in firefighting techniques. If the discoverer themselves has received proper fire safety training, they should quickly retrieve the closest appropriate fire extinguisher and make a controlled attempt to suppress the flames at their source while the fire is still in its early, manageable stages.
3. Fire Containment with Safety Priority: When attempting to extinguish the fire, personnel must maintain constant awareness of their surroundings and exit routes. The safety of all individuals takes absolute precedence over property protection. Firefighters must position themselves between the fire and an unobstructed escape path, ensuring they can retreat immediately if the situation escalates beyond their control.
4. Escalation to Professional Fire Services: if the fire persists after approximately two minutes of concentrated extinguishing efforts or shows signs of spreading, all firefighting attempts must cease immediately. The responder should then contact the nearest Ghana National Fire Service station, providing precise details about the fire's location, size, and nature, while ensuring all personnel evacuate to designated safe areas.
5. Post-Fire Investigation and Reporting: Following successful fire containment, a thorough investigation must be conducted to determine the root cause of the incident. The affected

area requires proper cleaning and hazard mitigation. The responding individual must submit a detailed incident report to the Emergency Response Team Leader and participate in any subsequent review sessions to improve future response effectiveness.

23.3.3.1.2 Large Fires

In the event of a fire emergency that exceeds the capacity of trained on-site personnel and requires intervention from the Ghana National Fire Service (GNFS), the following comprehensive evacuation procedures must be strictly followed:

Upon fire detection, the individual who discovers the blaze must immediately raise the alarm by shouting "FIRE! FIRE! FIRE!" at the top of their voice to alert all occupants, while simultaneously activating the nearest fire alarm if accessible. The discoverer must then promptly notify the closest Emergency Response Team (ERT) member and personally contact GNFS to report the emergency, providing precise details about the fire's location and nature before proceeding to the designated safe assembly point.

The alerted ERT member must take immediate action by contacting the nearest GNFS station to request professional firefighting support while simultaneously initiating evacuation procedures. The ERT member will identify and direct all personnel to the safest assembly area, ensuring an orderly evacuation process is conducted with calmness and efficiency. Throughout the evacuation, the ERT must verify that all workers and visitors have exited the danger zone by conducting a thorough headcount at the assembly point.

For medical emergencies arising from the incident, first aid must be administered immediately to individuals with minor injuries. In cases of severe injuries, the ERT must arrange for urgent transportation to the nearest healthcare facility without delay to ensure prompt medical attention.

Following successful fire suppression by GNFS, a detailed investigation must be conducted to determine the cause and circumstances of the fire. A comprehensive report documenting the incident must be prepared and submitted to both company management and the relevant government regulatory agencies. Finally, the entire event must be properly recorded in the company's incident log for future reference, analysis, and continuous improvement of emergency response protocols.

This systematic approach ensures the safety of all personnel while maintaining compliance with regulatory requirements and promoting organizational learning from emergency situations.

23.3.3.2 Accident or Injury response protocol

In the event of any workplace accident or injury, all personnel must adhere to the following standardized response procedures to ensure proper medical attention and incident documentation:

1. Mobile Victim Response: Should the injured party retain mobility, they must immediately report to the nearest Emergency Response Team (ERT) member for assessment. A qualified HSE Manager or ERT member with first aid certification will evaluate and administer appropriate initial treatment. The medical responder will determine if the injury requires

338 | Feasibility Studies Report

advanced care and, if necessary, arrange immediate transportation to the nearest medical facility.

2. Immobile Victim Protocols: For injuries where the victim cannot self-move but can be safely assisted, nearby workers must carefully transport the individual to the closest ERT member. The trained responder will provide first aid while coordinating urgent transfer to a healthcare provider. In cases where movement may exacerbate injuries, workers must stabilize the victim in place while immediately summoning ERT personnel, who will arrange for on-site medical intervention by professionals from the nearest health centre.
3. Investigation and Documentation: Following initial medical response, the HSE Manager or designated ERT member will conduct a thorough investigation of the incident. This includes documenting the injury specifics, identifying root causes, and recording environmental conditions. All accident details must be properly logged in the company's incident reporting system for regulatory compliance and preventive analysis.
4. Universal Reporting Requirement: Regardless of injury severity, every accident must be formally recorded by the responding ERT member. This documentation serves multiple purposes: tracking workplace safety trends, identifying hazard patterns, and ensuring proper medical follow-up. The report will include witness statements, treatment details, and any corrective actions implemented to prevent recurrence.

23.3.3.3 Spill Response Procedures

These procedures refer to accidental spills or releases of all petroleum products.
The procedures to follow include the following:

1. Immediate Notification and Hazard Awareness: Upon discovering a petroleum spill, the observer must immediately alert the nearest HSE Committee member or trained spill response personnel. The individual should simultaneously warn all nearby personnel to evacuate the affected area while avoiding direct contact with the spilled material. This rapid notification protocol ensures timely containment while preventing unnecessary exposure to hazardous vapours or potential ignition risks.
2. Ignition Source Control and Risk Assessment: The responding HSE team member must promptly secure the area by shutting down all potential ignition sources, including electrical equipment, engines, and other spark-producing devices. A qualified responder must then conduct a thorough hazard evaluation to determine the spill's severity, including its volume, rate of spread, flammability risk, and potential environmental impact before initiating containment efforts.
3. Controlled Containment and Emergency Coordination: If the spill poses an immediate danger or exceeds the response team's capacity, emergency services (192 or local fire department) must be contacted without delay. Only personnel with proper training and protective equipment may attempt containment using approved methods such as absorbents, dikes, or diversion barriers, ensuring their own safety is not compromised during the operation.
4. Specialized Fire Response Measures: In the event of ignition, responders must avoid using water, which can worsen petroleum fires, and instead deploy Class B fire extinguishers or foam suppression systems. If the fire escalates beyond control, all personnel must evacuate immediately and await professional firefighting assistance.
5. Post-Spill Investigation and Regulatory Reporting: Following containment, a detailed investigation must document the spill's cause, affected areas, and response effectiveness. A formal report must be submitted to the EPA within 24 hours, including spill metrics,

containment actions, environmental impact assessments, and preventive recommendations. Internal records should be maintained for compliance audits and procedural improvements..

NB: Small spills can be absorbed with paper towels or other absorbents. However, these materials can increase the surface area and evaporation rate, increasing the potential fire hazard if the material is flammable and airborne concentration reaches the flammability level.

A Spill Kit must be regularly available and should consist of:

- Overalls
- Gloves
- Shoe protectors
- Glass or plastic collection container
- Plastic bags
- Absorbent material such as Wipes or paper towels
- Barricade tape

23.3.3.4 Explosion

In the event of an explosion, prioritize immediate life safety by first ensuring your own protection—if no Emergency Response Team (ERT) member is present, independently evacuate to a secure location or designated assembly point while exercising sound judgment. Simultaneously, assist others by alerting nearby individuals to the danger, coordinating to identify safe escape routes, and contacting emergency services via the established hotline numbers. When ERT members arrive, follow their explicit evacuation instructions as they systematically clear all areas (including rooms, restrooms, and stairwells) while accounting for expected occupants. Proceed calmly but swiftly to the predetermined assembly area, ideally positioned uphill and upwind to avoid potential gas exposure, and remain there in organized groups until authorities declare the area safe. Be aware that gas explosions frequently ignite secondary fires in nearby combustible materials (vegetation, structures, etc.), requiring implementation of the standard Fire Emergency Response Protocol if flames are present. Throughout the incident, maintain collective situational awareness to support unified evacuation efforts and prevent unnecessary risks.

23.3.3.5 Malfunction of Pollution Control Plant

QPL management acknowledges the mechanical nature of the Pollution Control Plant and its potential for operational failures, implementing a comprehensive maintenance strategy to ensure continuous efficiency. This includes maintaining an inventory of critical spare parts for immediate replacements, coupled with specialized training programs for engineering technicians covering system operations, troubleshooting, and repair procedures. The company will establish a rigorous preventive maintenance schedule involving daily checks, weekly performance audits, and quarterly servicing, supported by predictive maintenance technologies to detect early warning signs of malfunction.

23.3.3.6 Manufacturer Collaboration and Support

To guarantee rapid response to technical issues, QPL will maintain constant communication channels with equipment manufacturers, including 24/7 technical support access and regular knowledge-

340 | Feasibility Studies Report

sharing sessions. This ensures immediate expert assistance is available when complex problems arise, minimizing system downtime and maintaining operational efficiency through collaborative problem-solving between QPL technicians and manufacturer specialists.

23.3.3.7 Complete System Failure Protocol

In the event of total system failure, QPL will immediately halt production operations and submit a formal incident report to the EPA within the mandated timeframe, detailing the failure circumstances and planned corrective actions. The maintenance team will initiate emergency repairs using pre-positioned spare parts while implementing temporary pollution control measures, followed by a thorough post-recovery analysis to identify the root cause and prevent future occurrences through updated maintenance procedures and staff training.

23.3.3.8 Continuous Improvement and Compliance

Following any system failure or repair, QPL will conduct a comprehensive review to evaluate response effectiveness and implement necessary improvements to both equipment and protocols. This includes submitting detailed compliance reports to regulatory authorities, updating training programs based on lessons learned, and enhancing the preventive maintenance schedule to incorporate new risk mitigation strategies, ensuring ongoing environmental protection and operational reliability.

23.3.3.9 Staff Competency Development

QPL is committed to maintaining a highly skilled technical team through regular certification programs and hands-on training workshops conducted in partnership with equipment manufacturers. This investment in human capital ensures engineering staff remain proficient in the latest maintenance techniques and system updates, enabling them to promptly address both routine issues and emergency situations with maximum efficiency.

23.3.3.10 Emergency Response from Odour Procedures

The procedures to follow include the following:

1. Immediate Alert and Evacuation Procedures: Upon detection of any unusual or potentially hazardous odours, the first responder must immediately notify all personnel in the affected area and alert the designated supervisor or safety officer. If the odour is strong, pervasive, or suspected to be toxic, initiate evacuation procedures by directing all occupants to move quickly but calmly to the predetermined safe assembly point. The evacuation route should avoid the contaminated area, and individuals should be instructed to cover their noses and mouths with clothing if respiratory protection is not immediately available.
2. Containment and Source Identification Measures: After ensuring personnel safety, contain the affected area by securing all doors, windows, and ventilation systems to prevent further spread of the odour. Only properly trained technical staff equipped with appropriate respiratory protection (such as NIOSH-approved respirators) and personal protective equipment should enter the area to investigate and identify the source. The technical team should use portable gas detectors or other monitoring equipment to assess air quality and determine the nature of the hazard before proceeding with mitigation efforts.
3. Decontamination and First Aid Protocol: Any individuals exposed to the hazardous odour require immediate attention. First responders should carefully remove contaminated clothing while avoiding unnecessary skin contact, then thoroughly rinse affected skin areas with clean,

lukewarm water and mild detergent for at least 15 minutes. Contaminated garments should be placed in sealed plastic bags for professional cleaning or proper disposal. Exposed personnel should receive medical evaluation, even if symptoms are not immediately apparent, as some chemical exposures may have delayed effects.

4. Post-Incident Cleanup and Verification: Once the odour source has been safely contained or removed, the affected area must undergo comprehensive decontamination. This includes deep cleaning all surfaces with appropriate neutralizing agents, followed by professional fumigation if necessary. Air quality testing must confirm the complete elimination of hazardous substances before the area is reopened for normal use. All response actions, including containment methods, cleanup procedures, and verification results, must be thoroughly documented for regulatory compliance and future reference in safety reviews.

23.3.3.11 Chemical Spill Procedures

23.3.3.11.1 Emergency Actions

Emergency actions are the following:

1. Initial Alert and Evacuation Procedures: Upon identifying a potential hazard, the first responder must immediately notify all personnel in the vicinity and inform the designated supervisor. When the situation presents immediate danger, initiate evacuation protocols by directing staff to move swiftly to pre-established safe zones while avoiding the affected area. Ensure evacuation routes remain unobstructed throughout the process.
2. Emergency Services Notification Protocol: For incidents requiring fire department intervention or medical assistance, promptly contact the Ghana National Fire Service (GNFS) as the primary emergency responder. Subsequently, alert the Environmental Protection Agency (EPA) when environmental contamination has occurred or is suspected, providing specific details about the incident location, nature of the emergency, and any special hazards present.
3. Decontamination and First Response Measures: For individuals exposed to hazardous substances, implement immediate decontamination procedures by carefully removing affected garments while minimizing skin contact. Thoroughly rinse all exposed skin areas with clean water for a minimum duration of fifteen minutes. Isolate contaminated clothing in designated containers for professional decontamination or proper disposal, and ensure all affected personnel receive prompt medical assessment.
4. Flammable Substance Spill Management: When handling spills of volatile or combustible materials, immediately alert all nearby personnel and eliminate all potential ignition sources, including electrical equipment and heat-producing devices. Implement area ventilation by activating exhaust systems or opening secured access points, provided such actions don't compromise safety. Restrict access to the spill zone until qualified personnel with appropriate protective equipment can properly contain and neutralize the hazard.

Table 23.6 Reference for chemical spill handling

Category	Size	Response	Treatment
Small	up to 300 mL	chemical treatment or absorption	Neutralization or absorption spill kit

342 | Feasibility Studies Report

Category	Size	Response	Treatment
Medium	300 mL to 5L	Absorption	Absorption spill kit
Large	More than 5L	Call regulatory authority	Outside help

23.3.3.11.2 Immediate Spill Response

Immediate Spill Response is the following:

1. Personal Protective Equipment (PPE) Requirements: All personnel must utilize appropriate PPE as specified in the Material Safety Data Sheet (MSDS) or equivalent safety documentation. Prior to engagement, carefully assess potential exposure risks and don necessary protective gear, including gloves, goggles, and chemical-resistant attire. Respiratory hazards require particular attention - evaluate whether air-purifying respirators or self-contained breathing apparatus (SCBA) are warranted based on vapor concentrations and material toxicity.
2. Respiratory Protection Protocol: Specialized training and medical clearance are mandatory prerequisites for respirator use. Untrained individuals must never attempt entry into contaminated spaces. Should respiratory hazards exist without qualified personnel present, immediately contact emergency medical services (Red Cross), local healthcare facilities, or relevant regulatory agencies. When respiratory protection is employed, maintain a safety observer outside the contamination zone for emergency communication. If unavailable, notify Public Safety before proceeding.
3. Spill Assessment and Reporting: Consult the spill classification chart to determine response level. For significant spills (large volume, environmental release, or lacking qualified responders), immediately engage the Environmental Protection Agency (EPA) and Ghana National Fire Service (GNFS). Containment efforts must prioritize preventing environmental migration - utilize spill socks and absorbent barriers to protect drainage systems and vulnerable areas.
4. Containment and Neutralization Procedures: Implement concentric containment strategies, applying absorbents from the perimeter inward to minimize splash hazards. Note that hydrofluoric acid requires specialized handling as conventional absorbents prove ineffective. For acid/base spills, employ colour-changing neutralizers to verify complete pH stabilization before proceeding with cleanup.
5. Waste Containment and Disposal: Collect spent absorbents using non-sparking tools, transferring materials to appropriately sized, chemically compatible containers (polyethylene bags for minor spills, lined drums for larger quantities). Prominently label all waste containers with completed hazardous waste tags, clearly identifying "Spill Debris" with specific chemical constituents. Coordinate with EPA's Chemical Control and Management Center for approved disposal methodologies.
6. Post-Cleanup Decontamination: Thoroughly cleanse affected surfaces using manufacturer-approved detergents and copious water rinses. Complete all required incident documentation, including spill volume, materials involved, containment methods, and disposal records. Submit formal reports to relevant regulatory bodies and maintain internal records for compliance auditing and process improvement.

Table 23.7 Reference for chemical spill handling

Category	Size	Response	Treatment
Small	Up to 300 mL	Chemical treatment or absorption	Neutralization or absorption spill kit
Medium	300 mL to 5L	Absorption	Absorption spill kit
Large	More than 5L	Call regulatory authority	Outside help

23.3.4 Accidents/Incidents During Transportation of Raw Materials

1. Immediate Area Containment: Swiftly establish a safety perimeter around the incident site by implementing appropriate traffic control measures. Activate hazard lights, deploy warning triangles/cones, and direct vehicular flow to prevent secondary collisions while maintaining clear access for emergency responders.
2. Regulatory Authority Notification: Promptly contact the Ghana Police Service to initiate official incident documentation and traffic management. Simultaneously alert the Ghana Environmental Protection Agency (EPA) to assess potential ecological impacts from vehicle fluids or hazardous material releases.
3. Fire and Medical Emergency Response: For incidents involving fire or immediate medical needs, prioritize contacting the Ghana National Fire Service (GNFS) through emergency hotlines. Provide precise location details and nature of emergency to facilitate appropriate resource deployment.
4. Medical Emergency Protocol: When injuries are present, immediately summon the Ghana Ambulance Service while administering basic first aid if trained to do so. Clearly communicate the number of casualties and injury severity to dispatch operators.
5. Incident Site Security: Maintain controlled access to the affected area until all regulatory procedures are complete. Preserve the accident scene for official investigation while ensuring public safety through continued traffic management and hazard mitigation.

23.4 Budget For Provisional Environmental Management Plan

The table below presents the budget for the Provisional Environmental Management Plan.

Table 23.8 Budget For Provisional Environmental Management Plan

Activity	Objective	Responsibility	Budget (USD) Year 1	Budget (USD) Year 2	Budget (USD) Year 3
Provision of waste bins	Purchase of waste bins and contracting professional waste management companies for collection and safe disposal	HSE Manager	4,550.00	4,550.00	5,550.00

344 | Feasibility Studies Report

Activity	Objective	Responsibility	Budget (USD) Year 1	Budget (USD) Year 2	Budget (USD) Year 3
Noise Management	Regular Servicing of machinery to avoid noise generated from squeaking and overworked machines.	Head of Engineering Department	1,500.00	2,000.00	4,000.00
Emergency Response Measures	Provision of emergency response systems such as fire equipment, emergency communication systems, etc.	HSE Manager	8,600.00	9,000.00	9,500.00
Air Pollution Equipment Tuning	Regular maintenance and tuning of scrubber and chimney to ensure emissions are below GS 1236, 2019	Head of Engineering Department	1,000.00	2,000.00	2,500.00
Staff training	Training of staff in environmental, health and first aid. Awareness creation on environmental management	Head of Production	2,000.00	2,000.00	2,500.00
Occupational Health and Safety Management	Provision of PPE Provision of well stocked First Aid Kit	HSE Manager	8,500.00	7,000.00	7,000.00
Documentation and Reporting	Preparation of reports for submission to EPA Preparing Annual Environmental	Head of Production	2,800.00	3,500.00	4,000.00

Activity	Objective	Responsibility	Budget (USD) Year 1	Budget (USD) Year 2	Budget (USD) Year 3
	Report (12 months after award of permit)				
TOTAL			**28,950.00**	**30,050.00**	**35,050.00**

23.5 Grievance Redress Mechanism

A grievance is defined as any formal or informal complaint, concern, or claim—whether actual or perceived—brought forward by individuals or community groups for resolution by QPL. Such grievances may encompass:

- Project-Specific Complaints: Allegations of direct harm, damages, or adverse impacts resulting from QPL's operations or activities.
- Operational Concerns: Objections or apprehensions regarding ongoing facility activities, perceived risks, or unintended consequences affecting surrounding communities.

Given the industrial nature of QPL's operations, which may influence nearby residents and ecosystems, the company acknowledges the possibility of grievances arising from affected stakeholders. These may include concerns related to noise, emissions, water usage, or other operational byproducts. QPL is committed to addressing such grievances transparently, fairly, and efficiently to maintain positive community relations and uphold corporate responsibility.

