cGMP COMPLIANCE FOR UNLOCKING MARKET ACCESS & GROWTH

An Industry Playbook

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Contents

INTRODUCTION

Ghana's pharmaceutical market is entering a pivotal new phase. As demand for high quality medicines rises across domestic, regional, and continental markets, there is a growing shift toward localised and continental production, contract manufacturing, and strategic partnerships.

Upholding current Good Manufacturing Practices (cGMP) is central to this growth. While many pharmaceutical manufacturers emphasize the importance of quality, it can be difficult to consistently demonstrate that commitment, sustain it under scrutiny, or translate it into a commercial advantage.

A cost benefit analysis of quality system investments by Nigerian manufacturers shows that well-sequenced GMP upgrades, when aligned to a viable product and market strategy, can deliver strong returns through access to larger and more diverse buyers, reduced internal failures, improved production efficiency, and lower regulatory disruption.

cGMP compliance also transforms how others perceive a firm: Investors view compliant facilities as bankable assets rather than investment risks, strengthening access to financing, technology transfer, and other opportunities.

The question facing Ghanaian manufacturers is no longer *whether* to invest in cGMP, but **how and when**. Those that move early can shape their strategic position and capture emerging opportunities. Those that delay risk finding that future markets have already moved on.

> **The impact of cGMP on a manufacturers' bottom line is immediate and sustainable. Improved compliance minimizes batch rejections, dramatically reduces expensive recalls and rework, ensures fewer disruptive regulatory interventions, and ultimately improves overall production efficiency and yield, while unlocking new private and public markets.**

Why this playbook

This playbook supports executive decision-making, not technical implementation. It is a tool for chief executive officers (CEOs), chief operating officers (COOs), and business development leads making critical strategic investment decisions and provides:

- A business-oriented roadmap for achieving and sustaining cGMP compliance
- Guidance on sequencing investments in people, systems, and facilities
- A structured framework for choosing between retrofit, brownfield, and greenfield facility strategies
- Practical insights from comparable African manufacturers

What is cGMP

cGMP refers to an integrated system of quality management, operational controls, and governance processes that ensures pharmaceutical products are consistently manufactured and controlled to

defined quality standards throughout their lifecycle.

cGMP compliance improves predictability, reduces risk, and unlocks growth opportunities across the pharmaceutical value chain. It is a continuous operating discipline that requires sustained management attention, investment, and accountability.

cGMP is **not** a one-time certification, a checklist for inspections, or a facility upgrade alone.

> **Increasing cGMP compliance and meeting international quality standards can help access new market opportunities, attract investment, and scale your business.**

Why cGMP now

cGMP is a fundamental requirement for competing in parts of the market that offer scale, price and volume stability, and better margins. As buyers and regulators raise expectations, quality and reliability often determine who wins contracts, secures partnerships, and scales beyond spot sales.

Early investment in cGMP reduces exposure to costly downstream risks, including recalls, market withdrawals, and lasting reputational damage that end-product testing alone cannot prevent.

In addition, regulatory shifts are occurring domestically. The Ghana Food and Drugs Authority (FDA) is tightening GMP enforcement with inspections, license downgrades, suspensions, and closures, and directing non-compliant manufacturers to remediate deficiencies.

At the same time, access to African Continental Free Trade Area (AfCFTA), emerging African pooled procurement mechanisms, and other initiatives like the Continental Listing of Human Medicinal Products with Positive Opinion, increasingly depends on cGMP compliance. Acting now creates a first-mover advantage.

BACKGROUND

The pharmaceutical market in sub-Saharan Africa is expanding fast, with forecasters predicting growth to reach US$32 billion by 2029. In Ghana alone, pharmaceutical sales reached approximately US$719 million in 2024 and analysts expect the market to continue to grow at a compound annual growth rate (CAGR) of 8.8 percent through 2029, reaching roughly US$1.1 billion.

Yet, despite this market growth, forecasts of pharmaceutical imports in Ghana totalled approximately US$521 million in 2025, with exports estimated at just US$16 million. This gap between market size, imports, and exports highlights that while demand is consistently high, the ability of local companies to manufacture reliably to standards that unlock import substitution, higher-value buyers, and regional supply opportunities remain a significant challenge.

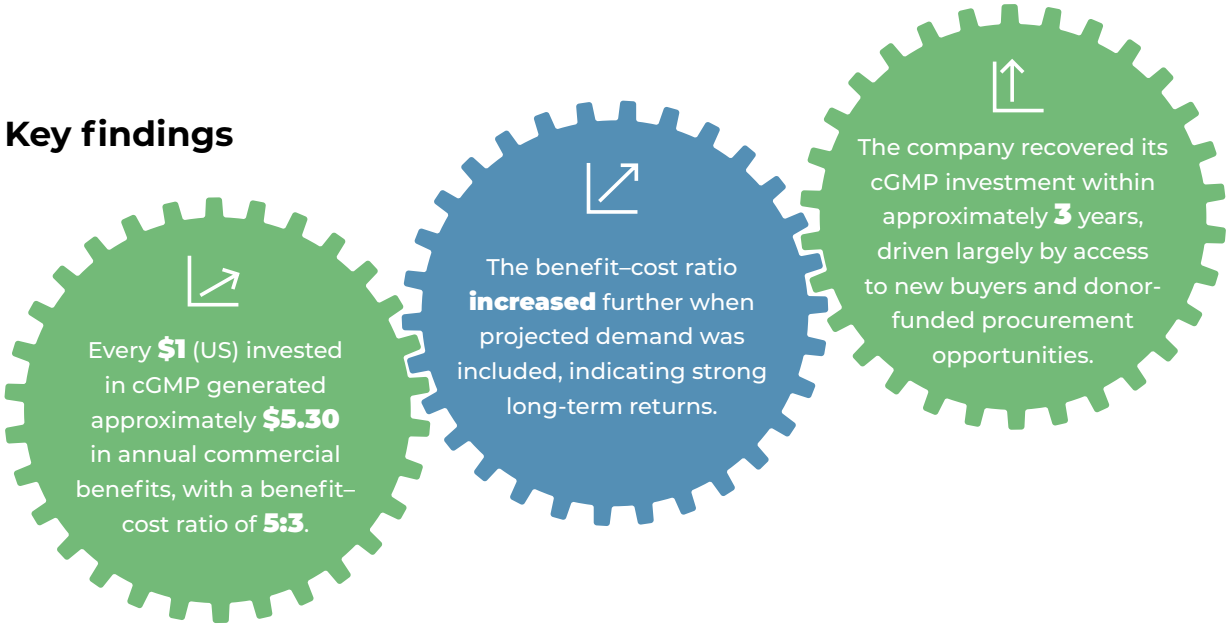
> **Why cGMP matters**
>
> **cGMP is a practical entry requirement for regulated and higher-value markets, including program-funded channels with large institutional buyers and regional supply arrangements. Firms that comply with cGMP can convert market growth into scale, partnerships, and competitiveness, while firms that don't face shrinking market opportunities.**

