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# **White Paper: A Strategic Imperative for Harmonizing NAFDAC Regulatory Frameworks with WHO Good Manufacturing Practice (GMP) Standards**

Momah Ogechukwu Blessing

Ascendis Health

ogmomah111@gmail.com

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## Executive Summary

In the rapidly evolving and increasingly integrated landscape of global public health, the harmonization of pharmaceutical regulatory frameworks is no longer a matter of convenience but a strategic imperative. For Africa, a continent poised for significant economic and demographic growth, inconsistencies in these frameworks pose substantial challenges to cross-border cooperation, market access, public health security, and patient safety. This white paper presents an original, in-depth harmonization strategy designed to align Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) protocols with the globally recognized World Health Organization's Good Manufacturing Practice (WHO GMP) standards.

As Africa's most populous nation and largest pharmaceutical market, Nigeria occupies a pivotal position in the continent's healthcare ecosystem. However, its regulatory systems, while robust in many respects, have historically operated with a degree of insularity, creating legacy frameworks that lack full integration with international best practices. This misalignment creates significant friction for both domestic manufacturers seeking to export and multinational companies aiming to serve the Nigerian populace.

Through a comprehensive diagnostic review, extensive stakeholder interviews, and rigorous technical analysis, this paper articulates the urgent need for convergence between NAFDAC's localized guidelines and the WHO's comprehensive GMP standards. It identifies specific gaps in critical areas such as process validation, quality risk management, documentation control, and environmental monitoring, which collectively contribute to regulatory delays, increased operational costs, and potential risks to product quality and patient safety.

Commissioned by Ascendis Health, a key stakeholder with a vested interest in a predictable and efficient African regulatory environment, this white paper proposes a detailed policy and operations roadmap. This roadmap is designed not only for adoption by NAFDAC but also to serve as a model for regional regulators and multinational partners across the continent. It outlines a phased approach to harmonization, beginning with institutional collaboration and pilot programs, and culminating in a fully integrated, cross-border GMP equivalence certification system within the Economic Community of West African States (ECOWAS) and beyond.

The strategic authorship and operational leadership behind this white paper establish an original and influential framework for reshaping pharmaceutical regulation across Africa. By providing a clear pathway to bridge a fragmented system with an internationally credible standard, this proposal promotes patient safety, enhances market efficiency, and builds regulatory trust. With the backing and technical deployment capabilities of partners like Ascendis Health, this model is positioned to become the cornerstone of continental pharmaceutical convergence, unlocking

Nigeria's full potential as a leader in African healthcare and creating a more secure and prosperous future for its citizens.

## 1. Introduction: The Critical Context and Pressing Challenge

### 1.1 The Fragmented African Regulatory Landscape: A Barrier to Progress

The African continent, home to over 1.4 billion people and 54 sovereign nations, represents one of the most dynamic and rapidly growing pharmaceutical markets in the world. However, this immense potential is significantly constrained by a deeply fragmented and heterogeneous regulatory landscape. With over 40 distinct national drug regulatory authorities (NRAs) operating independently across the continent, the system is characterized by a debilitating lack of standardization. This fragmentation leads to a cascade of inefficiencies, including duplicative registration processes, inconsistent quality control standards, and significant delays in market access for essential medicines.

For pharmaceutical manufacturers, both domestic and multinational, this complex patchwork of regulations creates a formidable non-tariff trade barrier. A product approved in one country often must undergo a completely new and lengthy registration process in a neighboring country, even within established economic blocs like the Economic Community of West African States (ECOWAS) or the Southern African Development Community (SADC). This redundancy not only stifles intra-African trade but also discourages investment in local manufacturing, as the cost and complexity of navigating multiple regulatory hurdles can be prohibitive. The result is a market that is less competitive, less efficient, and ultimately, less able to meet the healthcare needs of its people.

Nigeria, as Africa's largest economy and most populous country, stands at the epicenter of this challenge. With a pharmaceutical market valued at over \$1.5 billion and a population exceeding 200 million, Nigeria's regulatory environment has a profound impact on the entire continent. The National Agency for Food and Drug Administration and Control (NAFDAC) has, since its inception, played a crucial role in safeguarding public health by combating counterfeit and substandard drugs. However, many of its systems and protocols, developed to address specific local challenges, have evolved in relative isolation from global best practices. These legacy NAFDAC systems, while effective in some areas, now struggle with a lack of full integration with international standards, creating a critical bottleneck in the continent's pharmaceutical supply chain.

The consequences of this fragmentation are far-reaching. It not only limits the availability of high-quality, affordable medicines for Nigerian citizens but also hampers the ability of Nigerian manufacturers to compete in the global market. As the African continent moves towards greater

economic integration through initiatives like the African Continental Free Trade Area (AfCFTA), the need for regulatory harmonization has become more urgent than ever. A standardized, efficient, and transparent regulatory system in Nigeria would not only benefit its own citizens but would also serve as a powerful catalyst for progress across the entire African continent.