23.5.1 Grievance Redress Mechanism (GRM) Principles:

The GRM will not only address complaints but also welcome positive feedback and constructive suggestions. The mechanism must adhere to the following criteria:

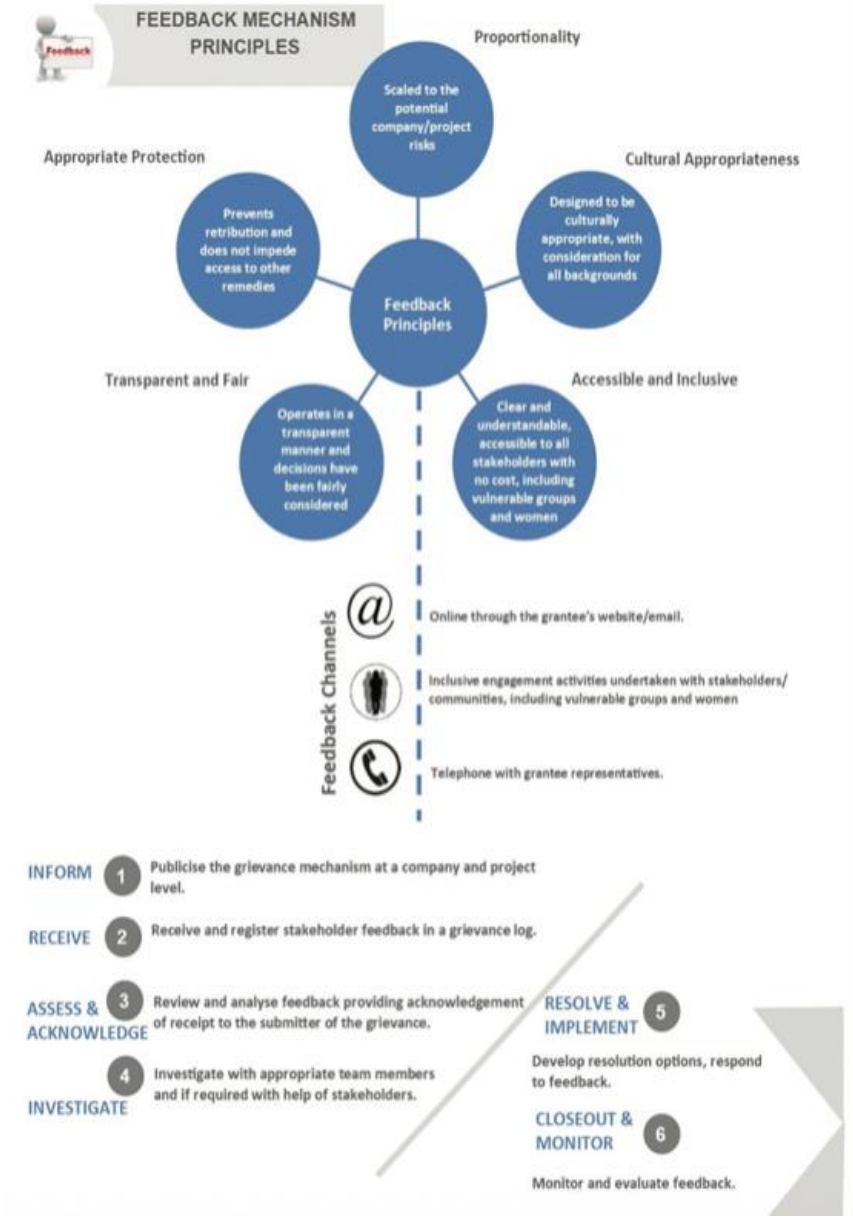
1. Comprehensive – It must account for all types of project-related complaints.
2. Transparent – Stakeholders must be aware of the GRM's existence, and all grievances must be formally recorded.
3. Context-Sensitive – The process should align with the project's scope, local conditions, and cultural norms.
4. Action-Oriented – Each grievance must receive a documented response, with timely resolutions to support project success.

The GRM will operate in accordance with the Bright International Free Zone's dispute resolution procedures, as outlined in Figure 8.

23.5.2 Roles and Responsibilities:

The HSE Manager has been appointed as the primary contact for receiving and escalating complaints to management. Management will receive regular updates on grievance resolution progress during meetings, ensuring accountability and corrective action.

Figure 23.1 Grievance Redress Mechanism Principle



24 Decommissioning Plan

24.1 Decommissioning Process

The decommissioning process will involve the complete removal of all project infrastructure and subsequent restoration of the site to a condition suitable for alternative uses. QPL management will assume full financial responsibility for all decommissioning activities, including waste management, site remediation, and regulatory compliance costs. This commitment ensures proper environmental stewardship throughout the project lifecycle and guarantees that the site will be left in an acceptable state for future development or community use.

24.1.1 Waste Management Strategy

The decommissioning activities will strictly follow the 3Rs hierarchy (Reduce, Reuse, Recycle) to minimize environmental impact. This approach prioritizes reducing waste generation through careful planning, reusing materials wherever possible, and recycling appropriate components. Specialized teams will sort and process all materials on-site to maximize recovery rates, with only non-recyclable residues being sent to approved disposal facilities in compliance with national regulations.

24.1.2 Building Decommissioning Process

All permanent structures will be systematically dismantled, with salvageable building materials and furniture being offered to the local municipality or sold to interested buyers. Concrete foundations and floor slabs will be broken down using controlled demolition techniques, with the resulting debris being transported by licensed operators for reuse as construction fill material in approved projects. This process will be supervised by qualified engineers to ensure safety and environmental compliance.

24.1.3 Energy Infrastructure Removal

Electrical installations and equipment will be carefully decommissioned by certified technicians. Functional components will be tested, refurbished where necessary, and made available for resale to secondary markets. All hazardous materials from electrical systems will be handled according to strict safety protocols and disposed of through licensed hazardous waste management providers to prevent environmental contamination.

24.1.4 Site Restoration Protocol

Following structural removal, the site will undergo comprehensive rehabilitation including soil testing, contamination remediation if required, and final landscaping. The restored land will be graded to match surrounding topography and revegetated with native plant species. A final inspection by environmental regulators will confirm the site's suitability for its intended future use before the decommissioning process is officially concluded.

348 | Feasibility Studies Report

24.2 Environmental Management/Monitoring for the Decommissioning Phase

Table 24.1 Decommissioning Environmental Management Plan

Issues	Recommended Mitigation	Responsible Party	Time Frame	Budget (USD)
Scraps and other debris on site	Use of an integrated solid waste management system i.e. through a hierarchy of options: Wastes generated as a result of facility decommissioning activities will be characterized in compliance with standard waste management procedures. The contractor based on the properties of the particular waste stream will select disposal locations. All buildings, machinery, equipment, structures and tools that will not be used for other purposes should be removed and recycled/ reused say in other projects Where recycling/reuse of the machinery, equipment, implements, structures, tools and other waste is not possible, the	Project Manager and Contractor	One-Off	150,000.00

24 Decommissioning Plan

Issues	Recommended Mitigation	Responsible Party	Time Frame	Budget (USD)
	materials should be taken to an approved dumpsite.			
· Vegetation Disturbance Land Deformation	Implement an appropriate re-vegetation program to restore the site to its original status During the re-vegetation period, appropriate surface water runoff controls will be taken to prevent surface erosion; Monitoring and inspection of the area for indications of erosion will be conducted and appropriate measures taken to correct any occurrences; Fencing and signs restricting access will be posted to minimize disturbance to newly-vegetated areas;	Project Manager and Contractor	One-Off	225,000.00
Occupational Hazards	Ensure that safety measures have been effectively integrated and positioned in respective areas of the project to control and manage fire outbreaks	HSEQ Manager and Contractor	During Decommissioning	250,000.00

350 | Feasibility Studies Report

Issues	Recommended Mitigation	Responsible Party	Time Frame	Budget (USD)
	The safety of the workers should surpass as a priority of all other objectives in the decommissioning project			
TOTAL				**625,000.00**

24.3 Guidelines for Decommissioning

In the event of decommissioning, the company shall follow the requirements specified in Ghana's Environmental Guidelines. A responsible approach as scheduled shall be used in the event of decommission.

24.3.1 Regulatory Compliance and Planning Framework

QPL will strictly adhere to Ghana's Environmental Guidelines throughout the decommissioning process. The company will develop a comprehensive work plan detailing all decommissioning procedures, which will be formally circulated to employees and relevant stakeholders to ensure full transparency and coordinated implementation of the process.

24.3.2 Permitting and Institutional Coordination

Prior to commencement, QPL will secure the necessary decommissioning permit from the Environmental Protection Agency (EPA). The company will conduct formal consultations with key institutions including the Ghana National Fire Service (GNFS), Factory Inspectorate Department (FID), and National Disaster Management Organization (NADMO) to incorporate their safety expertise and operational requirements into the decommissioning strategy.

24.3.3 Community Engagement Process

The company will implement a structured notification and consultation program with neighboring communities to address concerns and provide regular updates about the decommissioning timeline and safety measures. This engagement will include public meetings and information sessions to maintain open communication channels throughout the process.

24.3.4 Asset Management Strategy

Functional plant machinery and equipment with remaining economic value will be systematically dismantled by qualified technicians and relocated to secure storage facilities. QPL will initiate negotiations with relevant government agencies regarding potential transfer of these assets, exploring options including public sector takeover, private sale to interested parties, or relocation to alternative operational sites.

24 Decommissioning Plan

24.3.5 Materials Disposition Protocol

Fully depreciated materials and equipment will be processed through licensed scrap dealers, with all transactions documented to ensure proper chain of custody and compliance with waste management regulations. The company will maintain records of all asset dispositions for regulatory reporting purposes.

24.3.6 Site Rehabilitation Process

The company will implement comprehensive reclamation procedures to restore the site to its pre-project condition as much as practicable. This will include soil remediation, structural removal, and landscape rehabilitation conducted in accordance with EPA standards and approved closure plans.

24.3.7 Municipal Asset Transfer

QPL will engage in formal negotiations with the Lower Manya Krobo Municipal Assembly regarding the transfer of immovable assets. These discussions will address terms of handover, future maintenance responsibilities, and potential community benefits from repurposed infrastructure, ensuring a smooth transition of assets to local authority control.

24.4 Conclusion

24.4.1 Project Introduction and Location

Quintex Pharma Ltd. (QPL) proposes to establish a modern injectable medicines manufacturing facility in Akuse, located within Ghana's Lower Manya Krobo Municipality in the Eastern Region. This strategic development aims to enhance domestic pharmaceutical production capacity while adhering to international environmental standards and contributing to national industrial growth objectives.

24.4.2 Regulatory Compliance Framework

The project will strictly follow International Finance Corporation (IFC) Performance Standard 1 and Ghana's Environmental Assessment Regulations (LI 1652). These require thorough environmental and social impact assessments prior to facility construction and operation. Our comprehensive evaluation identifies potential risks and impacts while proposing practical mitigation strategies that consider cost-effectiveness, technical viability, and implementation feasibility.

24.4.3 Environmental Impact Management

The assessment reveals expected operational impacts including controlled air emissions, noise, solid waste generation, and heat discharge. While some effects will be continuous and require ongoing management, others will be temporary and localized. We emphasize that no industrial development occurs without environmental consequences, but our mitigation measures are designed to reduce impacts to acceptable, non-threatening levels that maintain ecological sustainability.

24.4.4 Proposed Mitigation Strategies

Our environmental management plan incorporates: advanced air filtration systems, noise reduction technologies, comprehensive waste handling protocols, and energy-efficient thermal regulation systems. These solutions have been carefully selected based on their proven effectiveness in similar pharmaceutical facilities, with special attention to local environmental conditions and community needs.

352 | Feasibility Studies Report

24.4.5 Socio-Economic Benefits

Beyond pharmaceutical production, the project will significantly boost local and national economic development through: direct employment opportunities, skills training programs, infrastructure improvements, and technology transfer. The facility will contribute to Ghana's healthcare sovereignty by increasing domestic production of essential medicines, reducing import dependence, and supporting the national industrialization agenda.

24.4.6 Sustainability Commitment

QPL maintains a firm commitment to sustainable industrial development that balances economic progress with environmental protection and social responsibility. We will implement ongoing monitoring programs, maintain open community engagement, and ensure full compliance with all regulatory requirements throughout the project lifecycle. This approach guarantees that the facility delivers both economic value and sustainable development for the Akuse community and Ghana as a whole.

25 Stakeholder Engagement & Communication

25 Stakeholder Engagement & Communication

25.1 Background

Quintex Pharma Ltd is undertaking a strategic initiative to establish a state-of-the-art biopharmaceutical injectable manufacturing facility through a joint venture with an international partner. This project represents a significant investment in the pharmaceutical sector. Given the project's scale, complexity, and long-term impact, a well-structured stakeholder engagement strategy is critical to aligning diverse interests, mitigating operational and regulatory risks, and securing the necessary approvals and institutional support for seamless execution.

As a key component of the project's feasibility assessment, the development of a comprehensive Stakeholder Engagement Plan (SEP) has been prioritized to ensure proactive and inclusive communication with all critical stakeholders. This plan is designed to actively involve key stakeholders throughout the project's lifecycle, including dialogue with regulators, investors, healthcare authorities, local communities, and industry partners, fostering transparency, trust, and collaborative decision-making throughout all phases—from feasibility to financing, operational readiness, and production. By systematically identifying stakeholder expectations, concerns, and influence levels, Quintex Pharma Ltd can anticipate potential challenges, optimize resource allocation, and strengthen strategic partnerships for long-term success.

25.2 Objectives

1. To identify the key stakeholders crucial to Quintex Pharma business and understand the relationship and influence between all stakeholders.
2. To enable alignment of strategy in line with changing trends and behaviours of the key stakeholders
3. To enable effective and efficient engagement and communication channels with key stakeholders across all stages of the development of the biopharmaceutical injectable manufacturing plant, to build trust and ensure alignment of expectations.
4. To drive stakeholder-driven decision-making by integrating feedback from stakeholders like investors, suppliers, healthcare providers, and policymakers into the plant's development strategy, ensuring commercial viability and long-term sustainability

25.3 Stakeholder identification and analysis

For the purposes of this plan, and consistent with Quintex Pharma terminology, Stakeholders are persons or groups who are directly or indirectly affected by the activities of this project or business, as well as those who may have interests in the project or business and/or the ability to influence its outcome, either positively or negatively.

Engagement is a two-way process whereby information is exchanged, and ideas and concerns are communicated and genuinely considered to inform and guide key business decisions and activities. The stakeholders relevant to this project are categorized into the following groups:

- Government & Regulatory Bodies
  - Ministry of Health (MoH) – Policy direction and regulatory oversight.
  - Ghana Health Service – Oversees public healthcare institutions and procurement.
  - Ghana Food and Drugs Authority (FDA) – Product approval, compliance, and Good Manufacturing Practice (GMP) certification.
  - Pharmacy Council of Ghana – Regulation of pharmaceutical professionals.
  - Ghana Standards Authority (GSA) – Quality and safety standards.
  - Ghana Investment Promotion Centre (GIPC) – Investment facilitation and incentives.
  - Ministry of Trade, Agribusiness, and Industry – Industrial policy alignment and incentives.
  - Ghana Revenue Authority (GRA) – Taxation and fiscal policy.
  - Environmental Protection Agency (EPA) – Environmental impact assessments.

- Healthcare Ecosystem & End Users (Customers)
  - Public Health Institutions (Korle-Bu Teaching Hospital, Komfo Anokye Teaching Hospital, regional hospitals, district hospitals etc.) – Key end-users (customers) of biopharmaceutical injectables.
  - Private Hospitals & Clinics (Nyaho Medical Centre, Trust Hospital, Focos Orthopaedics Hospital, Lister Hospital etc) – Key end-users (customers) of biopharmaceutical injectables.
  - National Health Insurance Authority (NHIA) – Reimbursement and insurance coverage for injectables.
  - Healthcare Professional Associations (Ghana Medical Association, Pharmaceutical Society of Ghana, etc.) – Advocacy and collaboration.

- Industry & Business Partners
  - Local Pharmaceutical Manufacturers – Potential collaborators and competitors.
  - International Pharma Partners – Joint venture partners.
  - Raw Material Suppliers – Local and international sourcing.
  - Distributors & Wholesalers – Supply chain partners.
  - Retail Pharmacies – Downstream distribution.

- Financial & Investment Institutions
  - Local & International Banks – Project financing.
  - Development Finance Institutions (e.g., AfDB, World Bank, IFC) – Potential funding and technical assistance.
  - Private Equity & Venture Capital Firms – Investment opportunities.

- Regional, Continental, and international stakeholders
  - World Health Organization – Public health impact, quality standards
  - Africa CDC – Public health impact

25 Stakeholder Engagement & Communication

- AfCFTA/African Union – Regional development, trade implications
- International Donors/Aid Organizations – Healthcare improvement, economic development

25.4 Stakeholder Engagement Plan

The following Stakeholder Engagement Plan (SEP) has been developed relative to the four key stages of this project and the necessary engagement activities. Each stage presents unique requirements and challenges necessitating targeted engagement with relevant stakeholders. These stages include:

25.4.1 Stage 1: Feasibility / Exploration

This stage focuses on assessing the viability of the manufacturing plant. It involves conducting in-depth feasibility studies, market research, regulatory assessments, and technical evaluations to determine the demand, operational requirements, and potential challenges. Key activities include; Market and demand analysis for injectable pharmaceuticals, regulatory and policy landscape assessment, site selection and infrastructure feasibility studies, stakeholder identification and preliminary engagement, cost estimation and initial business case development.

25.4.2 Stage 2: Financing / Strategic investment

During this stage, efforts are directed toward securing the necessary financial resources to develop the manufacturing facility. This involves engaging investors, financial institutions, and development partners. Key activities include; Development of a detailed investment and financing strategy, identification and engagement of potential investors and funding agencies, securing government incentives, grants, or public-private partnerships (PPPs), negotiations with financial institutions for loans or credit facilities, finalizing financial models and return-on-investment projections.

25.4.3 Phase 3: Operational Readiness / Commissioning

This stage marks the transition from plant construction to operational readiness. It includes the setup, installation, validation, and certification of manufacturing processes. Key activities include: construction and installation of manufacturing equipment, regulatory approvals and compliance validation, staff recruitment and training for plant operations, test production runs and quality assurance checks, official commissioning and launch of the facility.

25.4.4 Phase 4: Production / Commercialization

This final stage signifies full-scale manufacturing and distribution of injectable pharmaceutical products. The focus shifts to optimizing operations, ensuring product quality, and maintaining regulatory compliance. Key activities include: Full-scale production and quality control measures, market entry and product distribution strategies, continuous stakeholder engagement and regulatory reporting, process optimization and expansion planning, post-market surveillance and pharmacovigilance.

1 1

Table 2: Stakeholder Engagement Plan

Stage	Stakeholder type	Area of influence	Engagement Purpose	Engagement approach
Feasibility	International partner	Providing technical expertise from operating in multiple markets. Ensuring alignment with GMP, WHO guidelines and country specific requirements Providing steer regarding decisions on licensing, technology sharing agreements and capacity building for local biopharma expertise within Ghana and ECOWAS region.	Alignment, transparency, collaborative planning, and decision making	Regular meeting schedules and reporting mechanisms for the findings from feasibility studies
Financing	Banks and Development Finance Institutions (e.g., AfDB, World Bank, IFC) Multilateral & bilateral donors (The Global Fund, WHO, UNDP, EU, GIZ etc.) Private investors & Venture capital firms	Potential funding and technical assistance Provision of investment opportunities Managing financial risk	Securing funding from the right mix of investors while ensuring transparency, credibility, and alignment with stakeholder expectations	Engage donors to explore grant funding Conduct investment roadshows and presentations (e.g. utilize Ghana's health and investment forums to pitch to investors) Organize regular investor briefings and provision of access to due diligence reports as well as detailed financial projections and reports.
	International partner	Access to industry and investor networks Guidance on financial modeling to ensure sustainability.	Securing financial structuring support, risk mitigation and access to development finance	Organize regular briefings and provide access to due diligence reports as well as detailed financial projections and reports.

		Strengthening international investor confidence		
	Government agencies (MoH, GIPC)	Shaping investment climate through policies that affect financing risk and ROI.		Government engagement on incentive negotiations and public-private partnerships
Operational readiness	Ghana Food and Drugs Authority (FDA) Ghana Standards Authority (GSA) Environmental Protection Agency (EPA) Ghana Revenue Authority (GRA)	Regulatory, quality and standards compliance	Ensuring regulatory compliance, as well as market entry in-country.	Regular communication with FDA on dossier submissions, inspections, and approvals Organize quality and safety compliance checks or audits before production.
	Regional, Continental, and international stakeholders (WHO, AfCFTA, Africa CDC, Africa Medicines Agency	Enhanced market access, regional integration, and trade facilitation	Ensuring regulatory alignment, market access (regionally, across the continent and internationally) and public health impact	Attend industry forums and policy dialogues by AMA, Africa CDC, AfCFTA etc.
	Ministry of Health Ghana Health Service Healthcare institutions, Healthcare Professional Associations	Demand for manufactured injectable products. Distribution of manufactured injectable products Clinical adoption and confidence building	Ensuring market readiness and demand alignment Building strategic partnerships for smooth adoption and distribution of products manufactured	Organize briefings with key government agencies, healthcare institutions (Public hospitals and private hospitals) to introduce the plant's capacity and potential impact on local healthcare delivery.