Box 1: cGMP investment can deliver high commercial returns

Manufacturers often view cGMP upgrades as a necessary cost rather than a business investment that requires alignment between technical and commercial leadership. However, evidence from comparable African manufacturers shows that investment in cGMP can generate strong and measurable financial returns when aligned with a viable product and market strategy.

A peer-reviewed cost–benefit analysis of a Nigerian pharmaceutical manufacturer assessed the full costs and benefits of upgrading facilities and quality systems to achieve World Health Organisation (WHO) cGMP certification for a priority paediatric product, zinc sulphate dispersible tablets.

Key findings



Practical lessons for manufacturers

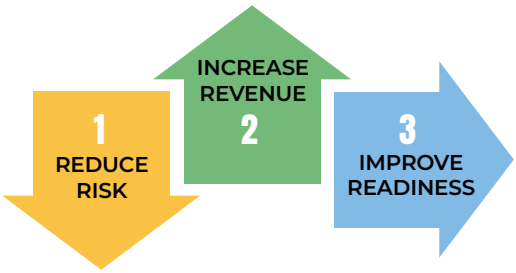
- cGMP investments deliver the highest returns when linked to a specific product and market opportunity, rather than undertaken in isolation.
- Products with clear public-sector or donor demand, like paediatric formulations or essential injectables, are more likely to generate rapid payback.
- Quality investments reduce not only regulatory risk, but also hidden operational costs associated with deviations, failed batches, and supply disruptions.
- cGMP compliance positions manufacturers for future partnerships, contract manufacturing, and technology transfer, creating upside beyond initial sales.

> **Manufacturers should assess cGMP upgrades not only in terms of upfront capital expenditure, but also by commercial value, risk reduction, and strategic optionality.**

cGMP: AN ACCELERATOR FOR YOUR BUSINESS

“If I invest in GMP, what do I actually get in return?”

cGMP compliance is an operating model that improves predictability, reduces risk, and unlocks growth opportunities across the pharmaceutical value chain. The business value of cGMP is best understood as three pillars: Risk, Revenue, and Readiness. Together, they demonstrate strategic growth and how cGMP can help transform your business, better positioning it to scale, innovate, and expand capabilities.



Pillar 1: Reduces business risk

cGMP reduces operational and regulatory unpredictability that stems from inconsistent product quality by strengthening process control and reliability, and helping detect quality issues early to prevent and contain problems before they become costly failures.

Action leaders can take this quarter

- Review quality KPIs monthly, including deviations, quality control complaints, and other quality management metrics.
- Avoid trade-offs between production vs quality by giving quality assurance teams final release authority and a clear escalation path to senior leadership.
- Prioritise solutions to root causes rather than quick fixes, trend repeat deviations and eliminate recurrence.
- Drive CAPA discipline with weekly tracking and escalate overdue actions to leadership.
- Tighten supplier control, qualify and re-qualify critical suppliers and strengthen incoming checks for high-risk materials.
- Link management incentives to quality by including quality and compliance metrics in management performance goals.

Weak cGMP leads to:

- Failed or delayed inspections
- Batch rejections, recalls, and market withdrawals
- Unplanned stoppages and emergency remediation costs

- Loss of credibility among regulators, buyers, and patients

Strong cGMP compliance leads to:

- Improved process controls and predictable outcomes
- Reduced likelihood and impact of adverse events
- Improved patient safety
- Better batch acceptance rates and improved deviation trends
- Reduced complaints and market recalls
- Access to bigger markets, including international tenders

Persistent under-performance on the indicators above signals latent compliance and business risk, even if an inspection is not imminent.

Buyer concerns and screening

For institutional and high-volume buyers, cGMP maturity is primarily a risk filter, not a value add. Weak cGMP increases the chance of non-delivery, post-award batch rejection, regulatory intervention mid-contract, and reputational exposure from quality failures. As a result, buyers often screen out suppliers with inconsistent quality performance before considering price or capacity.

Buyers typically review inspection history, including repeat findings; supply reliability; deviation trends and corrective and preventive action (CAPA) performance; and recall or market withdrawal history.

> **In practical terms, cGMP reduces commercial risk by making delivery outcomes more predictable, and defensible, for both manufacturer and buyer.**

Pillar 2: Increases revenue

While cGMP does not create demand, it increasingly determines **where** and **how** firms may sell their product. Without cGMP, manufacturers often operate in fragmented, low-scrutiny markets where they compete primarily on price and face volatile volumes. cGMP removes these structural constraints.

Actions leaders can take this quarter

- Select 3-5 stock keeping units (SKUs) where cGMP most directly unlocks larger buyers and stronger margins.
- Prioritise 2–3 buyer channels and document the minimum eligibility requirements for each.
- Prepare a tender readiness pack for priority SKUs, including product specs, quality and stability data, validation status, and supply plan.

cGMP improves access to:

- Government tenders
- Public, pooled, and donor-funded procurement
- Regional and cross-border markets
- Reliance and recognition pathways that reduce time to market
- Private sector institutional buyers, including large providers, employers, insurers, and corporate and NGO buyers

As regional frameworks like the West African Health Organization (WAHO) and African Medicines Agency (AMA) expand, cGMP will determine whether domestic manufacturers will supply regional markets.

cGMP unlocks commercial pathways to:

- Multi-year agreements and framework contracts, including long-term supply agreements
- Contract manufacturing for regional or multinational firms
- Technology transfer, licensing, and local production partnerships

While cGMP does not guarantee contract awards, it removes disqualifying barriers that otherwise cap growth regardless of price, capacity, or demand.