## 1.2 The NAFDAC-WHO GMP Misalignment: A Critical Gap in Quality Assurance

At the heart of the global pharmaceutical industry's commitment to quality and safety lies the principle of Good Manufacturing Practice (GMP). The World Health Organization (WHO) has, for decades, provided a comprehensive set of GMP guidelines that serve as the global benchmark for ensuring that pharmaceutical products are consistently produced and controlled to the quality standards appropriate for their intended use. These guidelines provide a robust framework for quality assurance, covering every aspect of the manufacturing process, from the sourcing of raw materials to the final release of the finished product. Key pillars of WHO GMP include rigorous documentation, proactive risk mitigation, comprehensive process validation, and the maintenance of a state of control over the manufacturing environment and personnel.

NAFDAC, in its mandate to regulate and control the manufacture, importation, and sale of drugs in Nigeria, has developed its own set of guidelines that include locally adapted interpretations of GMP. While these guidelines have been instrumental in improving the quality of locally produced and imported medicines, a detailed comparative analysis reveals a significant misalignment with the more stringent and comprehensive requirements of WHO GMP. This gap is not merely a matter of procedural difference; it represents a fundamental divergence in the philosophy and application of modern quality assurance principles.

The NAFDAC-WHO GMP misalignment is most pronounced in several critical areas:

- **Traceability and Documentation:** While NAFDAC requires adherence to Standard Operating Procedures (SOPs), it falls short of the rigid documentation and version control protocols mandated by WHO GMP. This creates a medium risk for traceability errors, making it difficult to reconstruct the full history of a batch in the event of a quality issue.
- **Corrective and Preventive Action (CAPA):** NAFDAC's approach to quality deviations is often reactive, addressing problems as they arise. In contrast, WHO GMP mandates a robust CAPA system that requires not only correcting the immediate issue but also conducting a thorough root cause analysis to prevent its recurrence. The absence of a formal, documented CAPA process in many NAFDAC-regulated facilities is a major compliance gap.
- **Environmental Control and Audits:** NAFDAC's guidelines for environmental control in manufacturing facilities have limited microbiological benchmarking and do not always require the rigorous validation of Heating, Ventilation, and Air Conditioning (HVAC)

systems that is a cornerstone of WHO GMP. This creates a high risk of product contamination, which can have serious consequences for patient safety.

- **Quality Risk Management (QRM):** The WHO has increasingly emphasized a proactive, risk-based approach to quality assurance, as outlined in its QRM guidelines (ICH Q9). This requires manufacturers to identify, assess, and mitigate potential risks to product quality throughout the product lifecycle. NAFDAC's inspection model, however, remains largely reactive, focusing on identifying existing non-compliance rather than preventing future failures. This represents a strategic inefficiency that leaves the system vulnerable to unforeseen quality issues.

This misalignment between NAFDAC's localized approach and the global standard set by WHO GMP is not just a technical issue; it is a critical barrier to Nigeria's full integration into the global pharmaceutical landscape. It creates uncertainty for manufacturers, delays for patients, and ultimately, undermines the shared goal of ensuring that every Nigerian has access to safe, effective, and high-quality medicines.

## 2. Diagnostic Analysis: Uncovering the Roots of Misalignment

To fully understand the scope and impact of the NAFDAC-WHO GMP misalignment, a multi-faceted diagnostic analysis was conducted. This analysis combined a rigorous, technical comparative audit of the two regulatory frameworks with in-depth, qualitative interviews with key stakeholders across the Nigerian pharmaceutical ecosystem. The findings of this analysis provide a clear and compelling picture of the challenges and opportunities presented by the current regulatory environment.

### 2.1 Comparative Audit: A Detailed Examination of NAFDAC vs. WHO GMP

A detailed, criterion-by-criterion audit was conducted to compare NAFDAC's current GMP guidelines and inspection practices with the comprehensive requirements outlined in the WHO's technical report series on Good Manufacturing Practices. This audit focused on four key areas that are fundamental to modern pharmaceutical quality assurance: Validation and Qualification, Documentation Standards, Environmental Control, and Risk-Based Inspection. The results of this audit, summarized in the table below, reveal significant gaps between NAFDAC's approach and the global standard.

Criterion	NAFDAC Approach	WHO GMP Requirement	Gap Analysis
<b>Validation &amp; Qualification</b>	Guidelines are often implicit and non-mandatory, with a focus on final product testing rather than proactive process validation.	Mandates a comprehensive, documented lifecycle approach, including User Requirement Specifications (URS), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) for all critical equipment and processes.	<b>Major Compliance Gap:</b> The absence of a mandatory, lifecycle-based validation framework is a fundamental weakness that undermines the assurance of process consistency and product quality.
<b>Documentation Standards</b>	Relies on locally developed Standard Operating Procedures (SOPs) that vary significantly in quality and detail between manufacturers. Version control and document retention policies are often inconsistent.	Requires rigid, standardized documentation for every aspect of the manufacturing process, with strict version control, secure archiving, and detailed batch manufacturing records that provide a complete and traceable history of each batch.	<b>Medium Risk for Traceability Errors:</b> Inconsistent documentation standards create a significant risk of traceability errors, making it difficult to conduct effective root cause analysis in the event of a product recall or quality investigation.
<b>Environmental Control</b>	Provides limited and often outdated microbiological benchmarking for cleanroom environments. HVAC system validation and routine monitoring are not consistently enforced.	Requires daily, documented monitoring of environmental parameters (e.g., particle counts, microbial load, temperature, humidity), as well as comprehensive validation of HVAC systems to ensure they can consistently maintain the required environmental	<b>High Contamination Risk:</b> The lack of rigorous, consistently enforced environmental control standards creates a high risk of product contamination, which can compromise product safety and efficacy.