	Healthcare Federation of Ghana Christian Health Association of Ghana (CHAG)		Strengthening public confidence and healthcare provider buy-in Secure endorsements from healthcare professionals	Partner with professional associations on clinical awareness and training programs (e.g. CPD) Collaborate with FDA and medical associations to organize scientific and regulatory forums (e.g. product standards, product education, quality assurance, GMP etc.)
	Raw material suppliers Pharmaceutical distributors and wholesalers Pharmaceutical Manufacturing Association of Ghana	Availability of raw materials (APIs, excipients, packaging etc.) for production Distribution of manufactured injectable products	Ensuring reliable, compliant, and cost-effective supply chain for the manufactured injectable products Identify partnership opportunities with other local manufacturing companies.	Identify potential suppliers of raw materials (APIs, excipients, packaging etc.) and conduct supplier audit & due diligence to verify compliance, quality, and supply reliability. Establish agreements with key suppliers for raw materials.

				Identify and onboard key pharmaceutical distributors though distributors partnerships.
Production	Banks and development finance institutions (e.g., AfDB, World Bank, IFC) Multilateral & bilateral donors WHO, UNDP, EU, GIZ etc.) Private investors & Venture capital firms	Provision of Financing and credit facilities Market access and partnerships Provision of equity investment opportunities Managing financial risk	Acquiring financing and credit facilities to enable operations. Leveraging technical assistance to improve financial sustainability. Developing strategic partnerships for market expansion and international collaboration	Engage DFIs to obtain and utilize blended financing (concessional loans, grants, equity investments) to de-risk commercial loans. Participate in donor-sponsored initiatives and forums to align with donor priorities and investment focus in healthcare and industrialization. Leverage industry networks and investment platforms
	Ghana Food and Drugs Authority (FDA) Ghana Standards Authority (GSA) Environmental Protection Agency (EPA) Ghana Revenue Authority (GRA)	Regulatory, quality and standards compliance	Ensuring compliance to all regulatory and quality standards in the country Ensuring sustainable operations	Organize regular quality and safety compliance checks or audits. Establish pharmacovigilance reporting systems. Maintain an open communication channel with all regulatory bodies
	Regional, Continental, and international stakeholders	Regulatory harmonization Market access Trade facilitation	Ensuring regulatory alignment, improving market	Establish formal communication channels. Attend relevant stakeholder events.

	(WHO, AfCFTA, Africa CDC, Africa Medicines Agency		access and public health impact	Leverage government partnerships with these stakeholders.
	Ministry of Health NHIA Ghana Health Service Healthcare institutions Healthcare Professional Associations Healthcare Federation of Ghana Christian Health Association of Ghana (CHAG)	Shaping of market access through policies Pricing and reimbursement Demand generation for manufactured injectable products. Distribution of manufactured injectable products Clinical adoption and confidence building	Ensuring policy alignment, public procurement inclusion and health financing support Ensuring market uptake, supply chain integration	Engage with government agencies on policy dialogues, MOU, and technical presentations. Ensure Public Procurement Authority compliance for government contracts. Organize hospital visits for round table discussions and product demonstrations and establishment of partnerships for distribution. Conduct pharmacovigilance programs for adverse event reporting. Engage Key Opinion Leaders (KOLs) for advocacy to improve adoption. Continue to partner with professional associations to provide capacity building initiatives (CPDs, Workshops etc.) Run patient awareness campaigns on treatment benefits and safety of injectable products (especially locally manufactured ones)

	Raw material Suppliers Pharmaceutical distributors and wholesalers Pharmaceutical Manufacturing Association of Ghana	Supply of raw materials (APIs, excipients, packaging etc.) to maintain production schedules. Cost of production and pricing strategy for final injectable products Quality of the final injectable products	Ensuring reliable, compliant, and cost-effective supply chain for the manufactured injectable products Establishing collaborative rather than purely competitive relationships with other local manufacturers	Improve strategic alliances with suppliers and distributors for supply chain efficiency. Offer incentives for distributors to increase market reach.

25.5 Communication Plan

As part of the biopharmaceutical injectable manufacturing plant feasibility study, Quintex Pharma has identified the need for a Strategic Communications Plan to assist in the implementation of the biopharmaceutical injectable plant, positioning the company to be a trusted industry leader while contributing to Ghana's health security as well as pharmaceutical self-sufficiency.

Effective communication is essential to building trust, securing stakeholder buy-in, and ensuring the smooth execution of the project. This Communication Plan outlines a structured approach to engaging key stakeholders—including government agencies, regulatory bodies, healthcare providers, investors, and the public. By fostering transparency, alignment, and support, the plan aims to drive awareness, manage expectations, and facilitate collaboration throughout the project lifecycle.

25.5.1 Objectives

- Establish credibility and trust with all stakeholder groups through maintaining clear, transparent, consistent, and timely communication throughout the project phases.
- Highlight Quintex Pharma's commitment to quality, safety, and compliance with international regulatory standards.
- Position the project as a strategic contributor to Ghana's healthcare sector.
- Support advocacy efforts for favourable policy and regulatory environment for biopharmaceutical manufacturing in Ghana.

25.5.2 Communication methods and strategic key messages

Effectively reaching each target audience requires a tailored communication approach. Different stakeholders have varying preferences for receiving information, and using the right channels ensures that messages are not only delivered but also understood and acted upon.

To maximize engagement and impact, it is crucial to select communication mediums that align with the audience's habits, expectations, and level of involvement in the project. Whether through traditional media, digital platforms, direct engagement, or industry events, the goal is to ensure clear, consistent, and impactful messaging.

Below is a breakdown of the recommended communication mediums and channels best suited for each audience, ensuring that Quintex Pharma's key messages are effectively conveyed to build awareness, foster collaboration, and drive stakeholder support.

Table 3: Communication methods and strategic key messages

Target Audience	Specific objectives	Communication channels	Strategic key messages
Government & Regulatory Bodies Ministry of Health (MoH) Ghana Health Service National Health Insurance Authority (NHIA) Ghana Food and Drugs Authority (FDA) Pharmacy Council of Ghana Ghana Standards Authority (GSA) Ghana Investment Promotion Centre (GIPC) Ministry of Trade, Agribusiness, and Industry Ghana Revenue Authority (GRA) Environmental Protection Agency (EPA)	Obtain necessary approvals and align with government policies	Formal letters Official meetings Policy papers Public-private dialogue platforms	"A strategic investment to strengthen Ghana's pharmaceutical industry and enhance self-sufficiency in biopharmaceuticals". "Our plant will be built to meet the highest international quality standards, ensuring that locally produced injectables are both safe and effective for patients". "By localizing the production of biopharmaceutical injectables, we will support Ghana's efforts to achieve Universal Health Coverage (UHC), ensuring that all citizens have access to high-quality healthcare services".
Healthcare Ecosystem & End Users (Customers) Public Health Institutions (All six (6) public teaching hospitals, all regional hospitals, All district hospitals etc. Private Hospitals & Clinics (Nyaho Medical Centre, Trust Hospital, Focos Orthopedics Hospital, Lister Hospital etc.) Healthcare Professional Associations (Ghana Medical Association, Pharmaceutical Society	Gain the trust and support of healthcare providers and professionals	Conferences Workshops Newsletters Featured articles Webinars	"We will ensure affordable and high-quality injectables for Ghana's healthcare needs". "Our products will meet stringent quality and safety standards". "Healthcare professionals will receive comprehensive product education and support".

of Ghana, Ghana National Chamber of Pharmacy etc.)			
Industry & Business Partners International Pharma Partners – Joint venture partners. Raw Material Suppliers. Distributors & Wholesalers Retail Pharmacies Pharmaceutical Manufacturers Association of Ghana	Build credibility and support within the pharmaceutical sector	Business roundtable meetings Trade fairs Investor briefings Conferences	"We are committed to strengthening Ghana's healthcare system by establishing a world-class biopharmaceutical injectable plant that will enhance the availability of life-saving treatments for patients across the nation". "This project will contribute to reducing Ghana's reliance on imported medicines and will help position Ghana as a regional pharmaceutical manufacturing hub". "We will engage local suppliers, contractors, and businesses, stimulating economic activity and fostering the growth of local industries".
Financial & Investment Institutions Local & International Banks – Project financing. Development Finance Institutions (e.g., AfDB, World Bank, IFC) – Potential funding and technical assistance. Private Equity & Venture Capital Firms – Investment opportunities.	Secure funding and technical collaboration	Investment proposals Presentations Financial reports	"A high-growth investment opportunity with strong market potential and government support". "The project has a robust business plan with clear milestones and returns". "Risk management strategies are comprehensive and proactive to address regulatory, financial, and operational challenges". "The business model balances commercial viability with social impact". "The joint venture structure leverages the strengths of both partners".

Regional, Continental, and international stakeholders World Health Organization – Public health impact, quality standards Africa CDC AfCFTA/African Union International Donors/Aid Organizations	Ensure regulatory compliance, access investment and funding opportunities as well as market expansion and trade facilitation	Official Letters Regulatory dossier submissions Conferences and forums Business roundtable meetings	"Regional market access will be pursued through regulatory harmonization initiatives". "We are dedicated to collaborating with local, regional, and international regulatory bodies, healthcare providers, and industry partners to ensure the successful development of the injectable plant and maximize its impact on public health".
General public	Foster public awareness and local support	Press releases Website Social media & digital platforms	"Advancing healthcare security and local production capacity in Ghana". "The establishment of the plant will create hundreds of direct and indirect job opportunities for skilled workers, supporting the local economy and workforce development". "We are committed to strengthening Ghana's healthcare system by establishing a world-class biopharmaceutical injectable plant that will enhance the availability of life-saving treatments for patients across the nation".

Stakeholder list

Stakeholder	Type	Contact	Geography level	Power-Interest plotting
Government & Regulatory Bodies				
Ministry of Health (MOH)	Government Agency	Chief Director	Local	Regularly engage
Ghana Health Service	Government Agency	Director General	Local	Regularly engage
National Health Insurance Authority (NHIA)	Government Agency	Director (Strategic Health Purchasing)	Local	Actively consult
Environmental Protection Agency (EPA)	Regulatory body	Ag. Deputy Chief Executive Officer (Operations)	Local	Regularly engage
Ghana Revenue Authority (GRA)	Regulatory body	Commissioner (Domestic Tax and Revenue Division) Commissioner (Customs Division)	Local	Regularly engage
Ghana Investment Promotion Centre (GIPC)	Government Agency	Chief Executive Officer	Local	Actively consult
Ghana Standards Authority (GSA)	Regulatory body	Ag. Director Standards Division Ag. Director Certification Division	Local	Regularly engage
Ghana Food and Drugs Authority (FDA)	Regulatory body	Head of Drugs and Herbal Medicine	Local	Regularly engage
Ministry of Trade, Agribusiness, and Industry	Government Agency	Chief Director	Local	Actively consult
Healthcare Ecosystem & End Users (Customers)				
Korle-Bu Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest
Komfo Anokye Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest
Cape coast Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest
Ho Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest
Tamale Teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest
Sunyani teaching Hospital	Public Hospital	Chief Executive Officer	Local	Maintain Interest
Greater Accra Regional Hospital (Accra)	Public Hospital	Medical Director	Local	Maintain Interest

Kumasi South Hospital (Kumasi)	Public Hospital	Medical Director	Local	Maintain Interest
Effia Nkwanta Regional Hospital (Takoradi)	Public Hospital	Medical Director	Local	Maintain Interest
Tema General Hospital (Tema)	Public Hospital	Medical Director	Local	Maintain Interest
37 Military Hospital	Quasi-government	Medical Director	Local	Maintain Interest
Police Hospital	Quasi-government	Medical Director	Local	Maintain Interest
The Bank Hospital (Accra)	Quasi-government	Medical Director / Managing Director	Local	Maintain Interest
International Maritime Hospital (Tema)	Quasi-government	Medical Director / Managing Director	Local	Maintain Interest
Volta River Authority Hospital (Akosombo	Quasi-government	Medical Director / Managing Director	Local	Maintain Interest
Ghana Ports and Harbours Authority Hospital (Takoradi)	Quasi-government	Medical Director / Managing Director	Local	Maintain Interest
Nyaho Medical Centre (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
Lister Hospital and Fertility Centre (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
The Trust Hospital (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
Medifem Multi-Specialist Hospital (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
Focos Orthopedic Hospital (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
Holy Trinity Hospital (Accra)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
CNJ Hospital (Tema)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
UQ Specialist Hospital (Takoradi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
TrustCare Hospital (Kumasi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
Asafo Boakye Specialist Hospital (Kumasi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
A1 Hospital (Kumasi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
Sycamore Hospital (Takoradi)	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest

368 | Feasibility Studies Report

Family Health Hospital	Private Hospital	Medical Director / Managing Director	Local	Maintain Interest
Christian Health Association of Ghana (CHAG)	Private, not-for-profit organization	Director	Local	Maintain Interest
Ghana Medical Association	Association	President	Local	Maintain Interest
Pharmaceutical Society of Ghana	Association	President	Local	Maintain Interest
Healthcare Federation of Ghana	Private, not-for-profit organization	Chief Executive Officer	Local	Maintain Interest
Industry & Business Partners				
International Partner	Joint-venture Partner	Managing Director / Chief Executive Officer	International	Regularly engage
Ernest Chemist Ltd	Distributor / Manufacturer	Managing Director	Local	Maintain Interest
Gokals Laborex Ltd	Distributor	Managing Director	Local	Maintain Interest
Osons Chemist Ltd	Distributor	Managing Director	Local	Maintain Interest
East Cantonments Pharmacy Ltd	Distributor	Managing Director	Local	Maintain Interest
Unichem Ghana group	Distributor	Managing Director	Local	Maintain Interest
Pharmaceutical Manufacturing Association of Ghana (PMAG)	Association	Executive Secretary	Local	Maintain Interest
Financial & Investment Institutions				
International finance Corporation (IFC)	Multilateral DFI	Country Director	International	Actively consult
African Development Bank (AfDB)	Multilateral DFI	Country Director	International	Actively consult
European Investment Bank (EIB)	Multilateral DFI	Country Representative	International	Actively consult
UK Foreign, Commonwealth & Development Office (FCDO)	Bilateral DFI	British high Commission	International	Actively consult
Deutsche Gesellschaft Fur Internationale Zusammenarbeit (GIZ)	Bilateral DFI	Country Director	International	Actively consult
Japan International Cooperation Agency (JICA)	Bilateral DFI	Chief Representative	International	Actively consult
West African Development Bank (WADB)	Regional DFI	Country Representative	Regional	Actively consult
Ghana Exim Bank	Bank	Managing Director	Local	Actively consult
Regional, Continental, and international stakeholders				

World Health Organization (WHO)	Development Partner	Country Representative	International	Actively consult
Africa CDC	Health Agency	Senior Country Representative	International	Actively consult
Africa Medicines Agency	Health Agency	Director General	International	Actively consult
Africa Continental Free Trade Area	Trade organization	Secretary General	International	Actively consult

370 | Feasibility Studies Report

26 Management Capabilities

26.1 Introduction

The management team of a pharmaceutical plant comprises key leadership roles responsible for overseeing diverse aspects of the facility's operations, ensuring efficiency, regulatory compliance, product quality, and profitability. At the senior or corporate level, high-level executives and managers guide the plant's strategic direction, financial performance, and overall success. These leaders play a critical role in aligning the plant's operations with the organization's broader objectives, often collaborating closely with corporate headquarters to achieve cohesive and sustainable growth.

This dual-tiered leadership structure—combining operational management with strategic oversight—ensures that the plant not only meets its day-to-day operational goals but also contributes to the long-term vision and success of the organization.

26.2 Function and functionality

When discussing an organogram, the terms function and functionality can be used to describe different aspects of how an organization operates.

26.2.1 Function in an Organogram

A function refers to the specific role, purpose, or responsibility of a department, team, or individual within the organization. It describes what a particular unit or position is supposed to achieve or contribute to the organization.

- Example in an Organogram: In a company, the "Marketing Department" has the function of promoting the company's products, managing brand awareness, and driving sales. On the organogram, this function is represented by the Marketing team's placement and its relationship to other departments like Sales or Product Development.

Functions are often tied to the structure of the organogram, showing how different roles and departments are organized to achieve the organization's goals.

26.2.2 Functionality in an Organogram

Functionality refers to the practical effectiveness or operational capability of the organogram or the organization as a whole. It describes how well the organogram enables the organization to perform its functions and achieve its objectives.

- Example in an Organogram: If the organogram clearly defines reporting lines, communication channels, and decision-making processes, it has good functionality. Conversely, if the organogram is overly complex or unclear, it may hinder the organization's ability to function effectively.

Feasibility Studies Report | 371

26 Management Capabilities

Functionality is more about the performance and efficiency of the organogram in enabling the organization to operate smoothly.

Table 26.1 Key Differences between function and functionality

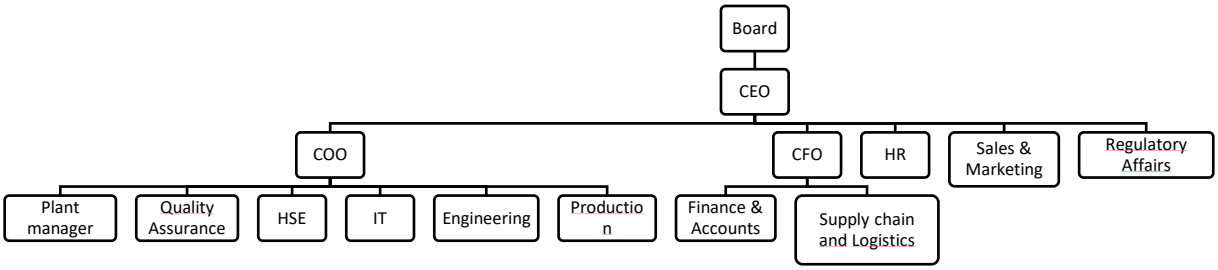
Aspect	Function	Functionality
Focus	Roles and responsibilities of units/teams	Effectiveness of the organogram's design
Representation	Shown by the structure of the organogram	Assessed by how well the organogram works
Example	"Finance Department handles budgeting."	"The organogram ensures clear communication between Finance and Operations."

In summary, function is about what each part of the organogram does (its role or purpose). Functionality is about how well the organogram enables the organization to perform those functions.

26.3 Proposed organisational structure

The hierarchical diagram below illustrates the structure of a typical pharmaceutical plant, with specific roles and responsibilities outlined to ensure efficient management and operations. It has to be stressed that each function in the presented organogram does not represent an individual but rather a needed function. The same individual can fit multiple purposes especially at the start of the operations.

Figure 26.1 Proposed Organogram



26.3.1 Board of Directors

The board of directors plays a crucial role in overseeing and guiding a pharmaceutical plant's operations and strategy. Their responsibilities are outlined in the paragraphs below.

26.3.1.1 Responsibilities

The board plays a critical role in providing strategic oversight by setting long-term goals and ensuring the plant aligns with the company’s mission and vision. It is responsible for compliance and risk management, ensuring adherence to laws, industry standards, and ethical practices while mitigating

372 | Feasibility Studies Report

potential risks. The board also maintains financial accountability by approving budgets, monitoring performance, and ensuring the plant's profitability and sustainability. Key decisions, such as launching new products, forming partnerships, or pursuing expansions and acquisitions, are reviewed and approved by the board. Additionally, it oversees executive supervision, including the appointment, evaluation, and potential replacement of senior leaders like the CEO or plant managers. Lastly, the board upholds corporate governance by establishing policies that promote transparency, accountability, and fairness across the organization.

26.3.1.2 Board members

The board typically includes:

- Executive Directors: These are individuals involved in day-to-day operations, such as the CEO or senior executives.
- Non-Executive Directors: They provide an independent perspective and oversee the executives' performance.
- Industry Experts: Professionals with specialized knowledge of pharmaceuticals or related fields.
- Financial Experts: Individuals skilled in finance or accounting for oversight of budgets and investments.
- Legal and Compliance Experts: To guide the plant on regulatory matters.
- Stakeholder Representatives: shareholders or key investors can a seat on the board.