Pillar 3: Improves readiness

Beyond immediate sales and revenue, cGMP determines whether a manufacturer is operationally ready to grow without increasing risk. It is a practical test of a manufacturer's capability and operational integrity, demonstrating stable processes, effective quality oversight, and controlled change, with an ability to sustain performance as volume and complexity rise.

Actions leaders can take this quarter

- Launch a cGMP upgrade program with one accountable lead and a weekly leadership check-in to remove blockers and track progress.
- Define the scope (which products/lines first).
- Make "inspection basics" non-negotiable: current SOPs, complete training records, and only the latest approved documents in use on the shop floor.
- Produce evidence of control for priority lines/products: show equipment works as intended and the process consistently meets specifications.
- Maintain a single readiness evidence pack (gap list, CAPA log, training completion, validation status, key KPIs) that can be used with regulators, buyers, and financiers.

Readiness to scale and partner

Partners look for manufacturers that demonstrate compliance, reliable delivery at scale, and operational integrity. In the absence of these elements, partnerships will fail despite demand.

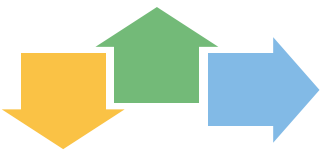
Readiness to finance

As business grows, revenues increase, and customers expand, manufacturers often need more working capital, trade finance, and capital expenditure (CapEx) financing. Firms with credible cGMP can access financing, negotiate improved terms, and attract strategic capital.

Readiness to export

cGMP strengthens readiness to enter new markets by aligning operations with expectations of foreign regulators and buyers. It reduces market entry friction by improving the credibility of dossiers, inspections, and supply performance, making cross-border growth more feasible and defensible.

Finally, cGMP protects enterprise value by reducing exposure to regulatory shocks as enforcement expectations tighten.



Main take-away

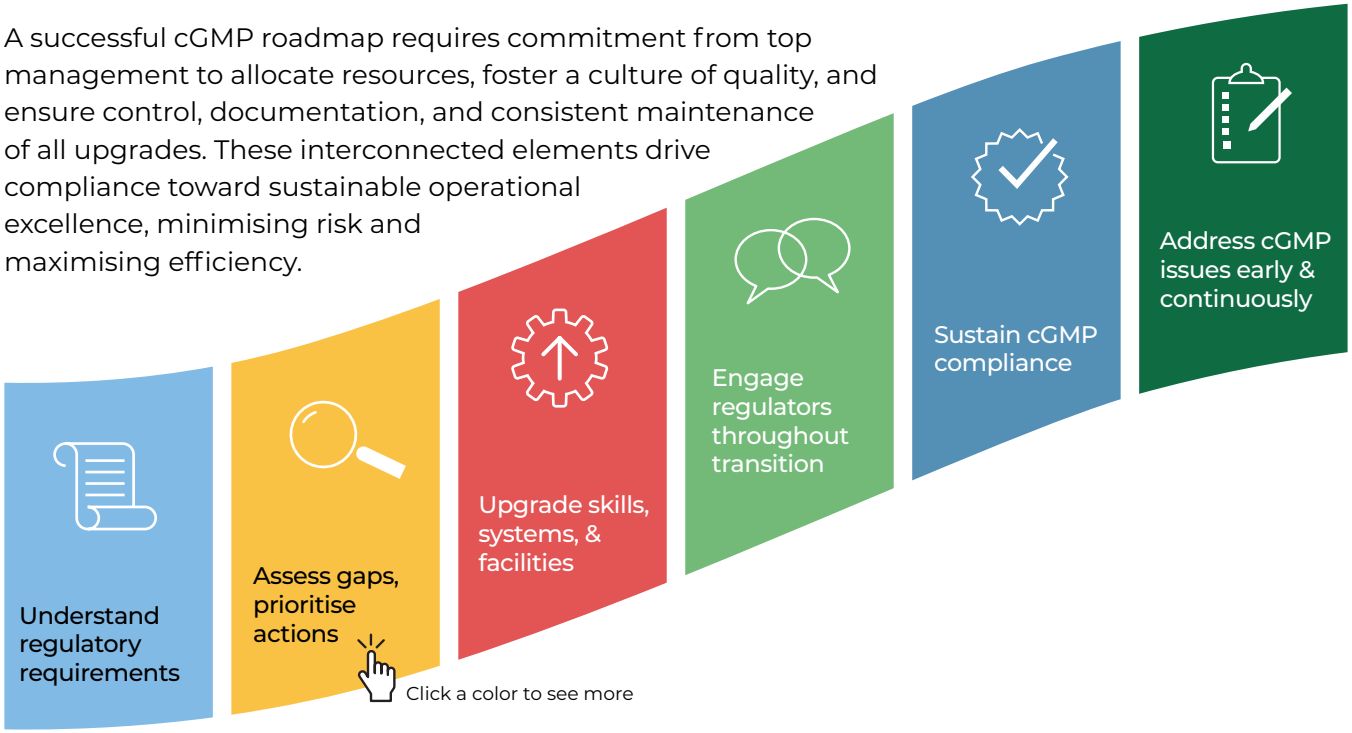
cGMP improves predictability, opens markets, and builds the credibility required to scale. When treated as a core commercial priority rather than a regulatory requirement, cGMP transforms into a powerful business accelerator, driving firm competitiveness, investment readiness, and growth.

ROADMAP TO cGMP COMPLIANCE

A practical guide

“What are the practical steps to reach cGMP compliance?”

A successful cGMP roadmap requires commitment from top management to allocate resources, foster a culture of quality, and ensure control, documentation, and consistent maintenance of all upgrades. These interconnected elements drive compliance toward sustainable operational excellence, minimising risk and maximising efficiency.



Step 1: Understand regulatory requirements

Ghana FDA provides oversight over pharmaceutical manufacturers, aligning cGMP requirements with WHO standards and providing routine inspections as part of licensing, product registration, and ongoing oversight.

Understanding regulatory requirements is not a one-time reading of guidelines; it is a repeatable management process to (1) interpret what the regulator requires, (2) translate it into internal controls and investments, and (3) keep the organization current as expectations evolve.