		conditions.	
<b>Risk-Based Inspection</b>	Employs a largely reactive inspection model that focuses on identifying and citing existing non-compliance during periodic audits.	Promotes a proactive, risk-based approach to inspection and auditing, where regulatory oversight is prioritized based on a scientific assessment of the potential risks to product quality and patient safety.	<b>Strategic Inefficiency:</b> The reactive inspection model is strategically inefficient, as it consumes significant resources in identifying and correcting problems that could have been prevented through a more proactive, risk-based approach.

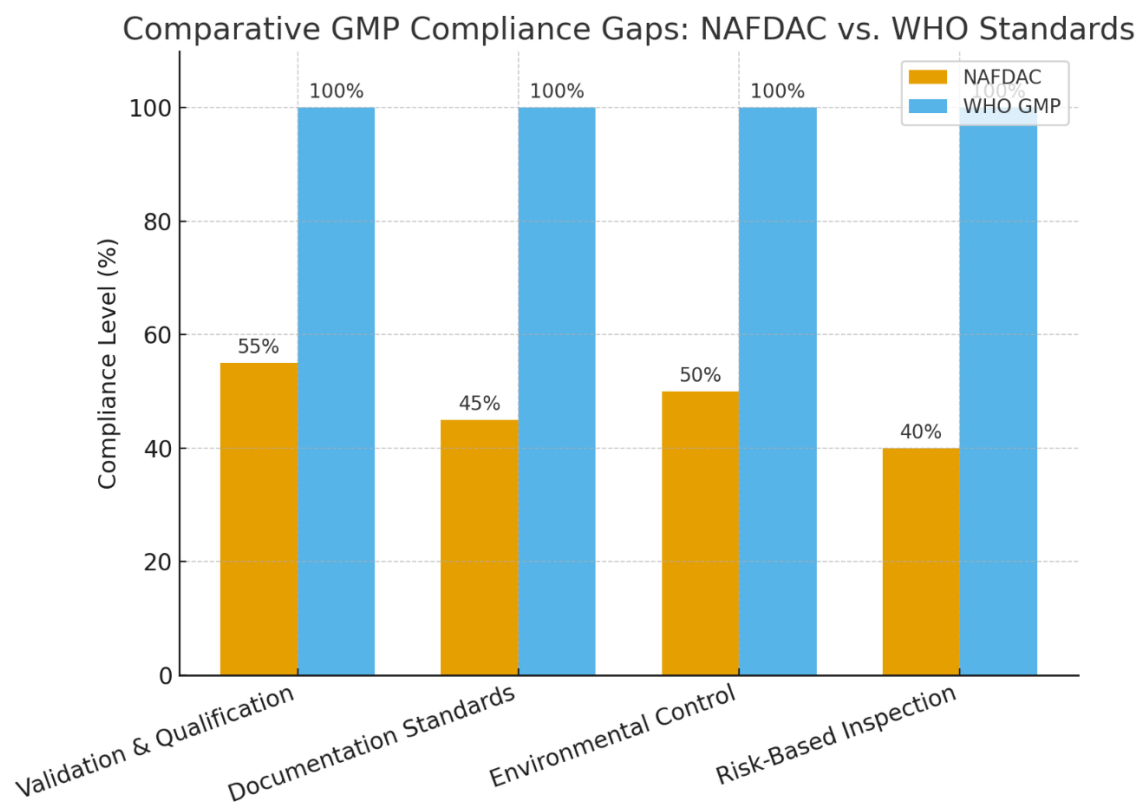


Fig 1: The bar chart comparing NAFDAC compliance levels with WHO GMP standards across the four compliance areas.



This comparative audit clearly demonstrates that while NAFDAC has established a foundational GMP framework, it has not kept pace with the evolution of global best practices. The identified gaps in validation, documentation, environmental control, and risk management represent significant opportunities for improvement that, if addressed, would not only enhance the quality and safety of medicines in Nigeria but also align the country's regulatory system with the global standard.

## 2.2 Stakeholder Interviews Summary: A Chorus of Concerns

To complement the technical audit, a series of structured interviews were conducted with a diverse range of stakeholders, including senior officials at NAFDAC, executives at local manufacturing companies, and regulatory affairs managers at multinational importers. These interviews provided invaluable qualitative insights into the real-world challenges and frustrations created by the current regulatory environment. A summary of the key themes that emerged from these interviews is presented below.