26.4 Proposed core management team

The core management team is responsible for guiding a company's strategic direction, ensuring operational efficiency, and driving sustainable growth. They set long-term goals, oversee day-to-day operations, manage financial health, and ensure compliance with regulatory standards. The team fosters innovation, develops talent, and maintains strong relationships with stakeholders, including shareholders, customers, and regulatory bodies. By monitoring performance, mitigating risks, and implementing continuous improvement initiatives, they ensure the company remains competitive, adaptable, and aligned with its mission and vision. Their collective leadership and expertise are critical to achieving organizational success and maintaining a positive workplace culture.

The following members are proposed to be part of the core management team.

26.4.1 Chief Executive Officer

The CEO (Chief Executive Officer) of Quintex Pharma LTD holds a pivotal leadership role, overseeing the plant's overall operations and ensuring its success.

26.4.1.1 Key Responsibilities of the CEO

26.4.1.1.1 Strategic Leadership

The CEO establishes the vision, mission, and long-term goals for the plant, providing a clear direction for its operations. He also formulates strategic plans to drive business growth, enhance innovation, and maintain a competitive advantage in the industry. As this company is a lifelong dream of its current CEO, the vision is already clear, the challenge now lies in the implementation.

26 Management Capabilities

26.4.1.1.2 Regulatory Compliance

Ultimately, the CEO is responsible for ensuring that the plant adheres to all legal, regulatory, and ethical standards in the production of pharmaceuticals. This includes navigating intricate approval processes and maintaining compliance with regulatory bodies such as the FDA, and other relevant authorities.

26.4.1.1.3 Operational Oversight

The CEO oversees the day-to-day operations of the plant, ensuring that production processes are efficient and meet stringent quality control standards. Additionally, the CEO is responsible for securing and managing essential resources, including skilled personnel, state-of-the-art equipment, and high-quality materials, to maintain smooth and effective operations.

26.4.1.1.4 Financial Management

26.4.1.1.5 The CEO is responsible for overseeing the financial health of the organization by closely monitoring budgets, revenue streams, and cost management. Additionally, the CEO evaluates and approves significant investments in critical areas such as infrastructure upgrades, research initiatives, and product development to drive long-term growth and innovation.

26.4.1.1.6 Team Management

The CEO is responsible for appointing and supervising senior managers or directors who lead specialized functions such as research and development, production, and marketing. Additionally, the CEO focuses on building and inspiring a high-performing leadership team, fostering a culture of innovation, collaboration, and excellence to achieve organizational goals and drive sustained success.

26.4.1.1.7 Stakeholder Communication

As the primary representative of the plant, the CEO plays a pivotal role in maintaining strong relationships with key stakeholders, including shareholders, investors, regulatory agencies, and the local community. The CEO is also responsible for effectively communicating the company's performance, strategic direction, and major decisions, ensuring transparency and fostering trust among all parties involved.

26.4.1.1.8 Crisis Management

As the ultimate leader of Quintex, the CEO is responsible for addressing and resolving critical challenges, including supply chain disruptions, regulatory complexities, and reputational risks, with efficiency and strategic foresight. By proactively managing these issues, the CEO ensures the company maintains operational stability, compliance, and a strong market position.

26.4.2 Chief Operations Officer (COO) or Director of Operations

The Director of Operations oversees the day-to-day operations of the plant, ensuring efficiency, productivity, and adherence to production schedules. This role focuses on optimizing workflows, managing resources, and ensuring the plant meets its output and quality targets.

374 | Feasibility Studies Report

26.4.2.1 Detailed Responsibilities

26.4.2.1.1 Production Management

The COO is responsible for overseeing production schedules to ensure the timely delivery of products, meeting both customer expectations and business objectives. Additionally, the COO focuses on optimizing workflows, identifying and eliminating bottlenecks, and implementing strategies to enhance overall operational efficiency and productivity.

26.4.2.1.2 Team Leadership

The COO oversees and manages production, engineering, and maintenance teams, ensuring seamless coordination and effective operations. Additionally, the COO provides coaching, guidance, and performance evaluations to foster a high-performing workforce, driving continuous improvement and professional growth within the teams.

26.4.2.1.3 Process Improvement

The COO implements lean manufacturing principles and continuous improvement initiatives to streamline processes and enhance operational effectiveness. Additionally, the COO monitors key performance indicators (KPIs) such as production efficiency, yield rates, and downtime, using data-driven insights to optimize performance and achieve sustainable growth.

26.4.2.2 Key Skills and Qualifications

Though not mandatory this is the advised profile for a COO:

- Bachelor's degree in Engineering, Operations Management, or a related field.
- Proven experience in pharmaceutical production and operations management.
- Strong leadership, problem-solving, and organizational skills.

26.4.3 Chief Financing Officer (CFO)

The Chief Financial Officer (CFO) oversees the financial health and sustainability of the pharmaceutical plant, ensuring effective financial planning, resource allocation, and compliance with regulatory and accounting standards. This role focuses on managing budgets, optimizing costs, and providing strategic financial insights to support the plant's operational and growth objectives.

26.4.3.1 Detailed Responsibilities

26.4.3.1.1 Financial Planning and Analysis

The CFO is responsible for developing and managing the plant's financial plans, including budgeting, forecasting, and long-term financial strategies. This includes analysing financial data to identify trends, risks, and opportunities, and providing actionable insights to support decision-making and ensure the plant's profitability and sustainability.

26.4.3.1.2 Cost Management and Optimization

The CFO oversees cost control measures, identifying areas for cost reduction and efficiency improvements without compromising quality or compliance. This involves monitoring expenses, analyzing production costs, and implementing strategies to optimize resource utilization and maximize financial performance.

26 Management Capabilities

26.4.3.1.3 Compliance and Risk Management

The CFO ensures compliance with financial regulations, tax laws, and industry standards, mitigating financial risks and maintaining the plant's reputation. This includes overseeing audits, managing internal controls, and ensuring accurate financial reporting to regulatory bodies and stakeholders.

26.4.3.1.4 Investment and Capital Management

The CFO evaluates and approves major investments in infrastructure, technology, or research and development, ensuring alignment with the plant's strategic goals. This includes managing capital allocation, assessing funding options, and maintaining strong relationships with investors and financial institutions.

26.4.3.2 Key Skills and Qualifications

Though not mandatory this is the recommended profile for a CFO:

- Bachelor's degree in Finance, Accounting, Business Administration, or a related field (Master's degree or CPA preferred).
- Proven experience in financial management within the pharmaceutical or manufacturing industry.
- Strong analytical, strategic planning, and problem-solving skills.
- In-depth knowledge of financial regulations, compliance standards, and risk management practices.
- Excellent leadership and communication skills to collaborate with cross-functional teams and stakeholders.

26.4.4 Human Resources (HR)

The HR Director oversees the recruitment and hiring process to attract and retain top talent for the plant. This includes developing job descriptions, conducting interviews, and collaborating with department heads to identify staffing needs. The HR Director also ensures a diverse and inclusive hiring process, leveraging employer branding and recruitment strategies to build a skilled and motivated workforce.

26.4.4.1 Detailed Responsibilities

26.4.4.1.1 Employee Development and Training

The HR Director designs and implements training programs to enhance employee skills, knowledge, and performance. This involves identifying skill gaps, organizing workshops, and promoting continuous learning opportunities. Additionally, the HR Director supports career development initiatives, such as mentorship programs and leadership training, to prepare employees for future roles and responsibilities.

26.4.4.1.2 Employee Engagement and Retention

The HR Director fosters a positive and inclusive workplace culture by implementing initiatives that boost employee morale and engagement. This includes conducting employee surveys, organizing team-building activities, and addressing workplace concerns. The HR Director also develops retention strategies, such as competitive compensation packages, recognition programs, and work-life balance initiatives, to reduce turnover and maintain a committed workforce.

376 | Feasibility Studies Report

26.4.4.1.3 Compliance and Workplace Policies

The HR Director ensures the plant complies with labour laws, industry regulations, and internal policies. This includes maintaining accurate employee records, managing workplace safety programs, and addressing legal or ethical issues. The HR Director also develops and updates employee handbooks, ensuring clear communication of company policies and procedures.

26.4.4.2 Key Skills and Qualifications

As mentioned for all the positions, though not mandatory this is the proposed profile for the position:

- Bachelor's degree in Human Resources, Business Administration, or a related field (Master's degree or HR certification preferred).
- Proven experience in HR management, preferably in the pharmaceutical or manufacturing industry.
- Strong knowledge of labour laws, compliance standards, and HR best practices.
- Excellent interpersonal, communication, and conflict-resolution skills.
- Ability to develop and implement HR strategies that align with organizational goals.

26.4.5 Sales and Marketing

The Sales and Marketing Director is responsible for driving revenue growth and market expansion for the pharmaceutical plant by developing and executing effective sales and marketing strategies. This role focuses on building strong customer relationships, promoting products, and ensuring the plant's offerings meet market demands and competitive standards.

26.4.5.1 Detailed Responsibilities

26.4.5.1.1 Sales Strategy and Execution

The Sales and Marketing Director develops and implements sales strategies to achieve revenue targets and expand market share. This includes identifying new business opportunities, managing key accounts, and overseeing the sales team to ensure effective customer engagement and satisfaction.

26.4.5.1.2 Marketing and Brand Management

The Director creates and executes marketing campaigns to promote the plant's products, enhance brand visibility, and differentiate offerings in the competitive pharmaceutical market. This involves market research, product positioning, and collaboration with cross-functional teams to align marketing efforts with business goals.

26.4.5.1.3 Customer Relationship Management

The Director builds and maintains strong relationships with customers, distributors, and stakeholders to ensure long-term loyalty and repeat business. This includes addressing customer needs, resolving issues, and gathering feedback to improve products and services.

26.4.5.1.4 Market Analysis and Trends

The Director monitors industry trends, competitor activities, and regulatory changes to identify opportunities and risks. This involves analysing market data to inform strategic decisions and ensure the plant's products remain competitive and aligned with market demands.

26 Management Capabilities

26.4.5.2 Key Skills and Qualifications

Though not mandatory this is the recommended profile for this position:

- Bachelor's degree in Marketing, Business Administration, or a related field (Master's degree preferred).
- Proven experience in sales and marketing within the pharmaceutical or healthcare industry.
- Strong leadership, communication, and negotiation skills.
- In-depth knowledge of pharmaceutical market dynamics, regulatory requirements, and customer needs.
- Ability to develop and execute innovative sales and marketing strategies to drive growth.

26.4.6 Regulatory Affairs

The Director of Regulatory Affairs is responsible for ensuring the pharmaceutical plant complies with all regulatory requirements and maintains effective communication with regulatory agencies. This role is critical for securing and retaining the plant's license to operate, ensuring product approvals, and navigating the complex landscape of evolving regulations.

26.4.6.1 Detailed Responsibilities

26.4.6.1.1 Regulatory Submissions

The Director oversees the preparation, submission, and management of regulatory filings to agencies such as the FDA, MOH and other relevant authorities. This includes compiling detailed documentation for new product approvals, process changes, and license renewals. The Director ensures that submissions are accurate, complete, and submitted within deadlines to facilitate timely approvals and maintain compliance.

26.4.6.1.2 Compliance Monitoring

The Director stays abreast of changes in regulatory requirements at both national and international levels, ensuring the plant's operations, products, and processes remain compliant. This involves conducting regular audits, updating internal policies, and developing strategies to address new or amended regulations. The Director also provides training and guidance to staff to ensure a culture of compliance across the organization.

26.4.6.1.3 Inspection Readiness

The Director ensures the plant is always prepared for regulatory inspections by maintaining up-to-date records, conducting internal audits, and addressing potential compliance gaps. During inspections, the Director acts as the primary point of contact, coordinating responses and providing necessary documentation. After inspections, the Director oversees the implementation of corrective actions to address any findings and prevent future issues.

26.4.6.2 Key Skills and Qualifications

Though not mandatory this is the recommended profile for this position:

- Bachelor's or Master's degree in Pharmacy, Regulatory Affairs, Life Sciences, or a related field.
- Extensive knowledge of global regulatory requirements, including FDA, EMA, and other relevant frameworks.

378 | Feasibility Studies Report

- Proven experience in preparing and managing regulatory submissions and interactions with regulatory agencies.
- Strong analytical, problem-solving, and project management skills.
- Excellent communication, negotiation, and interpersonal skills to effectively liaise with regulatory bodies and internal stakeholders.
- Attention to detail and the ability to interpret and apply complex regulatory guidelines.

26.5 Proposed middle management team

The second layer of management, or middle management, serves as a critical link between senior leadership and frontline employees, ensuring the company's strategic goals are effectively executed. They translate high-level plans into actionable tasks, oversee daily operations, and lead their teams to achieve departmental objectives. Middle managers mentor employees, monitor performance, and address operational challenges while fostering communication and collaboration across the organization. They also drive process improvements, manage change, and ensure customer or stakeholder needs are met. By balancing strategic oversight with hands-on leadership, they play a vital role in maintaining operational efficiency, employee engagement, and alignment with the company's overall mission.

The following members are proposed to be part of the middle management team.

26.5.1 Plant Manager

The Plant Manager is responsible for overseeing the overall operations of the pharmaceutical plant, ensuring efficient production, compliance with regulatory standards, and alignment with the company's strategic goals. This role is critical for maintaining product quality, meeting production targets, and fostering a safe and productive work environment.

26.5.1.1 Detailed Responsibilities

26.5.1.1.1 Production Management

The Plant Manager oversees the entire production process, ensuring that manufacturing schedules are met, and products are delivered on time without compromising quality. This includes optimizing workflows, managing resources, and addressing bottlenecks to enhance productivity and efficiency.

26.5.1.1.2 Quality Assurance and Compliance

The Plant Manager ensures that all operations comply with regulatory requirements, industry standards, and internal quality protocols. This involves working closely with the Quality Assurance and Regulatory Affairs teams to maintain certifications, prepare for inspections, and implement corrective actions as needed.

26.5.1.1.3 Team Leadership and Development

The Plant Manager leads and motivates a diverse team of employees, including production staff, engineers, and supervisors. They provide coaching, set performance goals, and foster a culture of accountability and continuous improvement. The Plant Manager also identifies training needs to enhance team skills and ensure operational excellence.

26.5.1.1.4 Safety and Environmental Standards

The Plant Manager prioritizes workplace safety and environmental sustainability by enforcing safety protocols, conducting regular audits, and ensuring compliance with health, safety, and

26 Management Capabilities

environmental regulations. They promote a culture of safety awareness and implement measures to minimize risks and environmental impact.

26.5.1.1.5 Budget and Resource Management

The Plant Manager manages the plant's budget, ensuring cost-effective operations while maintaining high standards of quality and efficiency. They oversee the procurement of materials, equipment, and resources, and make strategic decisions to optimize costs and maximize productivity.

26.5.1.2 Key Skills and Qualifications

Though not mandatory, this is the recommended profile for this position:

- Bachelor's or Master's degree in Engineering, Pharmacy, Business Administration, or a related field.
- Proven experience in pharmaceutical manufacturing or a similar regulated industry.
- Strong knowledge of Good Manufacturing Practices (GMP), regulatory requirements, and quality standards.
- Excellent leadership, problem-solving, and decision-making skills.
- Ability to manage budgets, resources, and complex production processes.
- Strong communication and interpersonal skills to collaborate with cross-functional teams and stakeholders.
- Commitment to safety, quality, and continuous improvement.

26.5.2 Quality Assurance (QA) and Quality Control (QC)

The Director of QA/QC is responsible for ensuring the pharmaceutical plant adheres to quality and regulatory standards, safeguarding the integrity, safety, and efficacy of pharmaceutical products. This role is essential for maintaining product quality, achieving regulatory compliance, and upholding the company's reputation for excellence.

26.5.2.1 Detailed Responsibilities

26.5.2.1.1 Quality Systems:

The Director oversees all QA/QC processes, including batch release, deviation management, and change control. They ensure compliance with Good Manufacturing Practices (GMP), international quality standards, and internal protocols to maintain consistent product quality.

26.5.2.1.2 Audits and Inspections

The Director manages regulatory inspections, acting as the primary point of contact and ensuring all documentation and processes meet regulatory expectations. They also conduct internal audits to identify gaps, implement corrective and preventive actions, and continuously improve quality systems.

26.5.2.1.3 Documentation

The Director ensures accurate and comprehensive documentation of all quality-related activities, including batch records, standard operating procedures (SOPs), and compliance reports. This documentation is critical for demonstrating adherence to regulatory requirements during inspections and audits.

380 | Feasibility Studies Report

26.5.2.2 Key Skills and Qualifications

Though not mandatory, this is the recommended profile for this position:

- Bachelor's or Master's degree in Pharmacy, Chemistry, Life Sciences, or a related field.
- Extensive experience in pharmaceutical quality systems, regulatory compliance, and GMP standards.
- Strong analytical and problem-solving skills to address quality issues and implement effective solutions.
- Excellent communication and leadership skills to collaborate with cross-functional teams and regulatory authorities.
- Attention to detail and a commitment to maintaining the highest standards of quality and compliance.

26.5.3 Health, Safety, and Environment (HSE)

26.5.3.1 The Director of HSE ensures compliance with health, safety, and environmental regulations, promoting a safe and sustainable work environment. This role is critical for protecting employees, minimizing risks, and reducing the plant's environmental impact.

26.5.3.2 Detailed Responsibilities

26.5.3.2.1 Safety Programs

The Director develops and implements safety protocols to protect employees, prevent accidents, and minimize workplace risks. They conduct regular safety training and drills to ensure a culture of safety awareness.

26.5.3.2.2 Environmental Compliance

The Director oversees waste management, emissions control, and energy efficiency initiatives to ensure compliance with environmental regulations. They also implement sustainability programs to reduce the plant's environmental footprint.

26.5.3.2.3 Risk Assessments

The Director conducts regular safety and environmental audits to identify potential risks and implement corrective actions. They also ensure that the plant is prepared for regulatory inspections and maintains all necessary certifications.

26.5.3.2.4 Housekeeping

The Director will oversee the housekeeping department to ensure it adheres to all HSE regulations.

26.5.3.3 Key Skills and Qualifications

Though not mandatory, this is the recommended profile for this position:

- Bachelor's degree in Environmental Science, Occupational Health, Safety Management, or a related field.
- Strong knowledge of OSHA, EPA, and other regulatory standards.
- Excellent communication, problem-solving, and leadership skills.
- Experience in developing and implementing HSE programs in a manufacturing or pharmaceutical environment.

26 Management Capabilities

26.5.4 IT

The Director of Information Technology (IT) oversees the implementation, maintenance, and optimization of the plant's IT systems and infrastructure. This role ensures that technology supports the plant's operations, enhances efficiency, and complies with regulatory requirements.

26.5.4.1 Detailed Responsibilities

26.5.4.1.1 IT Infrastructure Management

The Director manages the plant's IT infrastructure, including hardware, software, networks, and servers, to ensure reliable and secure operations. They oversee the implementation of new technologies and upgrades to support business needs.

26.5.4.1.2 Cybersecurity and Data Protection

The Director ensures the plant's IT systems are secure and compliant with data protection regulations. They implement cybersecurity measures, conduct risk assessments, and develop protocols to safeguard sensitive information.

26.5.4.1.3 System Integration and Optimization

The Director integrates IT systems across departments to streamline processes and improve data flow. They optimize existing systems to enhance productivity, reduce costs, and support decision-making through data analytics.

26.5.4.1.4 Compliance and Validation

The Director ensures IT systems comply with regulatory requirements, and oversees the validation of computerized systems used in production and quality control. They also prepare for IT-related audits and inspections.

26.5.4.2 Key Skills and Qualifications

Though not mandatory, this is the recommended profile for this position:

- Bachelor's or Master's degree in Information Technology, Computer Science, or a related field.
- Proven experience in managing IT systems in a pharmaceutical or regulated manufacturing environment.
- Strong knowledge of cybersecurity, data protection, and regulatory compliance.
- Expertise in system integration, cloud computing, and enterprise resource planning (ERP) systems.
- Excellent leadership, problem-solving, and communication skills.
- Ability to align IT strategies with business goals and drive digital transformation.

26.5.5 Engineering

The Director of Engineering is responsible for overseeing the design, maintenance, and optimization of the plant's equipment and facilities. This role ensures that the plant's infrastructure supports efficient, compliant, and sustainable operations, enabling the production of high-quality pharmaceutical products.