Who leads and supports

- Lead: Head of Quality/Quality Assurance (QA) Director (runs the process; maintains the requirements register)
- Supports: Regulatory Affairs, Production/Operations, Engineering/Maintenance, Supply Chain, HR/Training
- Executive sponsor: CEO/Managing Director (sets expectations and resources)

How to manage regulatory expectations: Practical actions

- Create a single requirements register. List applicable FDA GMP requirements and relevant WHO cGMP elements, mapped to your quality system (SOPs, records, facilities/utilities, validation, data integrity, vendor controls).
- Translate requirements into factory changes. For each high-risk area (documentation, deviations/CAPA, cleaning, utilities, QC lab, vendor qualification), define the specific behaviours, records, and controls expected.
- Stay current with evolving requirements. Define clear engagement channels, each with an assigned owner and review cadence, including:
  - **FDA communications** (circulars, guidance, inspection updates, and public notices) monitored by Regulatory Affairs/QA.
  - **Direct engagement** (pre-submission meetings, clarification requests, and inspection close-out learnings) coordinated by QA/Regulatory Affairs.
  - **Industry channels** (Pharmaceutical Manufacturers Association of Ghana (PMAG), peer forums) coordinated by an assigned core team members who tracks and communicates relevant updates to the requirements register, serving as an early-warning and interpretative layer.
- Run a quarterly review. Update the requirements register based on internal audits, deviations, supplier issues, and any recent inspection observations.
- Make it operational. Update SOPs and trainings and assign CAPAs with deadlines whenever a requirement change affects practice.

Step 2: Assess gaps and prioritise actions

A structured cGMP gap assessment aligned with Ghana FDA expectations underpins a credible upgrade plan. It helps define a site's current state and articulate what must change across the quality system, documentation, facilities and utilities, equipment, quality control (QC) laboratory controls, and staff capability.

A strong assessment goes beyond listing gaps; it rates risk and criticality, separates immediate fixes from sequenced, long-term actions, and converts findings into a practical remediation plan with owners, timelines, and costs.

Who leads and supports

- Lead: Head of Quality with Regulatory Affairs (conducts the assessment)
- Supports: Operations, QC, Engineering, Supply Chain/Warehouse, HR/Training
- Executive sponsor: CEO/Managing Director (sets expectations and resources)

How to conduct a gap assessment: Practical actions

Define scope and standard. Agree which lines or products are in scope, then assess with regulatory cGMP expectations.

- **Create a structured checklist**. Cover key cGMP domains, including QMS, documentation, data integrity, facilities, utilities, equipment maintenance and calibration, materials and suppliers, production, QC lab, validation and qualification, cleaning, complaints and recalls, change control.
- **Review evidence, not opinions**. Sample documents and records, including SOPs, batch records, deviations and CAPAs, trainings, calibration logs, environmental monitoring, QC records, and supplier qualification files.
- **Walk the process end-to-end**. Trace 1–2 products from receipt of materials → manufacturing → QC release → storage and distribution to identify where controls fail in practice.
- **Interview key roles**. Discuss what works or not across teams, including QA, Production, QC, Engineering, Warehouse, and Regulatory Affairs.
- **Rate each gap and identify root causes**. Classify gaps by severity, likelihood, effort, cost, and patient/regulatory risk to distinguish systemic issues like weak deviation and CAPA, poor document control, inadequate utilities, and weak supplier controls, from one-off fixes.
- **Translate findings into an action plan**. For each gap, define the CAPA, owner, which is often Operations/Engineering as well as QA, due date, resources, and how to verify effectiveness.
- **Create a prioritised roadmap**. Develop a short, sequenced plan (0–3 months, 3–6 months, and 6–12+ months) with budget ranges and dependencies.
- **Follow best practices**: Include an independent assessor (external GMP expert or peer auditor) to increase objectivity and credibility with financiers and partners.

Step 3: Upgrade skills, systems, and facilities

cGMP transformation requires early and sustained investments in people, as well as systems and facilities. Upgrades alone aren't enough; sustained compliance requires building skills, accountability, and discipline alongside infrastructure improvements.

Who leads and supports

- Lead: Head of Quality (QA Director) with Operations Lead (Site Head/Production Head) as co-lead for execution
- Supports: Regulatory Affairs, QC Lab Lead, Engineering/Maintenance & Utilities, Supply Chain/ Warehouse, HR/Training, Finance/Procurement
- Executive sponsor: CEO/MD (to resolve trade-offs, protect QA decision rights, and resource the program)

How to sequence upgrades: Practical actions

- ☑ **Start with workforce capability and leadership alignment.** Clarify decision rights and escalation pathways, including QA release authority; train management, supervisors and operators on cGMP requirements in *their* tasks; set day-to-day accountability (shift handovers, line checks, "stop-the-line" expectations).
- ☑ **Resolve quality management systems (QMS) issues next**. Fix the basics, including document control, deviations, CAPA quality and timeliness, change control, and data integrity. Ensure systems are usable by simplifying SOPs, standardising forms, and verifying trainings for practical application not just completion.
- ☑ **Upgrade facilities, utilities, and equipment**. Prioritise upgrades that drive cGMP risk, including flows and segregation, HVAC location, water systems, QC lab controls, and maintenance and calibration. Qualify equipment and utilities and validate processes for priority lines and products.
- ☑ **Provide ongoing supervision, coaching, and performance management**. To sustain compliance, introduce routine internal audits, performance reviews of quality KPIs, and supervisor coaching to reinforce correct behaviours. Track recurring deviations and drive root-cause fixes so problems do not return.
- ☑ **Address sterile operations, if in scope**. Develop a site-wide Contamination Control Strategy (CCS), run media fills, and define a PUPSIT (Pre-Use Post-Sterilisation Integrity Testing) strategy for sterilising filters, where applicable.

The exact sequencing depends on the Step 2 gap assessment, but the core principle is consistent: Do not defer workforce capability and operating discipline. Training alone is not enough; leaders must sustain compliance through clear roles, effective supervision, and accountability in daily work.