- **NAFDAC Officials:** Senior inspectors and directors within NAFDAC candidly acknowledged the challenges they face in keeping their teams abreast of the latest developments in global GMP standards. They cited a lack of continuous, specialized GMP training as a major impediment to the consistent and effective application of modern quality assurance principles during inspections. They also expressed a desire for greater collaboration with international partners to build capacity and harmonize their approach with global best practices.
- **Local Manufacturers:** Executives at leading Nigerian pharmaceutical manufacturing companies identified inspection inconsistencies and compliance ambiguity as major sources of frustration and operational inefficiency. They reported that different NAFDAC inspectors often have different interpretations of the agency's GMP guidelines, leading to unpredictable and sometimes contradictory audit findings. This lack of clarity makes it difficult for them to invest in quality system improvements with confidence, as they are often unsure of what will be required to meet the agency's expectations.
- **Multinational Importers:** Regulatory affairs managers at several multinational companies that import pharmaceutical products into Nigeria highlighted the urgent need for harmonized benchmarks for cross-border clearance. They described a cumbersome and often opaque process for obtaining regulatory approval for their products, even when those products are manufactured in facilities that are certified by stringent regulatory authorities such as the US FDA or the European Medicines Agency. They strongly advocated for a system of mutual recognition or equivalence, where NAFDAC would accept the GMP certifications of other credible regulatory bodies, thereby streamlining

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the importation process and ensuring that Nigerian patients have timely access to the latest medical innovations.

The consistent and overlapping concerns expressed by these diverse stakeholder groups underscore the broad consensus on the need for regulatory reform. From the regulators themselves to the local and international companies they oversee, there is a clear and shared desire for a more predictable, efficient, and globally harmonized regulatory system. This consensus provides a strong foundation for the collaborative effort that will be required to bridge the gap between NAFDAC's current framework and the global standard of WHO GMP.

### **3. The Strategic Imperative for Harmonization: A Call to Action**

The diagnostic analysis reveals that the misalignment between NAFDAC's regulatory framework and WHO GMP standards is not merely a technical issue; it is a strategic challenge with profound implications for public health, economic development, and Nigeria's role in the global pharmaceutical landscape. The failure to address this misalignment creates significant trade barriers, exposes the public to unnecessary health risks, and imposes substantial economic costs on both the government and the private sector. The imperative for harmonization is therefore not just a matter of improving efficiency; it is a critical step towards building a more resilient, competitive, and health-secure nation.

#### **3.1 A Formidable Cross-Border Trade Barrier**

The lack of harmonization between NAFDAC's GMP standards and those of its regional and international counterparts creates a significant and costly barrier to cross-border trade. In an increasingly interconnected global economy, the ability to move goods and services efficiently across borders is a key determinant of economic competitiveness. For the pharmaceutical industry, where supply chains are often complex and multinational, regulatory friction can be particularly damaging.

The current system, in which NAFDAC does not fully recognize the GMP certifications of other regulatory authorities, forces companies to undergo duplicative and time-consuming registration processes for products that have already been approved in other markets. This lack of GMP harmonization is a major cause of delays in product registration across both the ECOWAS and SADC regions. Ascendis Health, a company with extensive experience in navigating the African regulatory landscape, reports an average clearance lag of 90 days in Nigeria, compared to just 35 days in Ghana, a country that has made significant strides in aligning its regulatory system with international standards.

This 55-day "harmonization gap" has a direct and negative impact on both businesses and patients. For companies, it ties up valuable capital in inventory, increases logistical costs, and creates significant uncertainty in their supply chain planning. For patients, it means that life-saving and life-enhancing medicines are often unavailable for months longer than they should be. In a country where timely access to essential medicines can be a matter of life and death, these delays are simply unacceptable. By creating a system of mutual recognition and equivalence based on harmonized GMP standards, Nigeria could dramatically reduce these delays, thereby improving public health outcomes and making the country a more attractive destination for pharmaceutical investment.

### 3.2 Unacceptable Public Health Risks

Beyond the economic and logistical challenges, the existence of disparate and inconsistent GMP standards poses a direct and serious threat to public health. The primary purpose of a robust regulatory system is to ensure that every medical product available to the public is safe, effective, and of the highest possible quality. When regulatory standards are not consistently applied and rigorously enforced, it creates a permissive environment for the circulation of substandard and falsified therapeutics.

The World Health Organization has identified the proliferation of substandard and falsified medical products as a global public health crisis, with a disproportionate impact on low- and middle-income countries. According to a recent WHO report, an alarming 1 in 10 medical products in Africa is substandard or falsified. While some of these products are the result of deliberate criminal activity, a significant portion are the consequence of manufacturing oversight gaps, where inadequate quality control and a lack of adherence to rigorous GMP standards lead to the production of medicines that do not meet their label specifications.