382 | Feasibility Studies Report

26.5.5.1 Detailed Responsibilities

26.5.5.1.1 Capital Projects

The Director manages equipment upgrades, facility expansions, and other capital projects, ensuring they are completed on time, within budget, and in compliance with regulatory standards. This includes planning, coordinating, and overseeing the execution of engineering projects to enhance operational efficiency.

26.5.5.1.2 Maintenance

The Director oversees both preventive and corrective maintenance activities to ensure equipment reliability and minimize downtime. They implement maintenance strategies that optimize equipment performance and extend its lifespan, supporting uninterrupted production.

26.5.5.1.3 Compliance

The Director ensures adherence to Good Engineering Practices (GEP) and regulatory standards, maintaining the integrity and safety of the plant's infrastructure. They also ensure that all engineering activities align with quality and compliance requirements.

26.5.5.2 Key Skills and Qualifications

Bachelor's or Master's degree in Engineering (Mechanical, Electrical, or Chemical).
Extensive experience in pharmaceutical engineering and project management.
Strong technical, leadership, and problem-solving skills.

26.5.6 Production

The Director of Production oversees the manufacturing processes within the pharmaceutical plant, ensuring the timely and efficient production of high-quality products. This role is critical for meeting production targets, maintaining compliance with regulatory standards, and optimizing operational efficiency.

26.5.6.1 Detailed Responsibilities

26.5.6.1.1 Production Planning

The Director develops and implements production schedules to meet demand while ensuring optimal use of resources. They coordinate with other departments to align production plans with inventory levels, supply chain capabilities, and quality requirements.

26.5.6.1.2 Process Optimization

The Director identifies opportunities to improve production processes, reduce waste, and enhance efficiency. They implement lean manufacturing principles and continuous improvement initiatives to achieve operational excellence.

26.5.6.1.3 Compliance and Quality

The Director ensures that all production activities comply with Good Manufacturing Practices (GMP) and other regulatory standards. They work closely with the Quality Assurance team to maintain product quality and address any deviations or non-conformances.

26 Management Capabilities

26.5.6.1.4 Team Leadership

The Director leads and motivates the production team, providing guidance, training, and performance feedback. They foster a culture of accountability, collaboration, and continuous improvement to achieve production goals.

26.5.6.2 Key Skills and Qualifications

Though not mandatory, this is the recommended profile for this position:
Bachelor's or Master's degree in Pharmacy, Chemistry, Engineering, or a related field.
Proven experience in pharmaceutical production and manufacturing operations.
Strong knowledge of GMP, regulatory requirements, and quality standards.
Excellent leadership, problem-solving, and organizational skills.
Ability to manage complex production processes and drive continuous improvement.

26.5.7 Finance and Accounts

The Director of Finance and Accounts manages the financial operations of the pharmaceutical plant, ensuring accurate financial reporting, effective budgeting, and compliance with accounting standards. This role is essential for maintaining the plant's financial health and supporting strategic decision-making.

26.5.7.1 Detailed Responsibilities

26.5.7.1.1 Financial Planning and Analysis

The Director oversees budgeting, forecasting, and financial planning to ensure the plant's operations are financially sustainable. They analyse financial data to identify trends, risks, and opportunities, providing insights to support strategic decisions.

26.5.7.1.2 Cost Management

The Director monitors and controls production costs, identifying areas for cost reduction and efficiency improvements. They implement cost-saving measures while maintaining quality and compliance standards.

26.5.7.1.3 Financial Reporting

The Director ensures accurate and timely preparation of financial statements, including balance sheets, income statements, and cash flow statements. They also manage internal and external audits to ensure compliance with accounting standards and regulatory requirements.

26.5.7.1.4 Compliance and Risk Management

The Director ensures compliance with tax laws, financial regulations, and internal controls. They also identify and mitigate financial risks, safeguarding the plant's assets and reputation.

26.5.7.2 Key Skills and Qualifications

Though not mandatory, this is the recommended profile for this position:

- Bachelor's or Master's degree in Finance, Accounting, Business Administration, or a related field (CPA or equivalent certification preferred).

384 | Feasibility Studies Report

- Proven experience in financial management within the pharmaceutical or manufacturing industry.
- Strong knowledge of accounting standards, tax regulations, and financial compliance.
- Excellent analytical, strategic planning, and problem-solving skills.
- Proficiency in financial software and tools for budgeting, forecasting, and reporting.

26.5.8 Supply Chain and Logistics

The Director of Supply Chain and Logistics oversees the procurement of raw materials, inventory management, and distribution of finished products. This role ensures the plant has the necessary resources to meet production targets while optimizing costs and maintaining quality.

26.5.8.1 Detailed Responsibilities

26.5.8.1.1 Procurement

The Director ensures the timely delivery of high-quality raw materials and packaging components by negotiating with suppliers, managing contracts, and maintaining strong vendor relationships. They also work to optimize costs without compromising quality.

26.5.8.1.2 Inventory Management

The Director optimizes stock levels to minimize waste, reduce costs, and ensure the availability of materials for production. They implement inventory control systems to track and manage supplies effectively.

26.5.8.1.3 Logistics

The Director coordinates with distributors and logistics partners to ensure the timely and efficient delivery of finished products to customers. They also manage transportation, warehousing, and distribution processes to meet customer demands.

26.5.8.2 Key Skills and Qualifications

Though not mandatory, this is the recommended profile for this position:

- Bachelor’s degree in Supply Chain Management, Business Administration, or a related field.
- Proven experience in pharmaceutical supply chain management and logistics.
- Strong analytical, negotiation, and organizational skills.
- Knowledge of regulatory requirements related to pharmaceutical supply chains.

27 Departments organization

27.1 Introduction

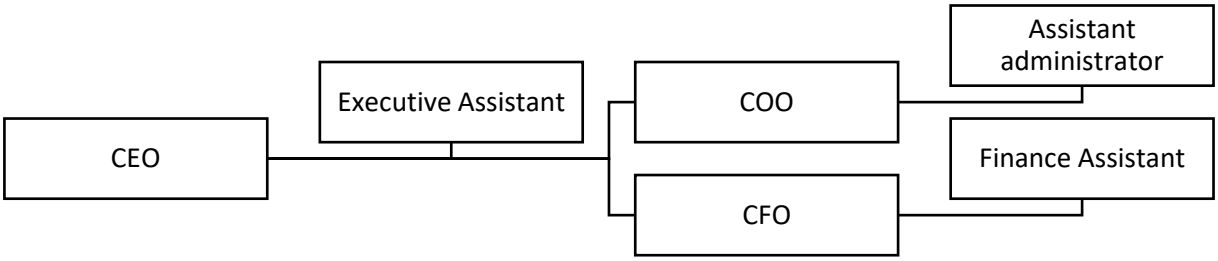
Apart from the above mentioned positions, each department will have to be organised to function optimally. Do note that the present document is meant to represent a fully functional plant. It is not advised to start the plant with all positions filled. However, this can serve as a guideline while the production grows.

Typically pharmaceutical companies have an R&D department. However, given the context and the purely commercial intent of Quintex we have not proposed to add that department.

27.2 Senior Management

The senior management and administration department is structured to ensure efficient operations, regulatory compliance, and strategic growth. At the top of the hierarchy is CEO, assisted by an Executive Assistant, who manages schedules, coordinates meetings, and handles communications. The COO oversees day-to-day operations and is supported by an Administrative Assistant who helps coordinate activities and maintain records. The CFO manages the plant's financial health and is often assisted by a Finance Assistant or Accountant, who handles day-to-day financial tasks and prepares reports.

Figure 27.1 Senior Management Proposed Organisational Structure



27.3 HR

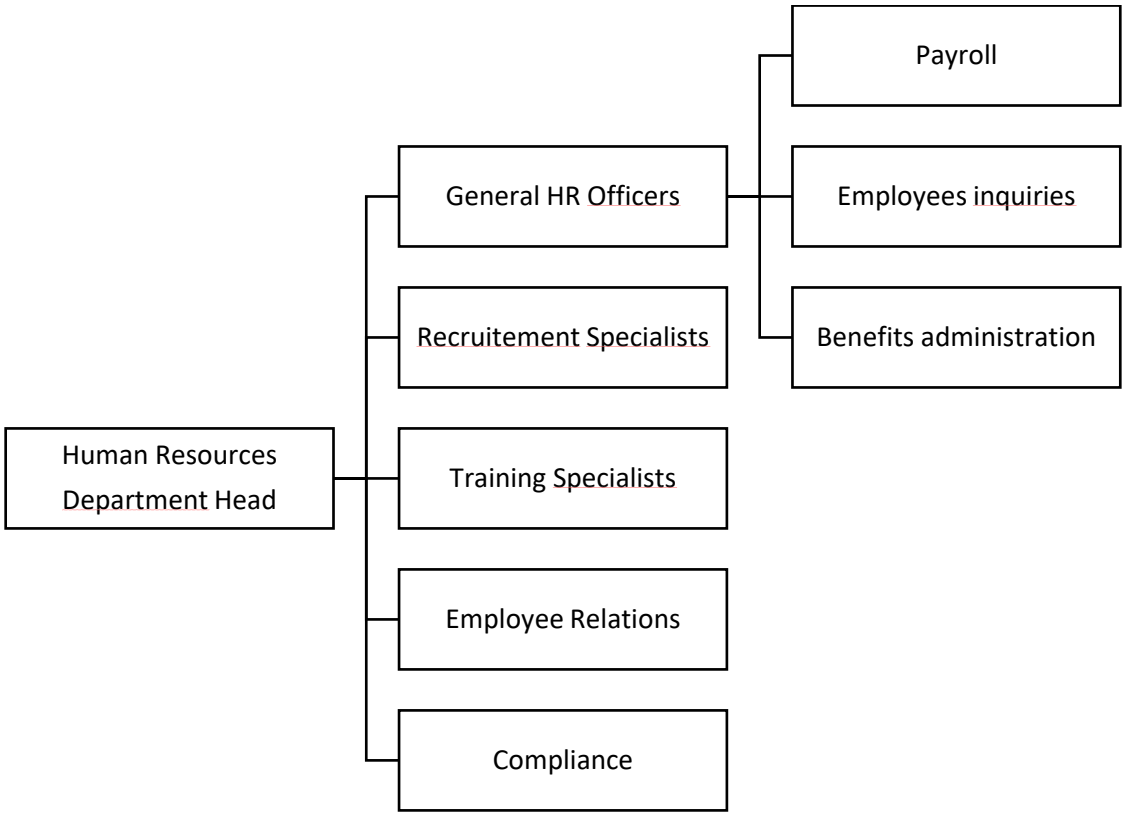
The Human Resources (HR) department exercises the vital function of managing the organization's workforce, ensuring compliance with labour laws, fostering employee engagement, and supporting the company's strategic goals. The HR department is typically organized into specialized teams, each focusing on specific aspects of human resource management. Below is a detailed explanation of how the HR department is proposed to be structured.

386 | Feasibility Studies Report

27.3.1 Organisational Structure

The HR department is usually organized hierarchically, with distinct roles and teams dedicated to various HR functions. At the top is the Head of HR, who oversees the entire department and aligns HR strategies with the company's business objectives. Reporting to the HR Director are HR Managers, who lead specialized teams such as recruitment, training, employee relations, and compliance. HR Generalists handle day-to-day HR operations, including employee inquiries, payroll, and benefits administration. Additionally, the department may include HR Business Partners (HRBPs), who work closely with other departments to provide strategic HR support and ensure alignment with organizational goals. This structure ensures that all HR functions are effectively managed and integrated into the company's operations.

Figure 27.2 HR Depatrment Proposed Organisational Structure



27.3.2 Recruitment and Talent Acquisition

One of the primary functions of the HR department is recruitment and talent acquisition, which involves attracting, hiring, and onboarding skilled professionals to meet the company's workforce needs. The recruitment team collaborates with department heads to identify staffing requirements and develop job descriptions. They use various channels, such as job portals, social media, and recruitment agencies, to source candidates. The team conducts interviews, assessments, and background checks to select the best talent. Once hired, the HR team facilitates the onboarding process, ensuring new employees are integrated smoothly into the organization and provided with the necessary resources and training to succeed in their roles.

27 Departments organization

27.3.3 Training and Development

The HR department plays a key role in training and development, ensuring that employees have the skills and knowledge required to perform their jobs effectively. The training team designs and implements programs tailored to the needs of different departments, such as GMP training for manufacturing staff or compliance training for regulatory affairs teams. They also focus on leadership development and career progression initiatives to help employees grow within the organisation. By fostering a culture of continuous learning, the HR department helps the company maintain a competitive edge and adapt to industry changes.

27.3.4 Employee Relations and Engagement

Maintaining positive employee relations and engagement is another critical function of the HR department. The employee relations team addresses workplace issues, such as conflicts, grievances, and disciplinary actions, ensuring fair and consistent treatment of employees. They also implement engagement initiatives, such as team-building activities, recognition programs, and employee surveys, to boost morale and retention. By creating a supportive and inclusive work environment, the HR department helps enhance productivity and job satisfaction.

27.3.5 Compensation and Benefits

The HR department is responsible for managing compensation and benefits, ensuring that employees are fairly compensated for their work. The compensation team conducts market research to design competitive salary structures and incentive programs. They also manage employee benefits, such as health insurance, retirement plans, and leave policies, ensuring compliance with legal requirements. Additionally, the team oversees payroll processing, ensuring accurate and timely payment of salaries. By offering attractive compensation packages, the HR department helps attract and retain top talent.

27.3.6 Compliance and Labor Law Adherence

Ensuring compliance with labour laws and regulations is a critical responsibility of the HR department. The compliance team stays updated on local and international labour laws, ensuring that the company adheres to legal requirements related to employment contracts, working hours, safety standards, and anti-discrimination policies. They also handle documentation and reporting, such as maintaining employee records and submitting required reports to regulatory authorities. By ensuring compliance, the HR department minimises legal risks and promotes a fair and ethical workplace.

27.3.7 Performance Management

The HR department oversees performance management, which involves evaluating employee performance and providing feedback to help employees improve. The performance management team designs appraisal systems, sets performance metrics, and conducts regular reviews in collaboration with department heads. They also identify high-performing employees for recognition and development opportunities, while providing support to those who need improvement. By fostering a culture of accountability and continuous improvement, the HR department helps drive organizational success.

388 | Feasibility Studies Report

27.3.8 Health, Safety, and Wellness

The HR department is responsible for promoting health, safety, and wellness in the workplace. The health and safety team ensures compliance with occupational health and safety regulations, conducting risk assessments and implementing safety protocols. They also organize wellness programs, such as health screenings, mental health support, and fitness initiatives, to promote employee well-being. By prioritising health and safety, the HR department helps create a safe and productive work environment.

27.3.9 HR Technology and Analytics

The HR department leverages HR technology and analytics to streamline processes and make data-driven decisions. They use Human Resource Information Systems (HRIS) to manage employee data, payroll, and benefits. Analytics tools are used to track key metrics, such as employee turnover, recruitment efficiency, and training effectiveness. By utilising technology, the HR department enhances efficiency and provides insights to support strategic decision-making.

27.3.10 Global vs. Local HR Operations

In multinational pharmaceutical companies, the HR department may be divided into global and local HR operations. The global HR team focuses on overarching strategies, such as talent management, leadership development, and compliance with international labour standards. The local HR team handles region-specific responsibilities, such as recruitment, employee relations, and adherence to local labour laws. This dual structure ensures consistency in HR practices while addressing the unique needs of each region.

27.4 Sales and Marketing

The Sales and Marketing Department in a pharmaceutical plant plays a pivotal role in driving product awareness, generating demand, and achieving revenue goals. This department is structured to align with the company's business objectives, market segments, and product portfolios. Below is a detailed explanation of how the Sales and Marketing Department is organized and functions within a pharmaceutical plant.

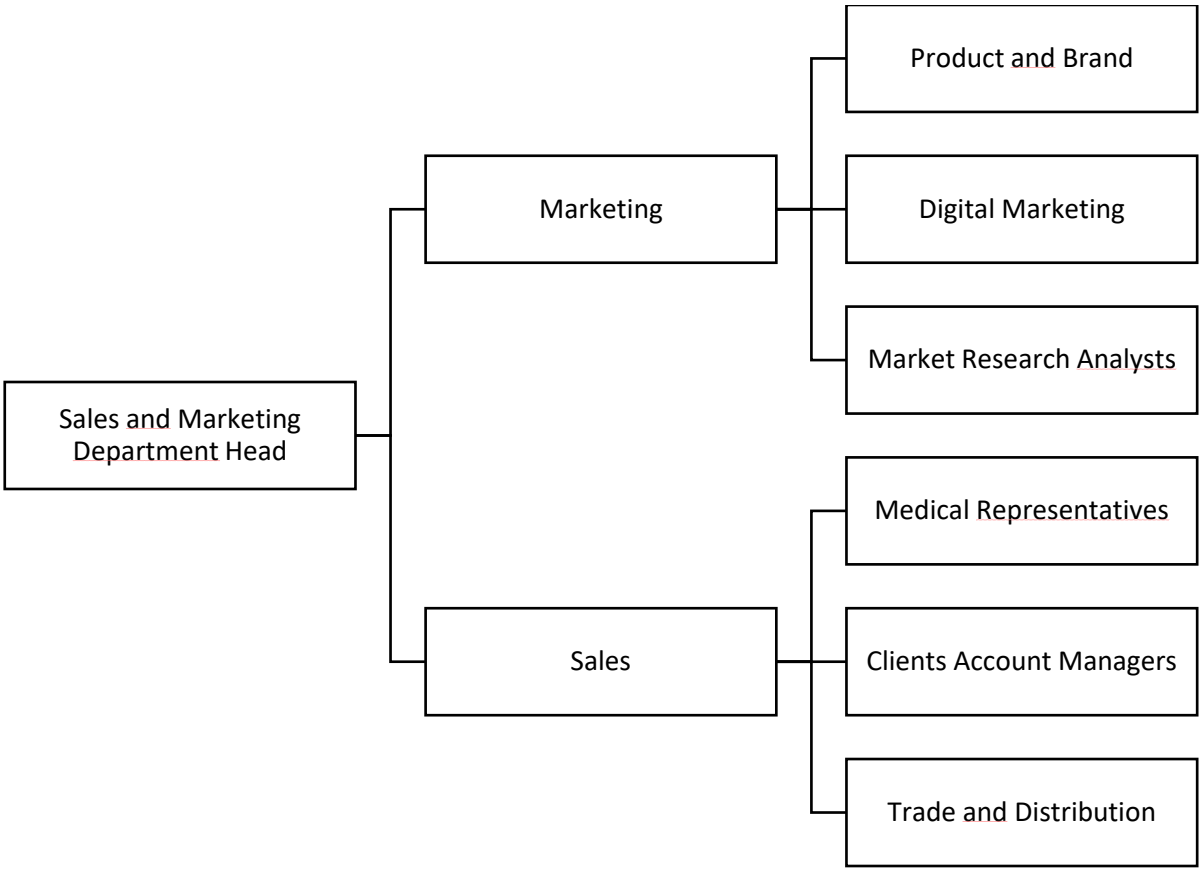
27.4.1 Organisational Structure

The Sales and Marketing Department is typically organized in a hierarchical manner, with distinct roles and teams focusing on various aspects of sales and marketing. At the top is the Head of Sales and Marketing, who oversees the entire department and develops overarching commercial strategies to meet revenue and market share targets. The Marketing Team is responsible for creating marketing strategies for the company's product portfolio. Within this team, Product or Brand Managers handle specific products or brands, focusing on market research, positioning, and promotional campaigns. Digital Marketing Specialists manage online marketing efforts, including social media, email campaigns, and website content, while Market Research Analysts gather data on market trends, customer needs, and competitor activities. The Sales Team sets sales targets and strategies. Regional Sales Managers oversee sales activities in specific geographic areas, while Medical Representatives engage directly with healthcare professionals to promote products and provide information. Key Account Managers focus on building and maintaining relationships with major customers, such as hospitals, pharmacies, and distributors. The Trade and Distribution Team includes Trade Marketing Managers, who optimize product distribution and availability, and Supply Chain Coordinators, who work with logistics teams to ensure timely delivery. Additionally, the Customer Support and Training

27 Departments organization

Team includes Customer Service Representatives, who handle inquiries and complaints, and Training Specialists, who provide product training to sales teams and healthcare professionals.