Audit & inspection readiness — what to keep “ready at all times”

- A single evidence pack: CAPA log and status, deviation trends, training completion, qualification and validation status, and the latest site layout and flows, where relevant.
- Controlled documents in use: current SOPs, batch records, cleaning logs, and QC methods available at point of use, removing obsolete versions.
- Two readiness checks: (1) a monthly internal spot-check on high-risk areas; and (2) a quarterly mock inspection on priority lines.
- Clear story for leadership: what changed, what risks remain, and how to control them, backed by evidence, not assurances.
- Fast retrieval discipline: define who pulls which documents during an inspection and run a short “document drill” periodically.

Step 4: Engage regulators throughout the transition

Regulatory engagement should be proactive and continuous, not limited to formal inspections. Early, transparent engagement helps manufacturers clarify expectations, test remediation plans, and reduce the risk of rework or adverse findings.

Who leads and supports

- Lead: Regulatory Affairs (or QA where Regulatory Affairs capacity is limited)
- Supports: QA, Engineering/Project Lead (for layouts/utilities), Production/Operations, QC, Documentation lead
- Executive sponsor: CEO/MD or Site Head (for timely decisions and consistent messaging)

How to facilitate regulatory engagement: Practical actions

- ☑ Agree on a clear engagement plan led by Regulatory Affairs/QA, including who meets, how often, and for what purpose.
- ☑ Share high impact changes early for feedback, including facility layouts and flows, utilities upgrades, and remediation plans for critical gaps.
- ☑ Use structured touchpoints, including pre-inspection or readiness meetings, technical consultations, and participation in FDA and industry workshops.
- ☑ Document and act on feedback, including capturing meeting outcomes, updating CAPAs and timelines, and communicating implications internally.

This approach reduces regulatory uncertainty, builds credibility, and keeps remediation aligned with compliance.

> **cGMP compliance is central to regulatory strengthening. It's not just a quality requirement, it's a roadmap for industry growth, global recognition, and sustained public health protection. Through strong collaboration between the FDA, pharmaceutical manufacturers, and key stakeholders, we are building a system that meets global standards and earns trust."**
>
> —Kwabena Frimpong-Manso Opuni
> Acting CEO, Ghana FDA

Step 5: Sustain cGMP compliance

Achieving cGMP compliance is just a starting point; sustaining it requires embedding cGMP into daily operations and leadership behaviour.

Who leads and supports

- Lead: Head of Quality (QMS owner)
- Supports: Operations leadership (Production/QC/Engineering), HR/Training, Supply Chain, Internal Audit/Compliance function (if present)
- Executive sponsor: CEO/MD and Senior Management Team (through routine management reviews and KPI oversight)

How to embed cGMP into processes: Practical actions

- ☑ Maintain robust documentation and data integrity practices
- ☑ Run regular internal audits with disciplined CAPA follow-up and effectiveness checks
- ☑ Continue training and competency management tied to role requirements
- ☑ Demonstrate visible leadership commitment through routine QMS management reviews and trending key KPIs, including deviation rates, cost of poor quality products, and recall and market withdrawal rates

A strong quality culture, where staff understand why cGMP matters and raise issues early without fear, is essential for long-term compliance. When leadership treats cGMP as a core business priority, systems stay effective, but when leaders provide mixed signals, compliance erodes over time.

Box 2: Building a quality culture

When quality culture is strong:

- Issues surface early and people report problems without fear
- Staff protects quality under pressure
- CAPAs prevent repeat issues
- Leaders prioritise quality data in daily operations, not just during inspections

When quality culture is weak:

- Informal workarounds become normal
- Issues escalate late or minimised
- Investigations are superficial
- CAPAs address symptoms, not root causes

Practical steps for leaders, managers, and employees

- Protect QA decision rights and escalation
- Fund and prioritise quality-critical work (training, maintenance, validation)
- Review quality trends monthly and make quality-informed decisions

- Conduct routine factory floor checks and correct behaviours in real time
- Contain and escalate deviations quickly; insist on root-cause investigations
- Follow CAPAs to closure and verify effectiveness

- Follow critical steps and document correctly the first time
- Raise abnormalities early and participate in investigations and improvements
- Maintain competence through refreshers and on-the-job coaching

Step 6: Address cGMP issues early and continuously

Effective deviation and issue management prevents small problems from becoming costly failures. Early detection and timely response reduce inspection risk, protect supply reliability, and build confidence with regulators and buyers.

Who leads and supports

- Lead: QA (Deviation/CAPA owner) with QC and Production as joint owners for investigations and corrective actions in their areas
- Supports: Engineering (utilities/equipment-related causes), Supply Chain (supplier/material issues), HR/Training (competency gaps), Regulatory Affairs (inspection follow-up and commitments)
- Executive sponsor: Site Head/CEO (to unblock recurring issues and ensure CAPAs are resourced and closed effectively)

How to facilitate continuous improvement: Practical actions

- ☑ Identify and document deviations as soon as they occur
- ☑ Investigate root causes thoroughly (not superficially)
- ☑ Implement CAPAs that address systems, not symptoms
- ☑ Track trends to prevent recurrence and escalate repeat issues

When manufacturers delay, minimise, or handle issues informally, regulatory findings accumulate, inspections become more difficult, and commercial risk increases. As a result, continuous issue management is not only a compliance requirement, but a core discipline for protecting performance and reputation.

STRATEGIC BUSINESS CHOICES:
RETROFIT VS BROWNFIELD VS GREENFIELD INVESTMENTS

“Which investment pathway fits our strategy—retrofit, brownfield, or greenfield?”

As manufacturers move toward cGMP compliance, the choice between **retrofitting existing facilities** and **investing in brownfield or greenfield capacity** is a strategic business decision with long-term implications, often driven by regulatory requirements.

- **Retrofit = modify existing production space**
- **Brownfield = develop new cGMP-compliant building on existing site**
- **Greenfield = build new site**

This investment choice shapes cost structure, regulatory risk, workforce needs, scalability, environmental performance, and critically, the ability to respond to evolving demand. As a result, facility decisions should consider current domestic sales, future regional demand, and the ability to pivot production when needed.

Manufacturers should base investment decisions on QMS maturity, the robustness of the qualification and validation approach, time to market, lifecycle economics of critical utilities, especially HVAC and pharmaceutical water systems, and the feasibility of reliance pathways (e.g., WHO and emerging regional mechanisms). Similarly, leaders should give equal attention to bankability, including whether investment size, structure, and risk profile can attract participation from Development Finance Institutions (DFI) or other strategic partners.