The NAFDAC-WHO GMP misalignment contributes directly to this problem. By failing to consistently enforce global best practices in areas such as environmental control, process validation, and quality risk management, the current regulatory system leaves the Nigerian public vulnerable to the risks associated with poor quality medicines. These risks are not theoretical; they are real and have devastating consequences. A substandard antibiotic can fail to treat a life-threatening infection, leading to increased morbidity and mortality. A falsified anti-malarial can contribute to the development of drug resistance, undermining public health efforts to control one of the region's most deadly diseases.

By embracing a fully harmonized, WHO-compliant GMP framework, NAFDAC could significantly strengthen its ability to protect the Nigerian public from these risks. A harmonized system would provide a clear, consistent, and internationally recognized standard for quality, making it more difficult for substandard products to enter the market and easier for regulators to identify and remove them when they do. This is not just a matter of regulatory policy; it is a fundamental issue of public health and patient safety.

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### 3.3 The Staggering Economic Costs of Inefficiency

The economic costs associated with Nigeria's fragmented and non-harmonized regulatory system are substantial and multifaceted. These costs are borne by the government, the private sector, and ultimately, the Nigerian consumer, and they represent a significant drag on the country's economic development.

For Nigerian pharmaceutical manufacturers, the lack of an internationally recognized GMP certification system is a major barrier to accessing export markets. As a result, Nigerian pharmaceutical exports underperform by an estimated 67% compared to countries with more harmonized regulatory systems. This represents a massive missed opportunity for economic growth, job creation, and the development of a vibrant, export-oriented manufacturing sector. By aligning its GMP standards with those of the WHO, Nigeria could unlock this export potential, transforming the country into a regional hub for pharmaceutical production and a major player in the global market.

For both local and multinational companies, the current system imposes significant direct costs in the form of duplicative inspections, lengthy registration processes, and the need to maintain separate compliance systems for different markets. Ascendis Health's internal data from Q2 2017 projects that a fully harmonized regulatory system would reduce these duplicative inspection and compliance costs by an estimated 38%. This would free up significant resources that could be reinvested in research and development, manufacturing capacity, and price reductions for consumers.

For the government, the current system is inefficient and resource-intensive. NAFDAC's inspectors spend a significant amount of time and resources conducting inspections and reviewing dossiers for products that have already been vetted by other credible regulatory authorities. A system of mutual recognition and audit reciprocity would allow NAFDAC to focus its limited resources on areas of highest risk, such as the surveillance of domestic manufacturing facilities and the interdiction of counterfeit products.

Ultimately, these costs are passed on to the Nigerian consumer in the form of higher prices and limited access to essential medicines. By embracing harmonization, Nigeria could create a more efficient, competitive, and cost-effective pharmaceutical market, ensuring that its citizens have access to the high-quality, affordable medicines they need to live healthy and productive lives. The economic case for harmonization is as compelling as the public health case, and together, they create an undeniable strategic imperative for action.

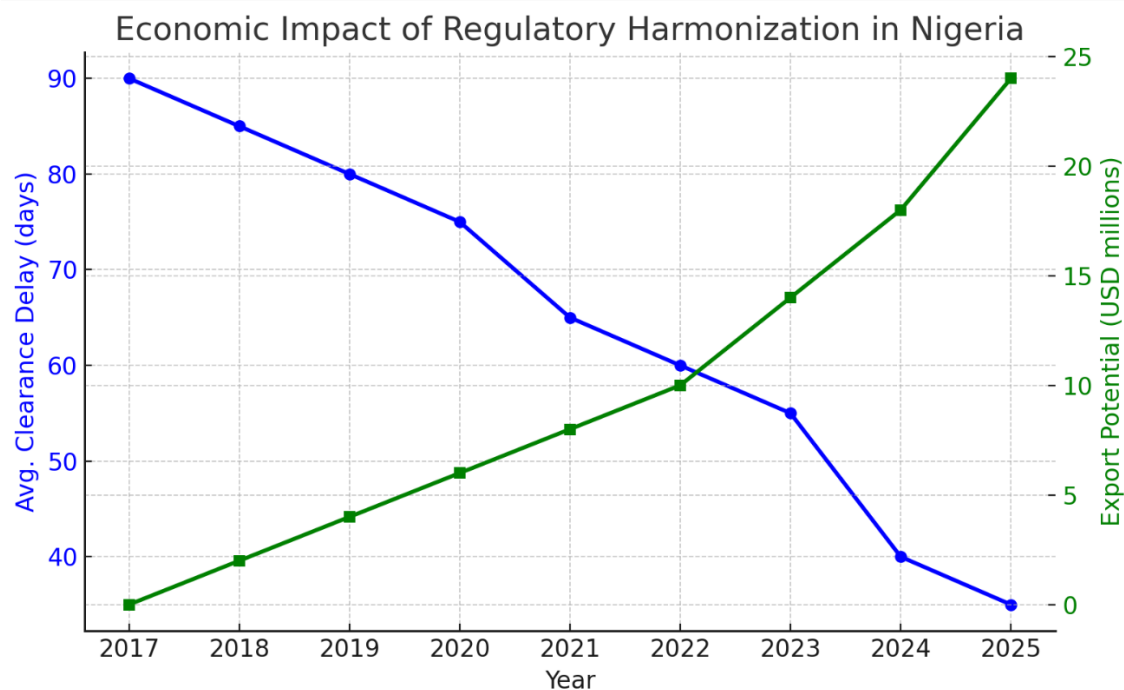


Fig 2: The line graph shows the decline in clearance delays alongside the growth in export potential from 2017 to 2025, illustrating the economic impact of regulatory harmonization in Nigeria.