Figure 27.3 Sales and Marketing Proposed Organisational Chart



27.4.2 Key Functions of the Sales and Marketing Department

The Sales and Marketing Department performs a wide range of activities to drive product sales and market presence. One of its primary functions is market research and analysis, which involves gathering data on market trends, customer preferences, and competitor strategies to inform decision-making. The department also focuses on product and brand management, where Product or Brand Managers develop and execute marketing plans, create promotional materials, and ensure consistent brand messaging. Another critical function is sales strategy and execution, which involves setting sales targets, developing strategies to achieve them, and managing relationships with healthcare professionals, distributors, and key accounts. The department also emphasizes digital marketing and online presence, leveraging tools like social media, email campaigns, and search engine optimization to enhance brand visibility and engage with customers. Additionally, the trade and distribution management team works to ensure product availability and visibility in the market by collaborating with distributors and retailers. Finally, the department provides customer support and training, offering product training to sales teams and healthcare professionals while addressing customer inquiries and complaints to ensure satisfaction.

390 | Feasibility Studies Report

27.4.3 Integration with Other Departments

The Sales and Marketing Department works closely with other departments to ensure alignment and achieve business objectives. The department works with the Regulatory Affairs team to ensure that all marketing materials and promotional activities comply with regulatory requirements and obtain necessary approvals. Collaboration with the Manufacturing and Supply Chain teams is essential to ensure product availability and timely delivery, with the Sales and Marketing Department providing input on production planning based on market demand. Additionally, the department coordinates with the Finance team to develop budgets for sales and marketing activities and monitor sales performance and return on investment.

27.4.4 Tools and Systems

To manage its activities efficiently, the Sales and Marketing Department relies on various tools and systems. Customer Relationship Management systems are used to track customer interactions and sales activities, while marketing automation tools help execute and monitor digital marketing campaigns. Sales analytics platforms are employed to analyse sales data and performance metrics, and market research tools are used to conduct surveys, focus groups, and competitor analysis. These tools enable the department to make data-driven decisions and optimize its strategies.

27.4.5 Global vs. Local Sales and Marketing

In multinational pharmaceutical companies, the Sales and Marketing Department is often divided into Global Sales and Marketing and Local Sales and Marketing. The global team focuses on overarching strategies and brand positioning across multiple regions, ensuring consistency in messaging and branding. The local team, on the other hand, handles region-specific strategies and execution, tailoring efforts to meet local market conditions, cultural preferences, and regulatory requirements. This dual structure allows the company to maintain a global presence while addressing the unique needs of each market.

27.5 Regulatory Affairs

The proposed Regulatory Affairs (RA) department in the new Quintex pharmaceutical plant is a vital function that ensures the company adheres to all regulatory requirements and guidelines set by authorities such as the FDA, EMA, and WHO. This department serves as the primary link between the company and regulatory agencies, ensuring that products are developed, manufactured, and distributed in compliance with legal and quality standards. Below is a detailed explanation of how the Regulatory Affairs department is proposed to be organized and functions within Quintex.

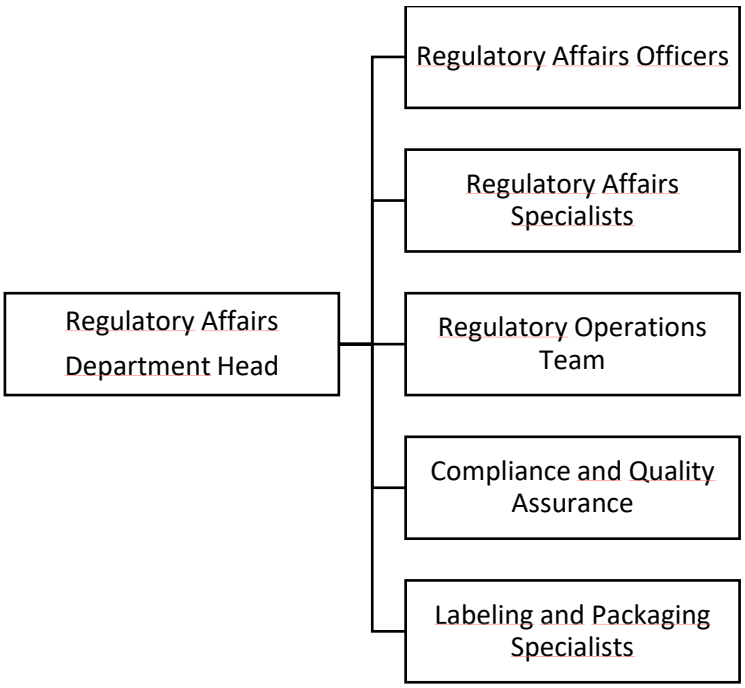
27.5.1 Organisational Structure

The RA department is structured hierarchically, with roles and responsibilities distributed based on expertise and experience. At the top is the Head of Regulatory Affairs who oversees the entire department, develops regulatory strategies aligned with business objectives, and serves as the main point of contact with regulatory agencies. Reporting to the Head are Regulatory Affairs Managers, who handle specific product portfolios or regions, such as Ivory Coast, Burkina Faso or any other emerging markets in West Africa as it is the ambition of Quintex. They coordinate regulatory submissions and approvals while supervising regulatory specialists and associates. Regulatory Affairs Specialists focus on preparing and reviewing regulatory documents, ensuring compliance with local and international regulations, and staying updated on regulatory changes. The Regulatory Operations Team manages the technical aspects of submissions, including electronic document management

27 Departments organization

systems, to ensure timely and accurate filing. Compliance and Quality Assurance Liaisons work closely with the QA department to address regulatory findings during inspections. Labelling and Packaging Specialists ensure that product labels and packaging comply with regulatory requirements.

Figure 27.4 Regulatory Affairs Department Prposed Organisational Structure



27.5.2 Key Functions of the Regulatory Affairs Department

The RA department performs a wide range of activities to ensure compliance and facilitate product approvals. One of its primary roles is regulatory strategy development, where it creates plans for product registration and approval across different regions while providing input during product development to ensure compliance. Another critical function is document preparation and submission, which involves compiling and filing regulatory dossiers as well as managing post-approval submissions like variations and renewals. The department also focuses on compliance monitoring, ensuring adherence to all standards, and staying updated on regulatory changes. Communication with regulatory agencies is another key responsibility, as the RA team acts as the main point of contact, responding to queries and addressing deficiency letters. Additionally, the department ensures labelling and packaging compliance by reviewing and approving product labels and packaging materials. It also maintains regulatory intelligence by monitoring changes in regulations and providing training to internal teams. Lastly, the RA department supports audits and inspections by ensuring documentation is in order and addressing any regulatory findings.

In Ghana, the pharmaceutical industry is regulated by several key bodies to ensure compliance with legal, safety, and quality standards. The most relevant regulatory bodies include:

- Food and Drugs Authority (FDA) Ghana: The primary regulatory agency responsible for the regulation and control of food, drugs, cosmetics, medical devices, and household chemical

392 | Feasibility Studies Report

substances. It ensures that pharmaceutical products meet safety, efficacy, and quality standards before they are marketed.

- Pharmacy Council of Ghana: This body regulates the practice of pharmacy and ensures that pharmaceutical products are dispensed by qualified professionals. It also oversees the licensing of pharmacies and pharmaceutical facilities.
- Narcotics Control Commission (NCC): Responsible for regulating and controlling the distribution and use of narcotic drugs and psychotropic substances to prevent abuse and ensure proper medical use.
- Ghana Standards Authority (GSA): Ensures that pharmaceutical products and manufacturing processes comply with national and international standards.
- Ministry of Health (MoH): Provides overarching policy direction and oversight for the healthcare sector, including pharmaceuticals, to ensure alignment with national health goals.
- Public Procurement Authority (PPA): Regulates the procurement of pharmaceuticals and medical supplies for public health institutions to ensure transparency and efficiency.

These department of RA will have to ensure Quintex Pharma adhere to their regulatory demands at all times.

27.5.3 Integration with Other Departments

The RA department collaborates closely with other departments to ensure regulatory compliance across the organization. It works alongside the Quality Assurance (QA) and Quality Control (QC) teams to ensure GMP compliance and address regulatory findings related to quality issues. The RA department also supports the production team by ensuring that manufacturing processes and facilities comply with regulatory standards and assisting with process validation and change control activities. Additionally, it collaborates with the Marketing and Sales teams to ensure promotional materials and claims comply with regulatory guidelines and provides input for new market entry strategies.

27.5.4 Tools and Systems

To manage its activities efficiently, the RA department can rely on various tools and systems. Electronic Document Management Systems (EDMS) are used to organize and maintain regulatory documents, while Regulatory Information Management Systems (RIMS) help track regulatory milestones and deadlines and compliance tracking tools are used to monitor regulatory changes and ensure adherence to updated requirements.

27.5.5 Global vs. Local Regulatory Affairs

As Quintex intends to be multinational pharmaceutical company, the RA department can be divided into Global Regulatory Affairs and Local Regulatory Affairs. The global team focuses on overarching strategies and compliance with international standards, while the local team handles country-specific requirements and submissions, ensuring that products meet the unique regulatory demands of each market.

27.6 Supply Chain and Logistics

The Supply Chain and Logistics Department in a pharmaceutical plant is a critical function responsible for ensuring the efficient flow of materials, products, and information from suppliers to customers. This department plays a key role in maintaining product quality, reducing costs, and meeting

27 Departments organization

regulatory requirements. Below is a detailed explanation of how the Supply Chain and Logistics Department is organized and functions within a pharmaceutical plant, with each point rephrased as a paragraph.

27.6.1 Organizational Structure

The Supply Chain and Logistics Department is typically organized into specialized teams, each focusing on specific aspects of the supply chain. At the top is the Supply Chain Director or Head of Supply Chain, who oversees the entire department and aligns supply chain strategies with the company's business objectives. Reporting to the Director are Supply Chain Managers, who lead teams such as procurement, inventory management, logistics, and distribution. Supply Chain Coordinators handle day-to-day operations, including order processing, shipment tracking, and supplier communication. Additionally, the department may include Quality Assurance Liaisons, who ensure that supply chain activities comply with Good Manufacturing Practices (GMP) and other regulatory standards. This structure ensures that all supply chain functions are effectively managed and integrated into the company's operations.

27.6.2 Procurement and Supplier Management

The procurement and supplier management team is responsible for sourcing raw materials, packaging materials, and other supplies required for production. They identify and evaluate suppliers, negotiate contracts, and ensure timely delivery of materials. The team also monitors supplier performance, ensuring that quality, cost, and delivery timelines meet the company's standards. By maintaining strong relationships with reliable suppliers, the procurement team helps ensure a steady supply of materials and minimizes production disruptions.

27.6.3 Inventory Management

The inventory management team oversees the storage and tracking of raw materials, work-in-progress, and finished goods. They use inventory management systems to monitor stock levels, forecast demand, and optimize inventory turnover. The team ensures that materials are stored under appropriate conditions to maintain quality and comply with regulatory requirements. By balancing inventory levels to meet production needs without overstocking, the inventory management team helps reduce costs and improve efficiency.

27.6.4 Production Planning and Scheduling

The production planning and scheduling team works closely with the manufacturing department to ensure that production runs smoothly and meets demand. They develop production schedules based on sales forecasts, inventory levels, and capacity constraints. The team also coordinates with procurement and inventory management to ensure that materials are available when needed. By optimizing production schedules, this team helps minimize downtime and ensure timely delivery of products.

27.6.5 Logistics and Transportation

The logistics and transportation team manages the movement of materials and products within the plant and to external destinations. They coordinate with carriers, freight forwarders, and customs agents to ensure timely and cost-effective transportation. The team also tracks shipments and

394 | Feasibility Studies Report

resolves any issues that arise during transit. By optimizing transportation routes and modes, the logistics team helps reduce costs and ensure on-time delivery.

27.6.6 Warehousing and Distribution

The warehousing and distribution team oversees the storage and distribution of finished goods. They ensure that products are stored under appropriate conditions to maintain quality and comply with regulatory requirements. The team also manages order fulfillment, ensuring that products are picked, packed, and shipped accurately and efficiently. By optimizing warehouse operations, this team helps improve order accuracy and customer satisfaction.

27.6.7 Quality Assurance and Compliance

The quality assurance and compliance team ensures that all supply chain activities comply with GMP, Good Distribution Practices (GDP), and other regulatory standards. They conduct audits of suppliers, warehouses, and transportation providers to ensure compliance. The team also handles documentation and reporting, such as maintaining batch records and submitting required reports to regulatory authorities. By ensuring compliance, the quality assurance team helps minimize risks and maintain product quality.

27.6.8 Demand Planning and Forecasting

The demand planning and forecasting team analyzes market trends, sales data, and customer feedback to predict future demand for products. They work closely with sales, marketing, and production teams to develop accurate demand forecasts. By aligning supply chain activities with demand forecasts, this team helps ensure that the company can meet customer needs without overproducing or underproducing.

27.6.9 Technology and Systems

The Supply Chain and Logistics Department leverages technology and systems to streamline processes and improve efficiency. They use Enterprise Resource Planning (ERP) systems to integrate supply chain activities, such as procurement, inventory management, and production planning. Transportation Management Systems (TMS) and Warehouse Management Systems (WMS) are used to optimize logistics and warehousing operations. By utilizing technology, the department enhances visibility, accuracy, and decision-making across the supply chain.

27.6.10 Global vs. Local Supply Chain Operations

In multinational pharmaceutical companies, the Supply Chain and Logistics Department may be divided into global and local operations. The global team focuses on overarching strategies, such as supplier relationships, global distribution networks, and compliance with international regulations. The local team handles region-specific responsibilities, such as local procurement, warehousing, and distribution. This dual structure ensures consistency in supply chain practices while addressing the unique needs of each region.

27.7 Accounts and Finances

The Finance and Accounts Department plant is responsible for managing the company's financial resources, ensuring compliance with accounting standards, and supporting strategic decision-making. This department plays a key role in budgeting, financial reporting, cost control, and

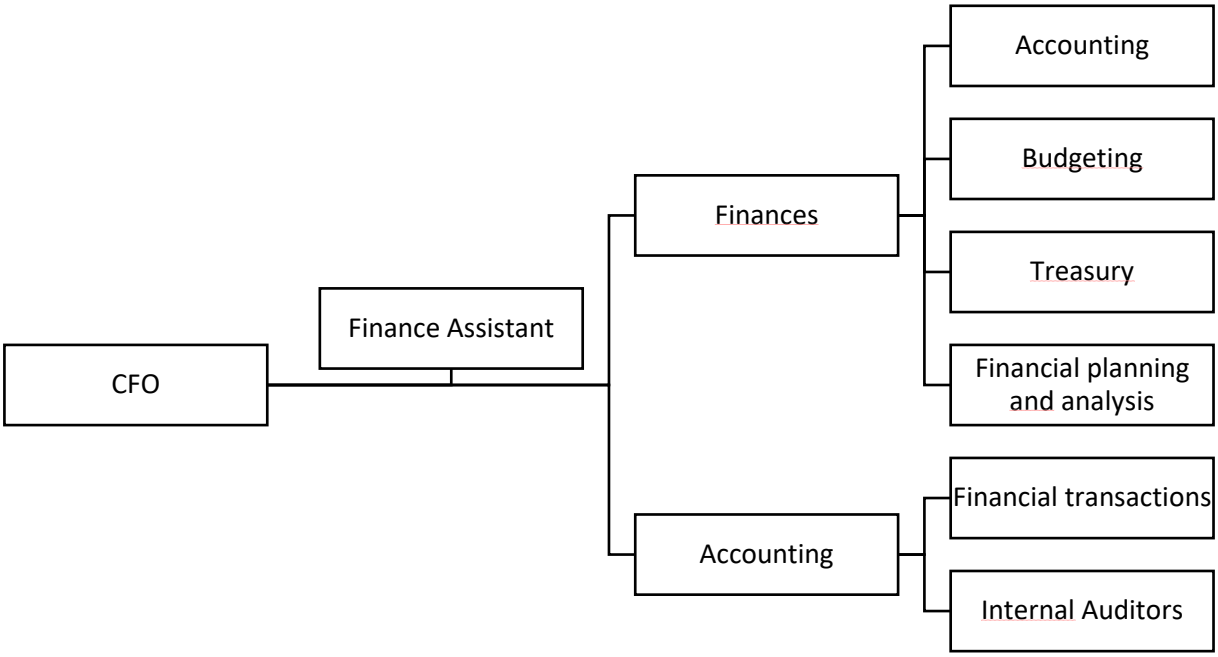
27 Departments organization

regulatory compliance. Below is a detailed explanation of how the Finance and Accounts Department is proposed to be organised.

27.7.1 Organizational Structure

The Finance and Accounts Department is typically organized hierarchically, with specialized teams focusing on different aspects of financial management. At the top is the CFO, who oversees the entire department and aligns financial strategies with the company's business objectives. Reporting to the CFO are Finance Managers, who lead teams such as accounting, budgeting, treasury, and financial planning and analysis. Accountants handle day-to-day financial transactions, including accounts payable, accounts receivable, and payroll. Additionally, the department may include Internal Auditors, who ensure compliance with financial policies and regulations. This structure ensures that all financial functions are effectively managed and integrated into the company's operations.

Figure 27.5 Accounts and Finance Department Proposed Organisational Structure



27.7.2 Financial Reporting and Compliance

The financial reporting and compliance team is responsible for preparing accurate and timely financial statements, such as income statements, balance sheets, and cash flow statements. They ensure compliance with accounting standards and regulatory requirements. The team also handles external audits, providing necessary documentation and addressing auditor queries. By maintaining transparency and accuracy in financial reporting, this team helps build trust with stakeholders and regulatory authorities.

27.7.3 Budgeting and Forecasting

The budgeting and forecasting team develops the company's annual budget and long-term financial plans. They work closely with department heads to gather input on revenue projections, cost

396 | Feasibility Studies Report

estimates, and capital expenditure requirements. The team also monitors actual performance against the budget, identifying variances and recommending corrective actions. By providing accurate financial forecasts, this team supports strategic decision-making and helps the company achieve its financial goals.

27.7.4 Cost Control and Analysis

The cost control and analysis team focuses on managing and reducing costs across the organization. They analyse production costs, overhead expenses, and other operational costs to identify areas for improvement. The team works with other departments, such as manufacturing and procurement, to implement cost-saving measures without compromising quality. By optimizing costs, this team helps improve profitability and operational efficiency.

27.7.5 Treasury and Cash Management

The treasury and cash management team is responsible for managing the company's liquidity and financial risk. They oversee cash flow, ensuring that the company has sufficient funds to meet its obligations. The team also manages investments, foreign exchange transactions, and debt financing. By effectively managing cash and financial risks, this team helps ensure the company's financial stability.

27.7.6 Accounts Payable and Receivable

The accounts payable and receivable team handles the company's financial transactions with suppliers and customers. The accounts payable team processes invoices, makes payments to suppliers, and manages vendor relationships. The accounts receivable team issues invoices, tracks customer payments, and follows up on overdue accounts. By ensuring timely and accurate processing of financial transactions, this team helps maintain healthy cash flow and strong relationships with stakeholders.

27.7.7 Payroll and Employee Benefits

The payroll and employee benefits team manages the company's payroll processes, ensuring that employees are paid accurately and on time. They also handle employee benefits, such as health insurance, retirement plans, and tax withholdings. The team ensures compliance with labour laws and tax regulations related to payroll. By managing payroll and benefits efficiently, this team helps maintain employee satisfaction and compliance.

27.7.8 Tax Planning and Compliance

The tax planning and compliance team is responsible for managing the company's tax obligations. They prepare and file tax returns, ensuring compliance with local, national, and international tax laws. The team also develops tax strategies to minimize liabilities and take advantage of available tax incentives. By ensuring compliance and optimizing tax planning.

27.8 Production

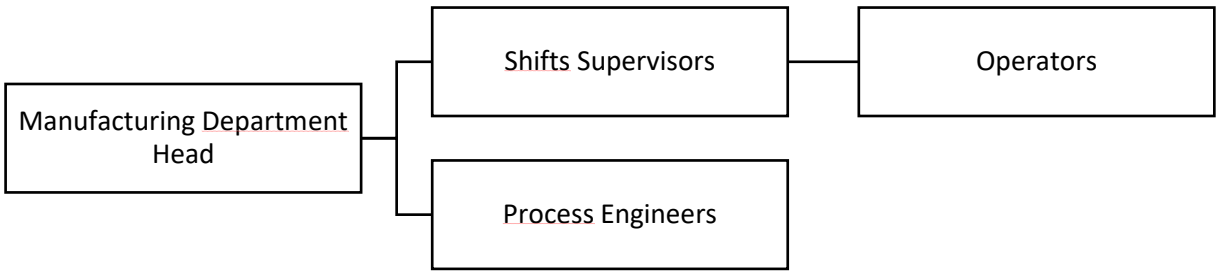
The Production or Manufacturing Department is the core function responsible for manufacturing high-quality sterile injectables products in compliance with regulatory standards. This department ensures that production processes are efficient, consistent, and aligned with the company's quality and safety requirements. Below is a detailed explanation of how the Production Department is proposed to be organised.

