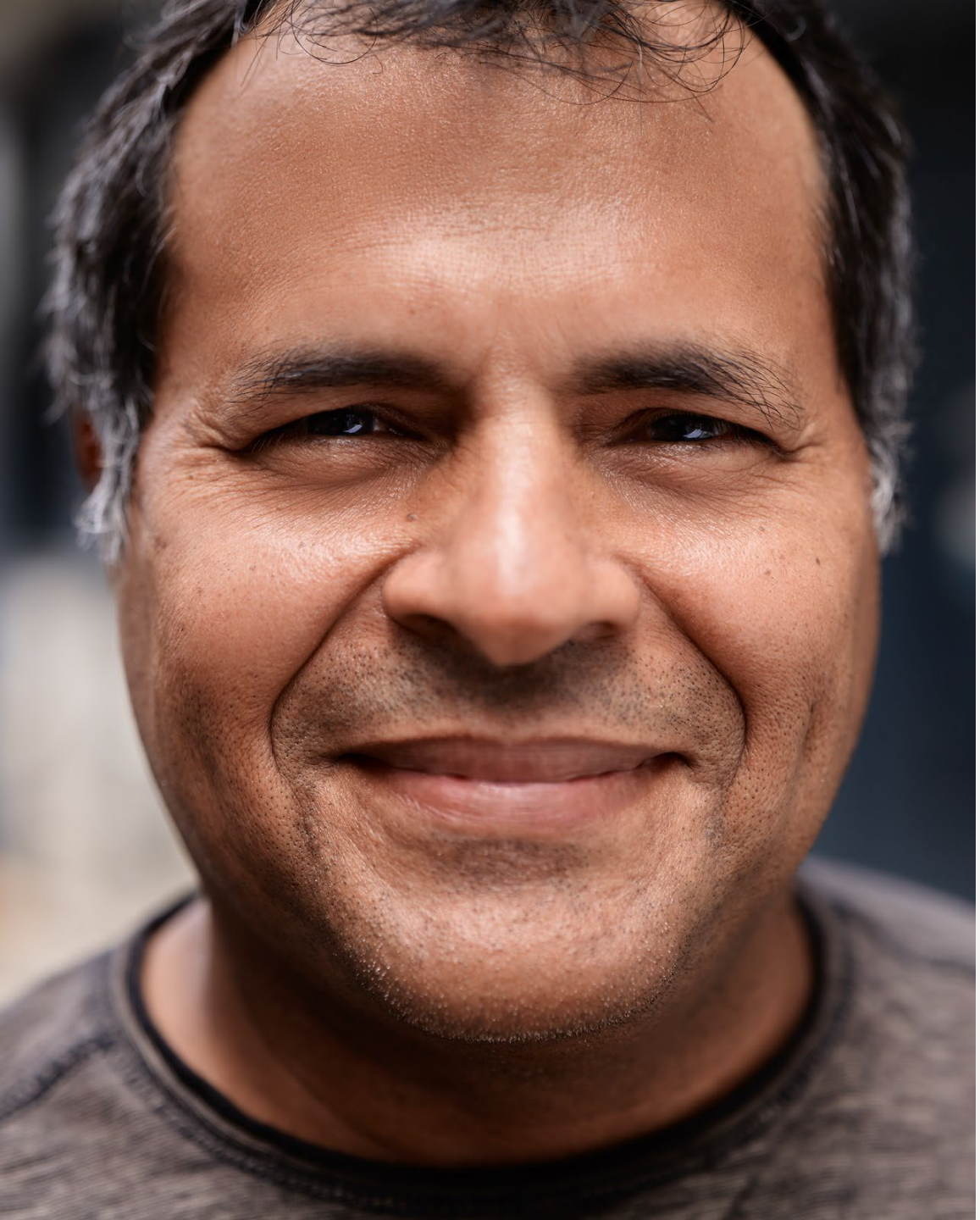

Authority in Action: Strengthening Medical Device Oversight Across the African Continent.

Strengthening Regulations Through Shared Progress

Christopher Odero, PhD

Head of Quality Assurance & Regulatory Affairs

Roche Diagnostics, Africa

12 October 2025 | for internal use only

Presentation outline

Authority in action

- Defining “Authority in Action”
- Core challenges and imperatives
- The strategic solution
  - Regulatory harmonization & reliance
- Pillars of authority in action
- Future-proofing oversight
- Conclusion
- Call to action

Defining “Authority in Action”

"The strategic, proactive, and efficient exercise of an NRA's mandate to assure the safety, quality, and performance of medical devices and IVDs, serving as both a guardian of public health and an enabler of market access for quality-assured technology."

Demonstrated Through:

Strategic Reliance: Trusting and accepting the competent work of other mature regulators (e.g., IMDRF members, peer African NRAs) to optimize resources.

Harmonized Enforcement: Implementing and enforcing globally and continentally harmonized standards (e.g., AMDF/WHO guidelines) consistently and predictably.

Proactive Vigilance: Shifting focus to robust, continuous, and mandatory Post-Market Surveillance (Materiovigilance) throughout the device lifecycle.

Good Regulatory Practices (GRP): Operating transparently and proportionately, ensuring regulatory power leads to efficient, science-based decisions.

Why we must ACT NOW

The African Regulatory reality - challenges

The reality is that inconsistent regulation creates a **"Medical Device Lag"**, hindering both public health and market efficiency.

Fragmented Foundations: Many countries lack dedicated, specific legal frameworks for Medical Devices and IVDs, often relying on outdated drug laws.

- *Example:* Oversight is sometimes reactive or limited only to basic products, exposing patients to substandard and falsified devices.