Key deciding factors for leaders

*Facility investment is often a **strategic business decision**, not a technical one.*

Cost and financing

Retrofit typically requires less upfront capital because it relies on existing buildings and infrastructure. However, retrofit projects risk hidden costs due to unforeseen structural limitations, redesign, and equipment integration challenges. Two design choices drive operating costs and compliance performance: HVAC sizing and control and pharmaceutical water systems.

Greenfield investments require higher upfront capital, but allow purpose-built cGMP layouts, optimised material and personnel flows, and modern utilities, often reducing inefficiencies and repeat remediation over time. Over a facility's lifecycle, greenfield projects can be more cost-effective if there is high utilisation and secure, viable financing.

Time to market

Retrofit delivers faster operational readiness where existing infrastructure is sound and upgrades are manageable, an advantage under compressed timelines.

Greenfield requires a longer pre-operational phase that includes site readiness, construction, commissioning, qualification and validation, and approvals, but offers greater stability once operational.

Workforce considerations

Retrofit leverages existing staff, but requires targeted upskilling and strong change management to replace legacy practices with cGMP discipline.

Greenfield enables a workforce model designed around modern quality systems and advanced operations, but recruitment, training, and retention add time and cost.

Scalability and adaptability

Retrofit legacy layouts may constrain expansion and often requires sequential upgrades.

Brownfield and greenfield facilities support modular expansion, multi-product lines, and validated changeovers, improving utilisation and resilience. Adaptability matters as much as volume; the ability to switch products reliably supports shifts in demand, procurement cycles, and regional needs.

Environmental and sustainability considerations

Retrofit reduces the construction footprint by reusing assets and lowering embodied carbon.	**Greenfield** has a higher initial footprint, but well-designed facilities can integrate energy efficient HVAC, water recycling, and renewable energy to improve long-term sustainability.

Product portfolio strategy

Retrofit works best for incremental additions of similar dosage forms within existing platforms, but struggles with major technology shifts, like moving from oral solids to sterile injectables.	**Greenfield** and well-designed **brownfield** support multi-platform capacity (e.g., small molecules and complex sterile products) and allow faster pivots to new technologies as disease burden and market needs evolve.

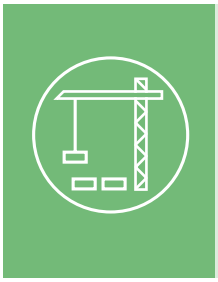
Decision guide: Retrofit vs greenfield vs brownfield

Choose retrofit when:

- Capital availability is limited
- Immediate capacity is required
- Existing facility supports compliant flows and utilities without major rework

Choose brownfield when:

- Moderate capital is available
- Reusing assets and expanding operations is preferable
- Medium to long-term scalability is a priority



Choose greenfield when:

- Regional supply and export ambitions take priority
- Diversifying product portfolio or changing technology are priority is preferable
- High sustainability standards are required
- Stronger production flexibility is needed

Overall **retrofit** often provides the fastest path to near-term continuity when capital constraints limit investment, *if* the existing site can support compliant flows, utilities, and validated operations without structural workarounds. Where it cannot, **brownfield** or **greenfield**—or **a phased combination**—tends to be the more prudent route for long-term competitiveness and export readiness.

See Annex 1 for a more detailed decision guide

Box 3: Lessons from Nigerian manufacturers

Three mid-sized pharmaceutical manufacturers in Nigeria, including Swiss Pharma Nigeria Ltd (Swipha), Emzor Pharmaceuticals, and Drugfield Pharmaceuticals initially upgraded cGMP compliance and expanded capacity by **retrofitting existing facilities**. As their portfolios grew and regional ambitions expanded, some firms adopted hybrid strategies, combining incremental retrofits with brownfield expansions, adding cGMP-compliant buildings on existing sites, pursuing selective greenfield investments, and strengthening quality systems.

Commercial impact of cGMP-driven investments

- Capacity growth: cGMP-aligned retrofit and brownfield upgrades increased production capacity by up to 50%, enabling reliable supply to large public health programmes.
- Priority product access: Upgraded facilities supported sustained production of sulfadoxine–pyrimethamine, cotrimoxazole, and chlorhexidine digluconate gel (3 g) for malaria, HIV, and maternal, neonatal, and child health programmes.
- New buyers and contracts: Compliance enabled supply to national disease programmes, procurement by UN agencies, including UN Office for Project Services (UNOPS), international wholesalers, and toll manufacturing for Sanofi Aventis.
- Regional market access: cGMP compliance unlocked multi-country marketing authorisations across Benin, Ghana, Burkina Faso, Côte d'Ivoire, Niger, Sierra Leone, and Liberia through harmonised regulatory pathways.
- Global procurement readiness: Continued quality investment resulted in WHO prequalification for essential dispersible formulations, enabling participation in donor-funded and international procurement markets.

What worked

- Retrofit enabled faster time to compliance and continuity of supply
- Incremental expansion supported public and donor-funded programmes
- Workforce continuity reduced transition risk
- Strong quality systems, not infrastructure alone, improved regulatory trust

Where retrofit reached its limits

- Repeated retrofit cycles increased cost and complexity
- Legacy layouts constrained scalability and portfolio diversification
- Utilities and zoning required frequent remediation
- Regulatory burden grew with each incremental expansion

What enabled regional expansion

- Early investment in quality systems and validation discipline
- Alignment with regional regulatory pathways
- Selective greenfield or brownfield investments to overcome structural constraints

Key lesson for manufacturers

Retrofit is an effective **entry and continuity strategy** for achieving cGMP compliance under capital constraints. However, manufacturers with regional ambitions or evolving product portfolios must plan early for **scalable and adaptable facilities**, often through phased or hybrid investment approaches. Infrastructure decisions deliver value only when paired with strong quality systems, skilled workforces, and sustained regulatory engagement.