27 Departments organization

27.8.1 Organizational Structure

At the top is the Head of Production, who oversees the entire department and ensures that production targets are met while maintaining quality and compliance. Reporting to the Production Manager are Shift Supervisors or Production Supervisors, who manage day-to-day operations on the production floor. The department also includes Process Engineers, who optimize manufacturing processes, and Technicians or Operators, who handle the actual production activities. Additionally, the department may have Quality Assurance (QA) Liaisons to ensure compliance with GMP and other regulatory standards.

Figure 27.6 Production Department Proposed Organisational Structure



27.8.2 Production Planning and Scheduling

The production planning and scheduling team is responsible for creating detailed production plans to meet demand while optimizing resources. They work closely with the supply chain, inventory management, and sales teams to forecast production needs and allocate resources accordingly. The team develops schedules for each production line, ensuring that equipment, materials, and personnel are available when needed. By balancing efficiency and flexibility, this team helps minimize downtime and ensure timely delivery of products.

27.8.3 Manufacturing Operations

The manufacturing operations team is at the heart of the Production Department, responsible for executing the production processes. This team includes Technicians and Operators who operate machinery, monitor production lines, and ensure that products are manufactured according to specifications. They follow Standard Operating Procedures to maintain consistency and quality. The team also performs routine checks and adjustments to ensure that equipment is functioning properly. By adhering to strict protocols, this team ensures that products meet quality and safety standards.

27.8.4 Process Optimization and Validation

The process optimization and validation team focuses on improving manufacturing processes to enhance efficiency and product quality. Process Engineers analyse production data, identify bottlenecks, and implement solutions to streamline operations. They also conduct process validation studies to ensure that manufacturing processes are consistent and reproducible. By continuously improving processes, this team helps reduce costs, increase productivity, and maintain compliance with regulatory requirements.

398 | Feasibility Studies Report

27.8.5 Equipment Maintenance and Calibration

The equipment maintenance and calibration team ensures that all production machinery and equipment are in optimal working condition. They perform regular maintenance, repairs, and calibrations to prevent breakdowns and ensure accuracy in production. The team also maintains records of maintenance activities and equipment performance. By ensuring that equipment is well-maintained, this team helps minimize production delays and maintain product quality.

27.8.6 Quality Control and Assurance

The quality control and assurance team works closely with the Production Department to ensure that products meet quality standards and regulatory requirements. Quality Control Technicians conduct tests on raw materials, in-process samples, and finished products to verify their quality. Quality Assurance Specialists monitor production processes to ensure compliance with GMP and SOPs. By maintaining rigorous quality standards, this team helps ensure that products are safe, effective, and consistent.

27.8.7 Documentation and Record-Keeping

The documentation and record-keeping team is responsible for maintaining accurate records of all production activities. This includes batch records, equipment logs, and quality control test results. The team ensures that all documentation complies with regulatory requirements and is readily available for audits. By maintaining detailed records, this team supports traceability, accountability, and compliance.

27.8.8 Training and Development

The training and development team ensures that production staff are well-trained and competent in their roles. They develop training programs on topics such as GMP, SOPs, equipment operation, and safety protocols. The team also conducts regular assessments to ensure that employees maintain their skills and knowledge. By investing in employee development, this team helps improve productivity, quality, and compliance.

27.8.9 Health, Safety, and Environment (HSE)

The HSE team ensures that production activities are conducted in a safe and environmentally responsible manner. They implement safety protocols, conduct risk assessments, and provide training on workplace safety. The team also monitors environmental compliance, such as waste management and emissions control. By prioritizing health, safety, and sustainability, this team helps create a safe and responsible work environment.

27.8.10 Technology and Automation

The Production Department leverages technology and automation to enhance efficiency and accuracy in manufacturing. This includes the use of automated production lines, process control systems, and data analytics tools. The department also implements technologies such as Clean-in-Place (CIP) systems for equipment cleaning and Manufacturing Execution Systems (MES) for real-time monitoring of production processes. By adopting advanced technologies, the department improves productivity, reduces errors, and ensures compliance with regulatory standards.

27 Departments organization

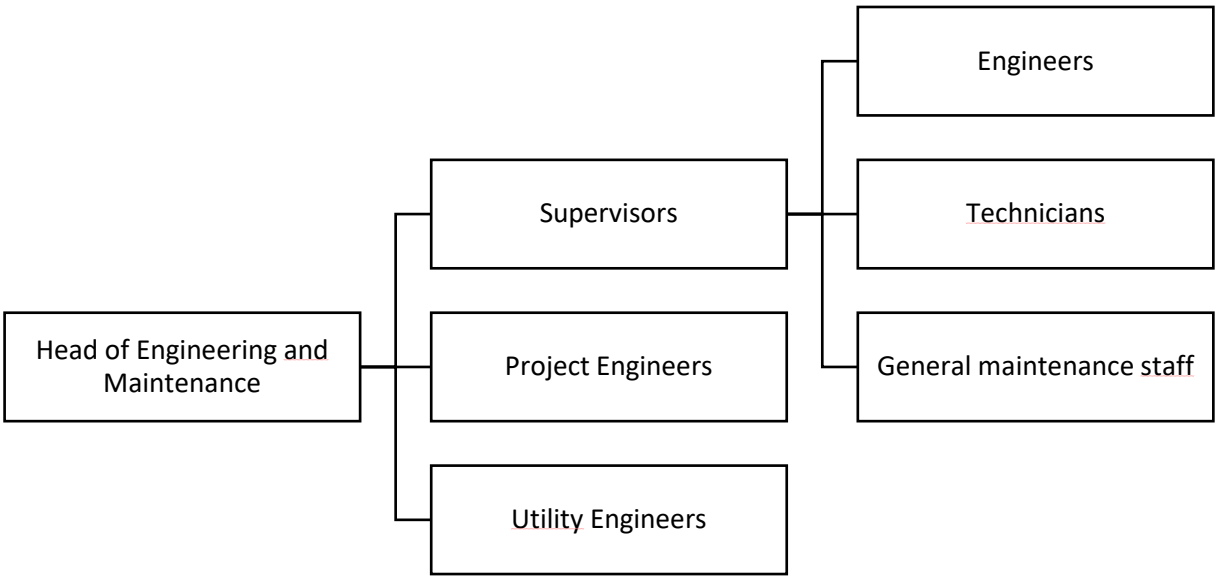
27.9 Engineering

The Engineering and Maintenance Department is responsible for ensuring the reliability, efficiency, and safety of the plant's equipment, facilities, and utilities. This department plays a critical role in supporting production operations, minimizing downtime, and ensuring compliance with regulatory standards. Below is a detailed explanation of how the Engineering and Maintenance Department is proposed to be organized.

27.9.1 Organizational Structure

The Engineering and Maintenance Department is led by a Head of Engineering, who oversees the entire department and ensures that all equipment and facilities are functioning optimally. Reporting to the Manager are Engineering Supervisors and Maintenance Supervisors, who lead teams of engineers, technicians, and maintenance staff. The department also includes Project Engineers, who handle capital projects and facility upgrades, and Utility Engineers, who manage the plant's utilities such as HVAC, water systems, and electrical systems. This structure ensures that all engineering and maintenance activities are well-coordinated and aligned with the plant's operational needs.

Figure 27.7 Engineering and Maintenance Department Proposed Organisational Structure



27.9.2 Preventive Maintenance

The preventive maintenance team is responsible for implementing and managing maintenance schedules to prevent equipment failures and ensure uninterrupted production. They conduct regular inspections, lubrication, and servicing of machinery and equipment based on manufacturer recommendations and operational requirements. The team also maintains detailed records of maintenance activities, including work orders, inspection reports, and equipment histories. By proactively addressing potential issues, this team helps minimize downtime, extend equipment lifespan, and maintain production efficiency.

400 | Feasibility Studies Report

27.9.3 Corrective Maintenance

The corrective maintenance team handles repairs and troubleshooting when equipment malfunctions or breaks down. They respond quickly to maintenance requests, diagnose issues, and perform necessary repairs to restore equipment functionality. The team also investigates the root causes of failures and implements corrective actions to prevent recurrence. By addressing equipment issues promptly, this team helps minimize production disruptions and ensure operational continuity.

27.9.4 Facility and Utility Management

The facility and utility management team oversees the maintenance and operation of the plant's infrastructure and utilities, such as HVAC systems, water purification systems, electrical systems, and compressed air systems. They ensure that these systems are functioning efficiently and comply with regulatory standards. The team also monitors energy consumption and implements energy-saving measures to reduce costs. By maintaining reliable utilities, this team supports the plant's production activities and ensures a safe working environment.

27.9.5 Capital Projects and Upgrades

The capital projects and upgrades team is responsible for planning and executing major projects, such as facility expansions, equipment upgrades, and new installations. Project Engineers work closely with other departments to define project requirements, develop budgets, and manage timelines. They also coordinate with contractors and vendors to ensure that projects are completed on time and within budget. By implementing capital projects, this team helps modernize the plant's infrastructure and enhance its production capabilities.

27.9.6 Calibration and Validation

The calibration and validation team ensures that all critical equipment and instruments are calibrated and validated to meet regulatory and operational standards. They develop calibration schedules, perform calibration activities, and maintain calibration records. The team also conducts validation studies to ensure that equipment and processes are consistent and reproducible. By ensuring accuracy and reliability, this team supports product quality and regulatory compliance.

27.9.7 Safety and Compliance

The safety and compliance team ensures that all engineering and maintenance activities adhere to safety regulations and GMP standards. They conduct risk assessments, implement safety protocols, and provide training on workplace safety. The team also ensures that maintenance activities are documented and comply with regulatory requirements. By prioritizing safety and compliance, this team helps create a safe and compliant work environment.

27.9.8 Spare Parts and Inventory Management

The spare parts and inventory management team is responsible for managing the inventory of spare parts and maintenance supplies. They maintain a database of spare parts, monitor stock levels, and reorder supplies as needed. The team also ensures that critical spare parts are readily available to minimize downtime during equipment repairs. By optimizing inventory management, this team helps reduce costs and improve maintenance efficiency.

27 Departments organization

27.9.9 Training and Development

The training and development team ensures that engineering and maintenance staff are well-trained and competent in their roles. They develop training programs on topics such as equipment operation, maintenance procedures, and safety protocols. The team also conducts regular assessments to ensure that employees maintain their skills and knowledge. By investing in employee development, this team helps improve productivity, safety, and compliance.

27.9.10 Technology and Automation

The Engineering and Maintenance Department leverages technology and automation to enhance efficiency and accuracy in maintenance activities. This includes the use of Computerized Maintenance Management Systems (CMMS) to schedule and track maintenance tasks, as well as predictive maintenance tools that use sensors and data analytics to monitor equipment condition. The department also implements automation technologies to streamline maintenance processes and reduce manual intervention. By adopting advanced technologies, the department improves maintenance efficiency, reduces downtime, and ensures compliance with regulatory standards.

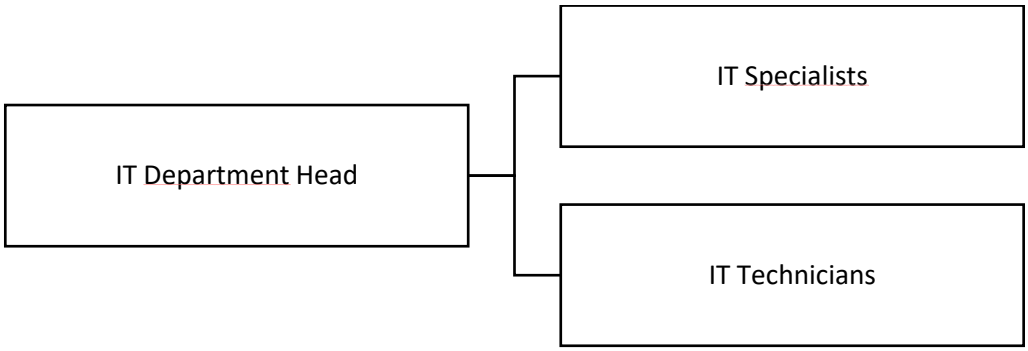
27.10 IT

The Information Technology (IT) department in a pharmaceutical plant is a crucial function responsible for managing the company's technology infrastructure, ensuring data security, and supporting business operations through digital solutions. This department plays a key role in enabling efficiency, compliance, and innovation across the organization. Below is a detailed explanation of how the IT department is organized and functions within a pharmaceutical plant, with each point rephrased as a paragraph.

27.10.1 Organisational Structure

At the top is the Head of IT, who oversees the entire department and aligns IT strategies with the company's business objectives. Reporting to the head are IT Team Leads or Supervisors, who manage teams such as network administration, software development, cybersecurity, and technical support. The department also includes IT Specialists and Technicians, who handle day-to-day IT operations and user support. This structure ensures that all IT functions are effectively managed and integrated into the company's operations.

Figure 27.8 IT Department Proposed Organisational Structure



402 | Feasibility Studies Report

27.10.2 Network and Infrastructure Management

The network and infrastructure management team is responsible for maintaining the plant's IT infrastructure, including servers, routers, switches, and communication systems. They ensure that the network is reliable, secure, and capable of supporting the plant's operations. The team also manages cloud-based systems and on-premises data centres, ensuring seamless connectivity and data accessibility. By maintaining a robust IT infrastructure, this team supports the plant's operational efficiency and scalability.

27.10.3 Software Development and Management

The software development and management team focuses on developing, implementing, and maintaining software applications that support the plant's operations. This includes Enterprise Resource Planning (ERP) systems, Manufacturing Execution Systems (MES), and Laboratory Information Management Systems (LIMS). The team works closely with other departments to understand their needs and develop customized solutions. By providing reliable and user-friendly software, this team helps streamline processes and improve productivity.

27.10.4 Cybersecurity and Data Protection

The cybersecurity and data protection team is responsible for safeguarding the plant's digital assets and ensuring compliance with data protection regulations. They implement security measures such as firewalls, encryption, and multi-factor authentication to protect against cyber threats. The team also conducts regular security audits, vulnerability assessments, and employee training to promote a culture of cybersecurity. By ensuring data security, this team helps protect the company's reputation and regulatory compliance.

27.10.5 Technical Support and Helpdesk

The technical support and helpdesk team provides assistance to employees for IT-related issues, such as hardware malfunctions, software problems, and network connectivity. They respond to support requests, troubleshoot issues, and ensure that employees have the tools and resources they need to perform their jobs effectively. The team also maintains an inventory of IT assets, such as computers, printers, and mobile devices. By offering timely and efficient support, this team helps minimize downtime and maintain productivity.

27.10.6 IT Compliance and Validation

The IT compliance and validation team ensures that all IT systems and processes comply with regulatory requirements, such as Good Manufacturing Practices (GMP) for electronic records and signatures. They conduct validation studies to ensure that IT systems are reliable, consistent, and secure. The team also maintains documentation and prepares for regulatory audits. By ensuring compliance, this team helps the company meet regulatory standards and avoid penalties.

27.10.7 Data Management and Analytics

The data management and analytics team is responsible for managing the plant's data assets and leveraging data to drive decision-making. They design and maintain databases, ensuring data accuracy and accessibility. The team also develops analytics tools and dashboards to provide insights into production performance, quality metrics, and business trends. By enabling data-driven decision-making, this team supports operational efficiency and strategic planning.

27 Departments organization

27.10.8 Project Management and Implementation

The project management and implementation team oversees IT projects, such as system upgrades, software implementations, and infrastructure expansions. They work with stakeholders to define project requirements, develop timelines, and allocate resources. The team also coordinates with vendors and contractors to ensure that projects are completed on time and within budget. By managing IT projects effectively, this team helps the company adopt new technologies and improve its operations.

27.10.9 Training and User Support

The training and user support team ensures that employees are well-trained in using IT systems and tools. They develop training programs on topics such as software usage, cybersecurity best practices, and data management. The team also provides ongoing support to users, helping them adapt to new technologies and resolve issues. By empowering employees with IT knowledge, this team enhances productivity and reduces reliance on technical support.

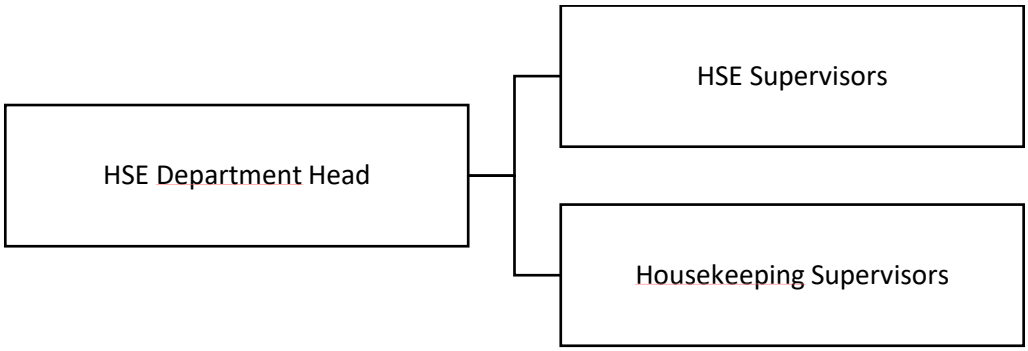
27.11 HSE

The Health, Safety, and Environment (HSE) department in a pharmaceutical plant is a critical function responsible for ensuring the safety of employees, protecting the environment, and ensuring compliance with health, safety, and environmental regulations. This department plays a key role in creating a safe and sustainable workplace while minimizing risks and environmental impact. Below is a detailed explanation of how the HSE department is organized and functions within a pharmaceutical plant, with each point rephrased as a paragraph.

27.11.1 Organisational Structure

The HSE department is typically led by the Head of HSE, who oversees the entire department and ensures that HSE strategies align with the company's business objectives. Reporting to the HSE Manager are HSE Supervisors or Coordinators, who lead teams responsible for safety, environmental compliance, and occupational health as well as housekeeping. The department also includes HSE Officers and Technicians, who handle day-to-day activities such as inspections, training, and incident investigations. This structure ensures that all HSE functions are effectively managed and integrated into the company's operations.

Figure 27.9 HSE Department Proposed Organisational Structure



404 | Feasibility Studies Report

27.11.2 Occupational Health and Safety

The occupational health and safety team focuses on ensuring a safe working environment for employees. They conduct risk assessments, implement safety protocols, and monitor compliance with occupational health and safety regulations. The team also investigates workplace incidents, identifies root causes, and implements corrective actions to prevent recurrence. By promoting a culture of safety, this team helps reduce workplace accidents and injuries.

27.11.3 Environmental Management

The environmental management team is responsible for minimizing the plant's environmental impact and ensuring compliance with environmental regulations. They monitor waste management, emissions, and energy consumption, implementing measures to reduce the plant's carbon footprint. The team also conducts environmental audits and prepares reports for regulatory authorities. By prioritizing sustainability, this team helps the company meet its environmental goals and regulatory obligations.

27.11.4 Emergency Preparedness and Response

The emergency preparedness and response team develops and implements plans to handle emergencies such as fires, chemical spills, and natural disasters. They conduct regular drills and training sessions to ensure that employees are prepared to respond effectively in case of an emergency. The team also coordinates with external agencies, such as fire departments and emergency medical services, to ensure a swift and coordinated response. By being prepared for emergencies, this team helps protect employees, assets, and the environment.

27.11.5 Regulatory Compliance

The regulatory compliance team ensures that the plant adheres to all relevant health, safety, and environmental regulations. They stay updated on changes in regulations and implement necessary changes to maintain compliance. The team also handles documentation and reporting, such as maintaining safety records and submitting required reports to regulatory authorities. By ensuring compliance, this team helps the company avoid legal penalties and maintain its reputation.