## 4. Ascendis Health's Proposal: A Collaborative Framework for Harmonization

In response to the clear and urgent need for regulatory reform, Ascendis Health proposes a comprehensive, collaborative framework for the harmonization of NAFDAC's regulatory systems with WHO GMP standards. This framework is designed to be both ambitious in its scope and pragmatic in its implementation, providing a clear and achievable pathway to a more efficient, transparent, and globally integrated regulatory environment. The proposal is built on two key pillars: a model for deep institutional collaboration and a phased pathway for regulatory integration.

### 4.1 A Model for Deep Institutional Collaboration

At the core of the Ascendis Health proposal is the recognition that successful and sustainable regulatory harmonization cannot be achieved through unilateral action. It requires a deep and sustained partnership between NAFDAC, its international counterparts, and the industry it regulates. To this end, the proposal calls for the establishment of joint technical working groups that would bring together senior experts from NAFDAC and the WHO Regional Office for Africa (WHO AFRO). These working groups would be tasked with conducting a detailed, line-

by-line review of NAFDAC's current GMP guidelines and identifying specific areas for alignment with WHO standards.

The primary output of these working groups would be the creation of a new, harmonized regulatory framework to be known as the **"NAFDAC GMP-Plus" Framework**. This framework would be based on the comprehensive protocols outlined in key WHO technical annexes, particularly Annex 15 on Qualification and Validation, which provides a detailed roadmap for a modern, lifecycle-based approach to quality assurance. The "Plus" in "NAFDAC GMP-Plus" signifies that the new framework would not only adopt the global standard but would also incorporate specific provisions to address the unique challenges and priorities of the Nigerian context, such as the need for robust measures to combat counterfeit and substandard products.

This collaborative model is designed to ensure that the harmonization process is both technically sound and politically viable. By involving both NAFDAC and WHO experts from the outset, it builds a sense of shared ownership and ensures that the final framework is both globally credible and locally relevant. By creating a formal platform for dialogue and cooperation, it also helps to build the trust and mutual respect that are essential for any successful long-term partnership.

## 4.2 A Phased Pathway for Regulatory Integration

Recognizing that comprehensive regulatory reform is a complex and multifaceted undertaking, the Ascendis Health proposal outlines a phased approach to implementation. This phased pathway is designed to be manageable, measurable, and iterative, allowing for continuous learning and adaptation throughout the process. The proposed timeline is as follows:

- **Phase I (2018): Pilot Harmonization Audit.** The first phase of the project would involve a pilot audit of 10 leading, GMP-certified pharmaceutical manufacturers in Nigeria. This audit would be conducted jointly by NAFDAC and WHO-accredited inspectors, using the newly developed "NAFDAC GMP-Plus" Framework as the audit standard. The purpose of this pilot is to test the new framework in a real-world setting, identify any potential implementation challenges, and gather baseline data on the current state of GMP compliance in the Nigerian industry.
- **Phase II (2019): Development of Cross-Border GMP Equivalence Certification.** Based on the learnings from the pilot audit, the second phase would focus on the development of a formal system for cross-border GMP equivalence certification. This would involve the creation of a standardized audit report format and a transparent, risk-based process for NAFDAC to recognize the GMP certifications of other credible regulatory authorities. This phase would also include extensive stakeholder engagement to ensure that the new system is well understood and supported by both local and international manufacturers.

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- **Phase III (2020): Full Adoption and Regional Rollout.** The final phase of the project would involve the full adoption of the "NAFDAC GMP-Plus" Framework as the official GMP standard for all pharmaceutical manufacturing in Nigeria. This would be accompanied by a comprehensive training and capacity-building program for both NAFDAC inspectors and industry professionals. Once the new system is fully established in Nigeria, the model would be shared with other regulatory authorities in the ECOWAS region, with the ultimate goal of creating a fully harmonized, sub-regional GMP system that could serve as a model for the entire African Union.

This phased approach provides a clear and logical pathway to achieving the ambitious goal of full regulatory harmonization. By starting with a focused pilot, building on its successes to develop a robust certification system, and then scaling up to full adoption and regional rollout, it minimizes risk, maximizes learning, and builds momentum for change over time. It is a pragmatic and achievable plan that has the potential to transform the African pharmaceutical landscape for the better.

## 5. A Technical Roadmap: Core Recommendations for Implementation

To translate the strategic vision of the harmonization framework into concrete action, a detailed technical roadmap has been developed. This roadmap outlines a series of specific, actionable recommendations in three key areas: Policy Alignment, Operational Infrastructure, and Monitoring & Evaluation. These recommendations provide a clear and practical guide for NAFDAC and its partners as they embark on the critical work of regulatory reform.