The Capacity Gap: We face critical shortages in **specialized regulatory personnel** (biomedical engineers, IVD experts) and technical resources for sophisticated reviews and QMS audits.

Market Unpredictability (Industry View): For manufacturers, non-harmonized, unique national requirements mean redundant efforts, long approval timelines (often years), and unpredictable costs—deterring investment in high-quality medical technology.

The Shared Goal: We need systems that are predictable, efficient, and science-based to ensure **Safety, Quality, and Performance** (SQP)

The blueprint for shared progress: Harmonization and Reliance

Harmonization and Global Convergence

Our strategic solution is to move from 55 distinct regulatory systems toward a unified, reliance-based framework.

Continental Leadership (AMDF) 🤝

- The **Africa Medical Devices Forum (AMDF)**, under the AMRH initiative, provides the non-negotiable blueprint.
- **Core Action:** Adopting IMDRF & AMDF guidelines—based on the **WHO Global Model Regulatory Framework**—for common classification, registration, and QMS inspection.
- *Industry Benefit:* Manufacturers can submit one **harmonized dossier**, drastically simplifying market entry across multiple countries.

The Smart Regulator: Reliance 🧠

- **Good Reliance Practices (GRelP)** are the hallmark of a modern, efficient regulator. We must stop doing work that others have competently done.
- **Authority in Action:** Formally and strategically **recognize** the marketing authorization and/or QMS audit reports (like **MDSAP**) from IMDRF member agencies and peer African regulators.
- *Impact:* An NRA with limited staff can accept the quality assessment of another trusted authority, shifting its scarce resources to critical, value-added national functions like **Post-Market Surveillance**.

Authority in Action: Implementing advanced regulatory practices

The Pillars of Authority: GRP and GBT

Authority is demonstrated through adherence to globally recognized standards (e.g. IMDRF) for how regulation is executed—**Good Regulatory Practices (GRP)** and **Maturity Level (GBT)**.

Good Regulatory Practices (GRP)

GRP ensures our rules are **clear, consistent, and proportionate**.

Commitment to Transparency: NRAs must publish a **National Register of all Regulations** and adhere to clear timelines. Industry needs to know *what* the rules are and *how long* compliance will take.

Commitment to Proportionality: Requirements must match risk. We must resist the temptation to require unique, in-country clinical data for devices already extensively proven elsewhere, especially for low-risk IVDs.

WHO Global Benchmarking Tool (GBT)

The **GBT + Medical Devices** provides the objective roadmap.

The Signal to Industry: An NRA's commitment to achieving a higher GBT **Maturity Level** (ML 3 or 4) signals to global innovators that the market is **predictable and safe**, boosting confidence and attracting high-quality technology.

Core elements of Good Regulatory Practices (GRP)

Application in the regulation of medical devices and diagnostics

- **Transparency and public engagement;**
  - All regulations, guidelines (like those from AMDF), fees, and processes must be **publicly accessible** and involve stakeholder consultation before finalization, ensuring clarity and predictability.
- **Risk-based proportionality;**
  - Regulatory requirements (e.g., dossier review depth, clinical data requirements) must be **commensurate with the device's risk classification** (Class A to D), preventing undue burden on low-risk devices.
- **Strategic Reliance (GRelP);**
  - NRAs must formally adopt a policy to **leverage and accept the scientific assessment work** performed by recognized, trusted regulatory bodies (peer African NRAs, IMDRF members) to accelerate local approvals and conserve national resources.
- **Scientific consistency;**
  - All decisions must be based on **sound science and adherence to globally recognized technical standards** (e.g., ISO, IEC), ensuring regulatory outcomes are objective, reproducible, and not arbitrary.
- **Defined performance metrics;**
  - The regulatory system must commit to and publish **clear service standards and timelines** for reviews, licensing, and inspections, demonstrating administrative efficiency.

Future focus: Technology and the local context

Emerging technologies & local suitability

Our regulations must look ahead to accommodate the unique challenges of our continent and the pace of global innovation (IMDRF, GHWP).

Regulating the Unseen (SaMD/AI): We must proactively adopt IMDRF/GHWP guidance on **Software as a Medical Device (SaMD)** and **AI-enabled Medical Devices (AIMD)**.

Action: Regulations must be **technology-neutral** and focus on **post-market algorithm performance** and **cybersecurity**, rather than static, slow pre-market reviews.

Local Suitability is Essential: For both imported and locally manufactured devices, our regulations must enforce the **Essential Principles of Safety and Performance** in the unique African context.

Example: Devices must be validated to handle extreme temperatures, humidity, and **unstable power supply (220V/50Hz)**. This is a critical national requirement that reliance alone cannot solve, and it is where our local authority is paramount.

Empowering Local Manufacturing: We must use **ISO 13485:2016** as the common QMS yardstick to nurture local manufacturers, positioning them to both serve their national market and be ready to export internationally.

Conclusion

Unified vision

Our success depends on moving forward, not as 55 individual bodies, but as a **cohesive African regulatory space.**

For Regulators: Adopt the IMDRF & AMDF frameworks and GRelP immediately. Commit to GBT.

For Industry: Commit to high-quality, harmonized submissions and robust, locally-aware post-market vigilance systems.

Let the **Authority in Action** of our NRAs be the force that creates the efficiency, quality, and predictability necessary for **Shared Progress** in healthcare access across the continent.

Common African proverb

Let's build a unified African regulatory space together.

If you want to go fast, go alone. If you want to go far, go together.

In medical device regulation, we must go together, to ensure we go further for our patients.

For A Healthier Africa

AFRiSUMMIT

2nd - 5th November 2025

Hilton Grand Nile Hotel, Cairo - Egypt

THANK YOU