27.11.6 Training and Awareness

The training and awareness team is responsible for educating employees on health, safety, and environmental practices. They develop training programs on topics such as hazard identification, emergency response, and environmental stewardship. The team also conducts awareness campaigns to promote a culture of safety and sustainability. By empowering employees with knowledge, this team helps reduce risks and improve compliance.

27.11.7 Incident Investigation and Analysis

The incident investigation and analysis team investigates workplace incidents, such as accidents, near-misses, and environmental spills. They identify root causes, analyse trends, and implement corrective actions to prevent recurrence. The team also maintains incident records and shares lessons learned with employees. By addressing incidents proactively, this team helps improve workplace safety and prevent future occurrences.

27 Departments organization

27.11.8 Risk Assessment and Management

The risk assessment and management team identifies and evaluates risks related to health, safety, and the environment. They develop risk management plans, implement control measures, and monitor their effectiveness. The team also conducts regular risk assessments to ensure that new risks are identified and managed promptly. By managing risks effectively, this team helps create a safer and more sustainable workplace.

27.11.9 Waste Management

The waste management team oversees the proper handling, storage, and disposal of waste generated by the plant. They ensure compliance with waste management regulations and implement recycling and waste reduction initiatives. The team also coordinates with waste disposal contractors to ensure that waste is disposed of safely and responsibly. By managing waste effectively, this team helps minimize the plant's environmental impact.

27.11.10 Sustainability Initiatives

The sustainability initiatives team focuses on implementing programs to enhance the plant's sustainability. This includes initiatives such as energy efficiency projects, water conservation, and green building practices. The team also monitors the plant's sustainability performance and sets goals for continuous improvement. By promoting sustainability, this team helps the company achieve its environmental and social responsibility objectives.

27.11.11 Housekeeping

Housekeeping is a critical function that ensures cleanliness, hygiene, and compliance with regulatory standards such as Good Manufacturing Practices (GMP). Proper organization of housekeeping is essential to maintain product quality, prevent contamination, and ensure a safe working environment. The housekeeping team is proposed to be structured and function as outlined below.

27.11.11.1 Dedicated Housekeeping Team

A specialized housekeeping team is assigned to manage cleaning and sanitation activities. This team is trained in GMP, safety protocols, and the use of cleaning agents and equipment. The team may be divided into shifts to ensure 24/7 coverage, especially in facilities operating around the clock.

27.11.11.2 Standard Operating Procedures

Housekeeping activities are governed by detailed SOPs that outline cleaning schedules, methods, and responsibilities. SOPs cover areas such as cleaning of production areas, equipment, and utilities, waste disposal procedures, cleaning validation and documentation, handling of spills or contamination incidents.

27.11.11.3 Zoning and Classification

The plant is divided into zones based on cleanliness requirements:

- Critical Areas: Cleanrooms and aseptic areas where sterile products are manufactured. These require the highest level of cleaning and disinfection.
- Controlled Areas: Areas where non-sterile products are handled. These have moderate cleaning requirements.

406 | Feasibility Studies Report

- General Areas: Offices, corridors, and restrooms. These have standard cleaning requirements.

The cleaning frequency and methods vary depending on the zone classification.

27.11.11.4 Cleaning Schedules

- Daily Cleaning: Routine cleaning of floors, walls, and equipment in production areas.
- Periodic Cleaning: Deep cleaning of hard-to-reach areas, HVAC systems, and utilities.
- Post-Production Cleaning: Cleaning after each batch or production run to prevent cross-contamination.
- Emergency Cleaning: Immediate response to spills or contamination incidents.

27.11.11.5 Use of Approved Cleaning Agents and Tools

- Only approved cleaning agents (e.g., disinfectants, detergents) that are validated for use in pharmaceutical environments are employed.
- Cleaning tools (e.g., mops, wipes, vacuum cleaners) are color-coded or labelled to prevent cross-contamination between areas.
- Dedicated tools are used for critical areas to avoid introducing contaminants.

27.11.11.6 Documentation and Record-Keeping

All housekeeping activities are documented to ensure traceability and compliance with GMP. Records include:

- Cleaning logs.
- Validation reports for cleaning procedures.
- Incident reports for spills or contamination.

Documentation is regularly audited to ensure adherence to standards.

27.11.11.7 Training and Compliance

Housekeeping staff receive regular training on:

- GMP requirements.
- Safety protocols for handling cleaning chemicals.
- Proper use of personal protective equipment (PPE).
- Compliance with regulatory standards is monitored through internal and external audits.

27.11.11.8 Integration with Quality Assurance (QA)

The housekeeping team works closely with the QA department to:

- Validate cleaning procedures.
- Investigate and resolve contamination issues.
- Ensure that cleaning practices meet regulatory requirements.

27.12 Quality Assurance

The Quality Assurance (QA) department has the important function of ensuring that all products meet the required quality standards and comply with regulatory requirements such as Good Manufacturing Practices (GMP). This department plays a key role in maintaining product quality,

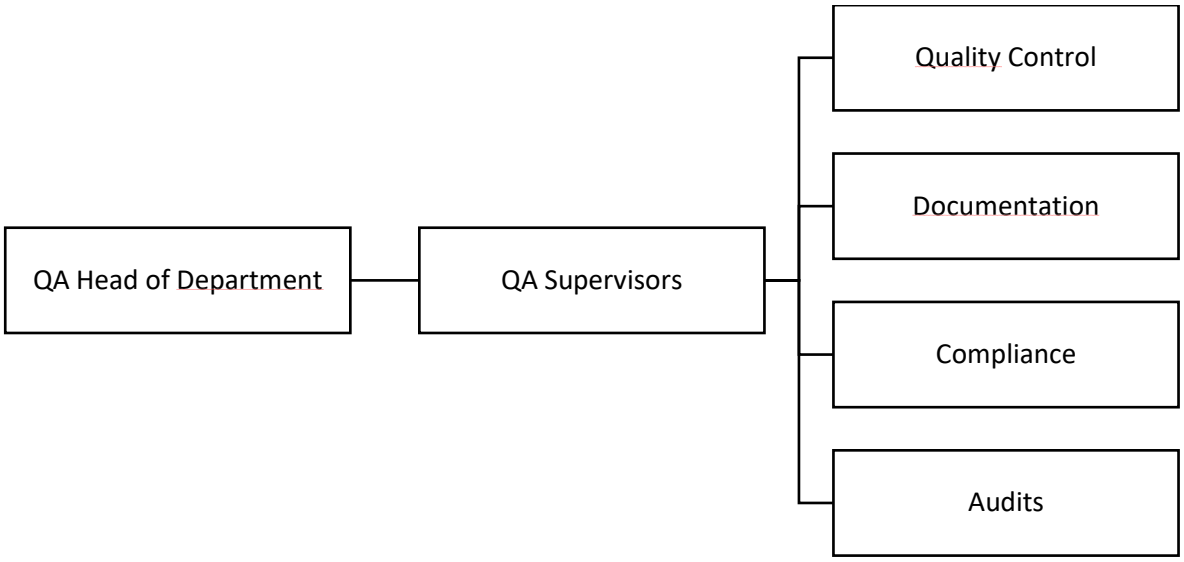
27 Departments organization

ensuring patient safety, and supporting regulatory compliance. Below is a detailed explanation of how the QA department is proposed to be organized.

27.12.1 Organizational Structure

The QA department falls under the responsibility of Head of Quality Assurance, who oversees the entire department and ensures that quality strategies align with the company's business objectives. Reporting to the QA Manager are QA Supervisors or Team Leads, who manage teams responsible for quality control, documentation, compliance, and audits. The department also includes QA Officers and Specialists, who handle day-to-day activities such as batch record reviews, deviation investigations, and quality risk assessments. This structure ensures that all QA functions are effectively managed and integrated into the company's operations.

Figure 27.10 QA Department Proposed Organisational Structure



27.12.2 Quality Control (QC) Oversight

The quality control oversight team works closely with the QC department to ensure that all raw materials, in-process samples, and finished products meet the required specifications. They review QC test results, ensure that testing methods are validated, and verify that equipment is properly calibrated. The team also investigates out-of-specification results and implements corrective actions. By maintaining rigorous quality standards, this team helps ensure that products are safe, effective, and consistent.

27.12.3 Documentation and Record-Keeping

The documentation and record-keeping team is responsible for maintaining accurate and comprehensive records of all quality-related activities. This includes batch records, standard operating procedures, and quality control test results. The team ensures that all documentation complies with regulatory requirements and is readily available for audits. By maintaining detailed records, this team supports traceability, accountability, and compliance.

408 | Feasibility Studies Report

27.12.4 Compliance and Regulatory Affairs

The compliance and regulatory affairs team ensures that the plant adheres to all relevant regulatory requirements, such as GMP, FDA regulations, and international standards. They stay updated on changes in regulations and implement necessary changes to maintain compliance. The team also handles regulatory submissions, such as drug applications and annual reports, and prepares for regulatory inspections. By ensuring compliance, this team helps the company avoid legal penalties and maintain its reputation.

27.12.5 Audits and Inspections

The audits and inspections team conducts internal audits to assess the effectiveness of the plant's quality systems and identify areas for improvement. They also prepare for and support external audits and inspections by regulatory authorities. The team ensures that audit findings are addressed promptly and that corrective actions are implemented. By maintaining a robust audit program, this team helps ensure continuous improvement and regulatory compliance.

27.12.6 Deviation and CAPA Management

The deviation and CAPA (Corrective and Preventive Actions) team investigates deviations from established procedures and implements corrective and preventive actions to address root causes. They ensure that deviations are documented, analysed, and resolved in a timely manner. The team also monitors the effectiveness of CAPA to prevent recurrence of issues. By managing deviations and CAPA effectively, this team helps maintain product quality and compliance.

27.12.7 Quality Risk Management

The quality risk management team identifies and evaluates risks related to product quality and compliance. They develop risk management plans, implement control measures, and monitor their effectiveness. The team also conducts regular risk assessments to ensure that new risks are identified and managed promptly. By managing risks effectively, this team helps ensure product quality and patient safety.

27.12.8 Validation and Qualification

The validation and qualification team is responsible for ensuring that all processes, equipment, and systems are validated and qualified to meet regulatory and operational standards. They develop validation protocols, conduct validation studies, and maintain validation records. The team also ensures that changes to processes or equipment are properly validated. By ensuring validation and qualification, this team helps maintain product quality and compliance.

27.12.9 Training and Development

The training and development team ensures that employees are well-trained in quality-related topics, such as GMP, SOPs, and quality risk management. They develop training programs, conduct training sessions, and assess employee competency. The team also promotes a culture of quality and continuous improvement. By investing in employee development, this team helps improve quality and compliance.

27.12.10 Supplier and Vendor Quality Management

The supplier and vendor quality management team ensures that all suppliers and vendors meet the company's quality standards. They conduct supplier audits, review supplier documentation, and

27 Departments organization

monitor supplier performance. The team also ensures that raw materials and components meet the required specifications. By managing supplier quality, this team helps ensure the quality of the final product.

410 | Feasibility Studies Report

28 Implementation

28.1 Introduction

The establishment of the Quintex plant will require a well-structured HR strategy to ensure the successful recruitment, development, and retention of a skilled workforce. The strategy below will cover both the pre-operational phase (planning and setup) and the operational phase (ongoing management).

28.2 Pre-operational HR strategy

28.2.1 Workforce Planning and Talent Mapping

The first step in the HR strategy is to conduct a detailed workforce needs assessment to determine the number and types of roles required for the plant. This includes positions in production, quality assurance, engineering, and administration. Identifying critical roles that need to be filled early, such as plant managers, regulatory affairs specialists, and quality assurance leads, is essential.
As the availability of skilled and trained staff is sometimes challenging, international experts should be considered (if budget permits). Also, with an eye on the future, mapping the local talent pool, including universities, technical institutes, and existing pharmaceutical companies, will help identify potential recruitment sources and build a strong talent pipeline.

28.2.2 Recruitment and Hiring

A robust recruitment strategy should be developed to attract both local and international talent. For senior and specialized roles, hiring expatriates or Ghanaians with international experience may be necessary. Partnering with local educational institutions to recruit fresh graduates and offering internships or apprenticeships can help build a talent pipeline. Multiple recruitment channels, such as job portals, social media, and recruitment agencies, should be utilized to attract a diverse pool of candidates. Ensuring that hiring processes are transparent, fair, and aligned with Ghanaian labour laws is critical for building trust and credibility.

28.2.3 Training and Development

A comprehensive training program should be designed to equip new hires with the skills needed to operate in a GMP-compliant environment. This includes technical training, safety protocols, and regulatory compliance. Partnering with international pharmaceutical companies or consultants can provide specialized training for key roles. In this case, it seems GL Rapha can be the preferred partner for Quintex. Additionally, a leadership development program should be established to prepare local employees for managerial and supervisory positions, ensuring long-term sustainability and growth.

28.2.4 Compensation and Benefits

Conducting a market survey to benchmark salaries and benefits against local and international pharmaceutical companies is essential. A competitive compensation package should be designed, including base salary, performance-based incentives, health insurance, and retirement benefits. For expatriates or employees relocating from other regions, offering relocation assistance and housing

Feasibility Studies Report | 411

28 Implementation

allowances will help attract and retain top talent. All these proposals will remain depending on the operational start capital.

28.2.5 Compliance with Labour Laws

Ensuring that all HR policies and practices comply with Ghanaian labour laws is a top priority. This includes employment contracts, working hours, and employee rights. Registering the company with relevant regulatory bodies, such as the Social Security and National Insurance Trust (SSNIT), and ensuring compliance with tax regulations will help avoid legal issues and build a positive reputation.

28.2.6 Organizational Culture and Employer Branding

Defining the company's mission, vision, and values will create a strong organizational culture that aligns with the pharmaceutical industry's focus on quality and patient safety. Developing an employer branding strategy to position the company as an employer of choice in Ghana is crucial. Highlighting opportunities for career growth, training, and working in a state-of-the-art facility will attract top talent.

28.2.7 Health, Safety, and Environment (HSE)

Establishing an HSE framework to ensure a safe and healthy work environment is essential. This includes developing safety protocols, conducting risk assessments, and providing safety training. Setting up an employee wellness program that includes health screenings, mental health support, and fitness initiatives will promote employee well-being and productivity.

28.3 Operational Phase HR Strategy

28.3.1 Onboarding and Integration

A structured onboarding program should be developed to help new hires integrate into the company culture and understand their roles and responsibilities. Assigning mentors or buddies to new employees will provide guidance and support during the initial months, ensuring a smooth transition and faster productivity.

28.3.2 Performance Management

Implementing a performance management system that includes regular performance reviews, goal setting, and feedback sessions is essential. Linking performance evaluations to rewards and career development opportunities will motivate employees and drive high performance.

28.3.3 Employee Engagement and Retention

Conducting regular employee engagement surveys will help gather feedback and identify areas for improvement. Implementing initiatives to boost employee morale, such as recognition programs, team-building activities, and career development opportunities, will enhance retention. Offering continuous learning opportunities, such as workshops, certifications, and online courses, will help employees grow in their roles and stay engaged.

412 | Feasibility Studies Report

28.3.4 Succession Planning

Identifying high-potential employees and developing succession plans for key roles will ensure business continuity. Providing leadership training and mentorship to prepare employees for future leadership positions will build a strong leadership pipeline.

28.3.5 Community Engagement

Building strong relationships with the local community through corporate social responsibility (CSR) initiatives, such as health camps, educational programs, and environmental projects, will enhance the company's reputation. Partnering with local schools and universities to provide scholarships, internships, and training programs will support talent development and community growth.

28.3.6 Technology and HR Systems

Implementing HR technology solutions, such as Human Resource Information Systems (HRIS), will streamline HR processes, including payroll, attendance, and performance management. Using data analytics to track key HR metrics, such as employee turnover, training effectiveness, and recruitment efficiency, will support data-driven decision-making.

28.4 Key Success Factors

The key success factors for the successful establishment of the new Quintex Sterile Injectables Plant are:

- Local Talent Development: Focusing on building local talent will reduce reliance on expatriates and ensure long-term sustainability.
- Regulatory Compliance: Ensuring that all HR practices comply with Ghanaian labour laws and international pharmaceutical standards is critical.
- Employee-Centric Approach: Prioritizing employee well-being, engagement, and development will build a motivated and productive workforce.
- Partnerships: Collaborating with educational institutions, industry associations, and government bodies will support talent development and regulatory compliance.

29 Conclusion

29.1 Final Reflections

This feasibility study presents a comprehensive, data-driven, and multidisciplinary assessment of the strategic, technical, financial, and environmental viability of establishing a sterile injectable manufacturing plant in Akuse, Ghana, for Quintex Pharma Ltd. Developed through the collaborative efforts of AMPC International Health Consultants, IQVIA, and PricewaterhouseCoopers Ghana, the study validates that the proposed facility is not only financially sound but also of strategic importance to Ghana's pharmaceutical ecosystem and the wider West African region.

With Ghana currently importing over 70% of its pharmaceuticals and facing frequent challenges in medicine security, the proposed facility will fill a significant supply gap—particularly in sterile injectables, a product category with high clinical demand and limited local production capacity. The project aligns with the Ghanaian government's Ten-Point Industrial Transformation Plan and JET Programme, which prioritize pharmaceutical manufacturing as a national development pillar.

29.2 Key Confirmations

The study affirms several crucial points:

- Market Demand: There is strong and sustained demand for injectable pharmaceuticals in Ghana and ECOWAS countries, with projected annual growth driven by increased healthcare access, demographic trends, and government prioritization of universal health coverage.
- Technical Feasibility: The proposed facility meets international GMP standards and includes state-of-the-art cleanroom infrastructure, automated filling lines, and robust quality control systems, ensuring product safety and export competitiveness.
- Financial Viability: Multi-scenario financial modelling demonstrates favorable Net Present Value (NPV), Internal Rate of Return (IRR), and Debt Service Coverage Ratios (DSCR), with enhanced outcomes under optimized CAPEX and reduced operational expenditure assumptions.
- Regulatory Readiness: Ghana's FDA has reached WHO Maturity Level 3, and the ECOWAS Joint Assessment Procedure (JAP) and WHO Prequalification mechanisms present clear pathways for regional and global market access.
- Environmental and Social Sustainability: The project incorporates a comprehensive Environmental and Social Management Plan (ESMP), including robust waste management protocols, emissions controls, and community engagement mechanisms, ensuring compliance with both national regulations and IFC performance standards.
- Risk Management: Identified project risks—including supply chain bottlenecks, regulatory delays, and financial uncertainties—are met with targeted mitigation strategies, such as diversified sourcing, phased development, and stakeholder outreach.

414 | Feasibility Studies Report

29.3 Strategic Recommendations

To capitalize on the strong foundation established through this feasibility study, the following strategic actions are recommended:

- Formalize Strategic Partnerships: Secure a joint venture agreement with a technical and commercial partner to bring global expertise, facilitate technology transfer, and ensure quality assurance.
- Engage Investors and DFIs: Present the financial and impact potential of the project to local and international investors, particularly development finance institutions (DFIs) that prioritize industrial health infrastructure in Africa.
- Initiate Regulatory Applications: Begin the plant and product registration processes with the Ghana FDA, while simultaneously preparing for WHO and ECOWAS market authorizations.
- Implement Governance and HR Readiness: Establish a capable management structure and initiate recruitment for key technical and operational staff, supported by training and onboarding aligned with international standards.
- Mobilize Construction and Procurement: Launch the construction phase with priority on cleanroom buildout and critical equipment procurement, leveraging the finalized facility layout and workflow plans.
- Expand Stakeholder Engagement: Continue meaningful engagement with public authorities, community leaders, and downstream health institutions to build trust and ensure alignment with national health goals.

29.4 Conclusion

In conclusion, this feasibility study provides Quintex Pharma and its prospective stakeholders with an unambiguous roadmap toward the successful establishment of a locally anchored, regionally competitive, and globally compliant sterile injectables plant in Ghana. The project not only enhances Ghana's pharmaceutical sovereignty but also supports job creation, industrial innovation, and regional healthcare resilience.

Positioned at the intersection of public health imperatives and industrial development, this initiative offers a compelling case for strategic investment. Quintex Pharma is thus well-placed to emerge as a flagship contributor to West Africa's pharmaceutical future.

Annexes

Annex I	List of Molecules
Annex II	Conceptual Facility Layout
Annex III	Sensitivity Analysis

416 | Feasibility Studies Report

Annex I
List of Products
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Annex II
Conceptual Layout
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Annex III
Sensitivity Analysis
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