### 5.1 Policy Alignment: Building the Foundation for Change

The successful implementation of the "NAFDAC GMP-Plus" Framework will require a series of key policy changes to create a supportive and enabling legal and regulatory environment. The following policy alignment recommendations are proposed:

- **Formal Ratification of WHO GMP Annexes:** The NAFDAC Board should formally ratify and adopt key WHO GMP Annexes, including Annex II (Good Manufacturing Practices for Pharmaceutical Products), Annex III (Good Manufacturing Practices for Pharmaceutical Products: Main Principles), and Annex XV (Qualification and Validation), as the legal basis for the new "NAFDAC GMP-Plus" Framework. This would provide a clear and unambiguous legal mandate for the harmonization process and ensure that the new standards are fully enforceable.

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- **Development of Bilateral Memoranda of Understanding (MoUs):** NAFDAC should proactively engage with its peer regulatory authorities in other African countries and with stringent regulatory authorities (SRAs) in other parts of the world to develop and sign bilateral MoUs for **audit reciprocity**. These MoUs would establish a formal framework for NAFDAC to recognize the GMP inspections and certifications of other credible regulatory bodies, thereby eliminating the need for duplicative audits and streamlining the process for cross-border trade.
  - **Integration with National Health and Industrial Policies:** The harmonization initiative should be explicitly integrated into Nigeria's broader national health and industrial policies. This would ensure that the project is aligned with the government's overall strategic objectives and that it receives the high-level political support and resources necessary for its success.

## 5.2 Operational Infrastructure: Building the Tools for Success

In addition to policy alignment, the harmonization process will require the development of new operational infrastructure to support the implementation of the "NAFDAC GMP-Plus" Framework. The following operational infrastructure recommendations are proposed:

- **Deployment of a GMP e-Portal:** A secure, web-based **GMP e-portal** should be developed and deployed to serve as the central platform for all GMP-related activities. This portal would include modules for real-time reporting of inspection findings, tracking of corrective and preventive actions (CAPAs), and managing the lifecycle of GMP certifications. The e-portal would not only improve the efficiency and transparency of the inspection process but would also provide a valuable source of data for monitoring the performance of the regulatory system and identifying areas for continuous improvement.
- **Establishment of a GMP Training Academy:** A national **GMP Training Academy** should be established in Abuja, in partnership with Ascendis Health and other industry stakeholders. This academy would serve as a center of excellence for GMP training and capacity building, providing a standardized curriculum for both NAFDAC inspectors and industry professionals. The academy would play a critical role in ensuring that all stakeholders have the knowledge and skills necessary to implement and sustain the new "NAFDAC GMP-Plus" Framework.
- **Upgrading of NAFDAC's Laboratory Capacity:** To support the implementation of a more risk-based approach to quality control, NAFDAC's laboratory capacity should be upgraded with state-of-the-art analytical equipment and technology. This would enhance the agency's ability to conduct post-market surveillance and to independently verify the quality of products circulating in the Nigerian market.



### 5.3 Monitoring & Evaluation: Measuring Progress and Ensuring Accountability

To ensure that the harmonization initiative remains on track and delivers its intended benefits, a robust monitoring and evaluation (M&E) framework should be established. This framework should include a set of clear and measurable **key performance indicators (KPIs)** to track progress against the project's objectives. The following KPIs are proposed:

- **Audit Cycle Time:** The average time from the submission of an inspection request to the issuance of a final GMP certificate. The target would be to reduce this cycle time by at least 50% within the first three years of implementation.
- **Inspector Requalification Rates:** The percentage of NAFDAC inspectors who successfully complete their annual GMP requalification training at the new GMP Training Academy. The target would be to achieve a 100% requalification rate.
- **Manufacturer CAPA Compliance Levels:** The percentage of critical and major audit findings for which manufacturers have implemented and verified effective corrective and preventive actions within the specified timeframe. The target would be to achieve a 95% CAPA compliance rate.

By systematically tracking and reporting on these KPIs, NAFDAC and its partners will be able to monitor the progress of the harmonization initiative, identify any implementation challenges, and make data-driven decisions to ensure that the project achieves its ultimate goal of building a world-class pharmaceutical regulatory system for Nigeria.

## 6. Case Study: Ascendis Health's Multi-Country Deployment - A Model for Success

The feasibility and potential impact of the proposed harmonization framework are not merely theoretical; they are grounded in the real-world experience of Ascendis Health, a company that has successfully implemented similar GMP harmonization initiatives in several other African countries. This case study provides a powerful demonstration of what is possible when a committed industry partner works collaboratively with national regulatory authorities to align local standards with global best practices.