Box 4: Product portfolio strategy and manufacturing design

Product portfolio decisions shape revenue potential, manufacturing risk, compliance, and competitiveness. Manufacturers should build portfolios around **evolving disease burdens** and **regional demand**, not just current sales, while accounting for seasonal cycles. Flexible manufacturing across products on the same production line at different times of year strengthens commercial resilience. Portfolio choices drive:

- Facility layout and zoning, including segregation, cleaning regimes, and changeover requirements
- Utility systems and equipment, such as HVAC capacity, dust control, and material handling
- Validation scope and workforce requirements, including cleaning validation, line clearance procedures, and operator competence

Manufacturers should design facilities and processes that support safe, validated product changeovers, allowing seasonal shifts, like for antimalarials, antibiotics, and paediatric formulations, without compromising cGMP compliance. Flexibility at the line level enables manufacturers to balance utilisation, respond to procurement cycles, and manage demand volatility.

Common mistakes and how to avoid them

Manufacturers often underestimate the operational implications of flexible manufacturing, including:

- Planning seasonal product shifts without validated cleaning and line clearance protocols, increasing cross-contamination risk. Before committing to seasonal shifts, confirm that your facilities, systems, and staff can support repeatable changeovers.
- Using the same line for multiple products without adequate segregation or documentation, leading to inspection findings. Similarly, before harnessing multi-product strategies, ensure facilities and staff support necessary changeovers.
- Overlooking workforce and supervision requirements for frequent changeovers, including training, checklists, and accountability. Remove any mismatches that may trigger repeated remediation, delayed approvals, and increased inspection scrutiny.
- Designing for peak demand only, resulting in idle capacity and inefficiency during off-season periods. Ensure appropriate designs for on- and off-peak operations to maximize efficiency.

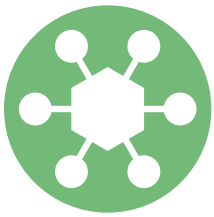
ENABLERS FOR cGMP SUCCESS

“Who can support our cGMP journey—and how do we access that support?”

As pharmaceutical manufacturers pursue cGMP compliance, success depends on strong execution and effective use of Ghana’s industry, policy, regulatory, and financing ecosystem. Early engagement with industry associations, government, regulators, and financing and development partners can ease the burden, lower costs, shorten timelines, and strengthen return on investment (ROI).

Industry associations: Collective acceleration

Industry platforms, most notably PMAG, can ease burdens on individual firms by coordinating shared support. Manufacturers can:



- Propose mentoring opportunities: Advocate for peer-learning with cGMP-advanced firms to share practical lessons, templates, and inspection insights.
- Request shared capability building: Pool cGMP training and combine mock inspections and peer audits to reduce costs and improve readiness.
- Coordinate externally: Engage collectively with the FDA, financiers, and development partners on common bottlenecks (e.g., utilities, validation capacity, training needs).

In India, mid-sized manufacturers shared learnings through association-led peer audits and trainings to reduce repeat inspection failures.

Government: Incentives, market shaping, and policy signals

Government support is most powerful when it **reduces input costs** and **rewards compliance**. Manufacturers should capitalize on important government incentives that reward cGMP upgrades, including:

- Advocate for price preferences for locally manufactured medicines and other similar incentives exclusively for cGMP compliant manufacturers.
- Ensure cGMP compliance to qualify for restricted or preferential procurement
- Advocate for market- and demand-shaping policies, including framework contracts and volume commitments, that may impact investment decisions
- Monitor active signals in the market at the policy level that may impact investment

Predictable, quality-linked incentives ensure compliant firms compete fairly.

Regulators: Guidance, predictability, and market protection

The FDA's role goes beyond inspection. Clear guidance and early engagement can significantly reduce redesign and costly rework during upgrades.

Manufacturers can:

- Seek pre-construction design review: Submit layouts, flows, and utilities plans for FDA review before construction approval to embed cGMP requirements from the start.
- Leverage the Industrial Support Unit (ISU): Request technical support from the FDA's ISU, including inspections shortcomings, remediation planning, and clarifying expectations.
- Enable market surveillance: Strong post-market surveillance protects compliant manufacturers by limiting substandard and falsified products and price undercutting.

As regional regulatory cooperation expands, early alignment with FDA expectations also strengthens multi-market readiness and buyer confidence.

Financing and development partners: Making upgrades investable

Financing constrains many Ghanaian manufacturers. Commercial banks, DFIs, and development partners can support cGMP upgrades, especially when firms engage early and transparently. The strongest partnerships use phased investment that link compliance upgrades to clear market access and revenue opportunities.

Typical sources include:

- Local commercial banks (working capital, trade finance, and selective capex)
- DFIs and strategic partners (larger, longer investments)
- Blended finance and donor programmes (technical assistance with guarantees or concessional capital)

Financier readiness checklist

This checklist helps manufacturers prepare for discussions with lenders and investors. Financing structures vary by institution and transaction; manufacturers should seek tailored advice from qualified financial and legal professionals.

The ask (be clear and specific)

Define what you need (working capital, trade finance, and/or capex), how much you need and when, and how you will repay it (high-level cashflow logic).

The plan (develop phases and costs)

Provide a clear, phased cGMP upgrade plan with timelines for 0-3 months, 3-6 months, and 6-12 months; a budget with capex vs opex split; and key assumptions and dependencies (equipment lead times, utilities upgrades, downtime plan).

Evidence of progress (illustrate momentum and intent)

Demonstrate improvements through a summary of gap assessment findings; CAPA plan with assigned owners, deadlines, and measured effectiveness; qualification and validation status for priority lines and products; and a quality KPI snapshot with deviation trends, CAPA aging, batch right-first-time (RFT), and complaints/recalls.

The commercial story (connect upgrades to revenue)

Connect compliance to cashflow through priority products/lines and the buyers they unlock; demand signals (tenders targeted, buyer conversations, potential offtake); and a plan to protect supply reliability during upgrades.

Regulatory engagement (reduce redesign risk)

Engage regulators early to review design/layout and discuss remediation, if applicable; prepare an inspection readiness plan, and document progress.

CALL TO ACTION FOR MANUFACTURERS

Ghana's pharmaceutical market is growing. Successful manufacturers will treat cGMP as a business upgrade that unlocks bigger buyers, more stable contracts, and regional expansion – not a compliance exercise. Start with clarity, not construction, and be clear on where you will compete and what you will produce.

1 Start with the portfolio: choose where you will win

- Define a product portfolio based on demand outlook and commercial fit.
- Prioritise products/SKUs with high domestic and regional demand, and where quality unlocks scale (institutional buyers, program markets, regional supply) and improves margins and reliability.
- Align choices to your competitive strengths (platform, quality capability, supply chain, speed to upgrade).

2 Let the portfolio drive the facility strategy

- Once the portfolio is clear, choose the facility pathway—retrofit, brownfield, or greenfield—based on what the products require (flows, utilities, segregation, validation needs), timelines, and financing realities.
- This should help you develop a phased facility and utilities plan tied to the priority lines/products, with cost ranges and milestones.

3 Build capability early and often

- Practice daily cGMP discipline to sustain upgrades
- Align leadership and decision rights, including escalation and QA release authority
- Ensure document control, deviations, CAPA, change control, and data integrity
- Establish supervision routines that reinforce correct behaviours and eliminate repeat issues
- Develop a minimum-viable QMS strengthening plan and a capability plan for supervisors/operators on priority lines.

4 Engage regulators early and regularly

- Treat the regulator as part of the upgrade pathway. Engage early on designs and remediation plans, and maintain a simple inspection-ready evidence pack that shows progress and control.

5 Make it investable

- Translate the portfolio decision and upgrade pathway into a phased investment case that financiers can assess, linking upgrades to buyer eligibility, revenue stability, and risk reduction.

Annex 1

Facility investment decision guide: Retrofit vs brownfield vs greenfield

START → **Define your target portfolio and ambition**

- Platform/technology (e.g., oral solids vs sterile)
- Target markets (domestic vs regional/export)
- Required scale and timeline

Q1 **Can the existing site reach cGMP for priority lines without major structural compromise?**

(Check compliant flows and segregation, utilities capacity, QC/lab controls, ability to validate without workarounds)

YES → Q2

NO → Q4

Q2 **Do you prioritise speed and continuity?**

(Need capacity within ≤12–18 months and you must keep current operations running)

YES → **RETROFIT (phased, line-by-line)**

NO → Q3

Q3 **Do you require major scale-up, export readiness, or a significant portfolio/technology shift?**

YES → Q3a

NO → **RETROFIT (optimize, standardise, validate priority lines)**

Q3a ***Can the existing site support a purpose-built, compliant expansion?***

(Check land/space, independent cGMP flows, utilities capacity like HVAC/pharma water, and construction feasibility without crippling operations and with acceptable permitting)

YES → **BROWNFIELD (purpose-built module on existing site)**
Balances purpose-built design and existing site assets.

NO → **GREENFIELD**
Choose this when the site cannot support the required layout, segregation, utilities, or future expansion.

Q4 **If retrofit is not viable, can you build compliant capacity on the existing site?**

(This checks brownfield feasibility: land/space, separation, utilities backbone, construction feasibility, permitting)

YES → **BROWNFIELD (modular if needed) → Q5**

NO → **GREENFIELD → Q5**

Q5 Is this facility financially realistic?

Check two conditions:
1. Can you secure capital at the right ticket size and tenor?
2. Can the business repay debt without starving working capital?

YES → **Proceed with the chosen path from Q4 (Retrofit/Brownfield/Greenfield)**

NO → Q6

Q6 If financing is constrained, choose a bridging pathway (“the fourth way”)

Pick one and combine as needed:

- Choose a phased brownfield module (one compliant line + critical utilities), then expand
- Create a hybrid: minimum stabilisation works now + build a compliant module in parallel
- Use a partner/CMO bridge for priority products while you build and finance
- Anchor financing with demand, secure credible buyer/offtake commitments to improve bankability

RESULT → **Select the facility pathway that aligns portfolio needs, site feasibility, timeline, and financing reality.**

Annex 2

Market readiness questionnaire

cGMP enables eligibility; go-to-market readiness converts it into revenue. This checklist helps manufacturers frame questions to translate cGMP compliance investments into market access and commercial growth, and should be used alongside cGMP upgrade planning to shape go-to-market strategies.

A. Target markets and buyers (be specific)

- Which 2–3 priority markets or channels will we target first (e.g., domestic public procurement, donor programs, private institutional buyers, regional exports)?
- Which buyer types matter most (tender authorities, procurement agents, wholesalers, large providers)?
- What is our clear value proposition beyond price, including quality assurance, reliable supply, short lead times, tailored packaging, pharmacovigilance support?
- Is demand structural, seasonal, or programme-driven, and what does that mean for timing and volumes?

B. Regulatory pathway and submission readiness

- What approvals does each target market require, and what is the critical path (dossier, inspection readiness, product-specific requirements)?
- Can we leverage regional harmonisation or reliance pathways where possible?
- Do our dossiers, validation status, and cGMP evidence meet target market requirements (not just reflect what we already have)?

C. Commercial viability and pricing logic

- What is our per unit cost after cGMP-related expenses (quality staffing, testing, validation, utilities, compliance overhead)?
- What price and margin ensure sustainability at realistic volumes, and do they align with buyer expectations?
- What are the top two risks to profitability (input volatility, low utilisation, long payment cycles) and how will we manage them?

D. Demand, capacity, and supply plan (deliverability)

- What data informs demand (tender history, buyer pipeline, consumption data, wholesaler intelligence), and what assumptions underpin it?

- Do batch sizes, production schedules, utilities, and QC release timelines match the forecast?
- Can we flex production for seasonal or program spikes without losing cGMP (validated changeovers, capacity buffers, contingency plans)?

E. Execution and partnerships

- Do we have distribution and logistics in place for selected channels (cold chain, last-mile delivery, reverse logistics)?
- Have we engaged buyers and partners early with a credible plan (timeline, evidence pack, service levels, risk controls)?
- What partnerships will accelerate results (contract manufacturing, technology transfer, QA/QC support, logistics partners)?
- Do we have contingency plans for supply disruptions (dual sourcing, safety stock, alternate pack sizes, backup logistics)?

After answering the questions posed in this checklist, produce a one-page go-to-market action plan that covers:

- **Priority products and markets:** Top 3–5 SKUs and 2–3 channels
- **Regulatory critical path:** Key submissions, required evidence, and timeline
- **Commercial actions:** Pricing logic, buyer engagement plan, and value proposition
- **Supply plan:** Capacity assumptions, service levels, and contingencies
- **Owners and next 90-day actions:** What we deliver, who owns it, and by when

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