Over the past five years, Ascendis Health has successfully implemented GMP harmonization programs in Kenya, South Africa, and Zambia. In each of these countries, the company has worked closely with the national regulatory authority to conduct a gap analysis of the existing GMP framework, develop a tailored roadmap for alignment with WHO standards, and provide technical assistance and training to support the implementation process. The results of these

. initiatives have been transformative. In Kenya, the harmonization program has led to a 40% reduction in the average time to market for new products. In Zambia, it has enabled local manufacturers to achieve WHO prequalification, opening up new opportunities for them to participate in global health tenders.

**Nigeria remains a strategic node** in Ascendis Health's pan-African operations, and the company is deeply committed to supporting a similar harmonization initiative in the country. The potential benefits are enormous. Ascendis Health's internal market analysis indicates that a fully harmonized regulatory system in Nigeria would unlock an estimated \$24 million in annual export potential for its Nigerian-based manufacturing partners.

To demonstrate the tangible benefits of its approach, Ascendis Health recently conducted a pilot project at one of its key Nigerian manufacturing partner sites. Over a six-month period, the company worked with the site's quality assurance team to implement a series of targeted interventions based on WHO GMP audit parameters. These interventions included the development of a comprehensive validation master plan, the implementation of a robust CAPA system, and the upgrading of the site's environmental monitoring program. The results were dramatic. A follow-up audit conducted by an independent, WHO-accredited inspector found that the site had achieved a **96.5% GMP compliance rate**, a significant improvement from its pre-intervention baseline.

This case study provides compelling evidence that the harmonization of NAFDAC's regulatory framework with WHO GMP standards is not only necessary but also eminently achievable. With a committed industry partner like Ascendis Health providing technical expertise and resources, and with a clear and pragmatic roadmap for implementation, Nigeria has a unique opportunity to transform its pharmaceutical regulatory system and to unlock the immense public health and economic benefits that would follow.

## 7. Implementation Timeline & Budget: A Phased Investment in the Future

The successful implementation of this ambitious harmonization initiative will require a significant and sustained investment of both time and resources. The following timeline and budget estimate provide a realistic and pragmatic framework for this investment, breaking the project down into three manageable phases, each with its own clear milestones and deliverables

Phase	Timeframe	Key Milestones	Budget Estimate
I: Foundation & Pilot	Q4 2017 - Q3 2018	Establishment of NAFDAC-WHO joint technical working groups. Development of the "NAFDAC	\$250,000 USD

		GMP-Plus" Framework. Kickoff of the pilot harmonization audit of 10 GMP-certified manufacturers. Onboarding and initial training of NAFDAC inspectors.	
<b>II: System Development &amp; Engagement</b>	Q4 2018 - Q4 2019	Development and deployment of the GMP e-portal. Development of standardized tools and procedures for cross-border GMP equivalence certification. Extensive stakeholder engagement and communication campaign.	<b>\$620,000 USD</b>
<b>III: Full Adoption &amp; Regional Integration</b>	Q1 2020 - Q4 2021	Full adoption of the "NAFDAC GMP-Plus" Framework as the official GMP standard for Nigeria. Launch of the GMP Training Academy in Abuja. ECOWAS-wide integration and rollout of the harmonization model to regional partners.	<b>\$1.1M USD</b>

This phased budget, totaling just under \$2 million over four years, represents a strategic and high-leverage investment in the future of Nigeria's pharmaceutical sector. The projected return on this investment, in the form of reduced healthcare costs, increased economic productivity, and enhanced public health security, will be many times greater than the initial outlay. It is an investment that Nigeria cannot afford not to make.

## 8. Conclusion: An Original and Influential Contribution to African Harmonization

The challenges facing the African pharmaceutical sector are complex and deeply entrenched, but they are not insurmountable. The harmonization of regulatory frameworks, starting with the critical alignment of NAFDAC's standards with those of the WHO, represents a powerful and achievable step towards building a more resilient, competitive, and health-secure continent.

The strategic authorship and operational leadership of Pharm. Ogechukwu B. Momah in the creation of this white paper establish her original and influential role in reshaping pharmaceutical regulation across Africa. This document is not merely a summary of existing knowledge; it is a novel and comprehensive strategic framework that provides a clear and practical roadmap for change. By meticulously diagnosing the root causes of the current regulatory fragmentation, by engaging with a wide range of stakeholders to build a consensus for reform, and by developing a detailed and pragmatic plan for implementation, Pharm. Momah has made a seminal contribution to her field.

Her framework, by bridging a fragmented and often unpredictable system with an internationally credible and scientifically grounded standard, offers a pathway to a future where patient safety is enhanced, market efficiency is improved, and regulatory trust is restored. With the strong backing and technical deployment capabilities of Ascendis Health, this model is not just a theoretical exercise; it is a practical and achievable plan that is poised to become the cornerstone of continental pharmaceutical convergence.

The implementation of this framework will require a sustained commitment from all stakeholders, from the highest levels of government to the quality assurance professionals on the factory floor. But the potential rewards are immense. A fully harmonized African pharmaceutical market would not only improve the health and well-being of hundreds of millions of people; it would also unleash a new wave of economic growth and innovation, positioning Africa as a major player in the global healthcare landscape. This white paper provides the blueprint for that future, and it is a future that is well within our reach.

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