Bridging regulatory gaps: Navigating vaccine approvals in LMICs

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What we do

***For over 200 years**, USP has been advancing its vision of a world where all have access to safe, quality medicines, and trusted diagnostics*

Our mission

To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medical products, including vaccines

Regulatory Authorities & Vaccine Manufacturers

Constantly interacting to maintain balance

Regulatory Authorities

Vaccine Access

- Products patients can rely on
  - Maximize benefit
  - Minimize potential risk

Manufacturers

Regulatory Authorities & Vaccine Manufacturers

Constantly interacting to maintain balance through dynamic, unique and complementary roles

Regulatory Authorities

- Safety and compliance
  - Standards
  - Regulations
  - Ethics
- Suitability
- Trust

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Manufacturers

- Driving innovation
  - New products
  - Improve processes
- Efficiency and productivity
- Economic growth

Regulatory authority & vaccine manufacture runway

Potential imbalance areas

Capability and capacity

- Misaligned upskilling
- Lack of vaccine acumen
- Differing implementation of standards

Inefficiencies

- Slow, misaligned processes
- Urgency vs stringency
- Redundancy
- Strained resources

Effects

- Cautious and risk adverse
- Prolonged timelines for development and registration
- Missed opportunities
- Lower business sustainability
- Delays in access to needed vaccines
- Reduced trust

Most evident in the emerging context and in times of global health emergencies

End-to-End research, development and GMP manufacturing at Afrigen

(final GMP inspection target Q2 2025)

Quality Management System (GMP)
- Qualified Utilities
- Material Handling
- QC Laboratories & Stability

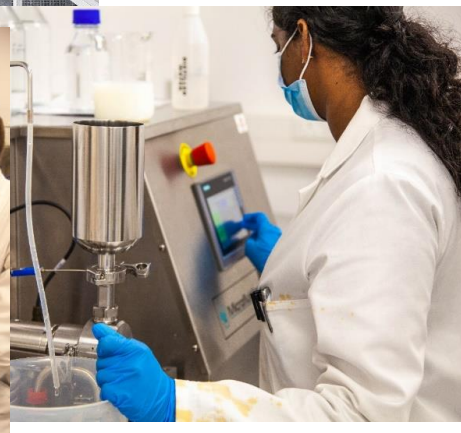
Research & Development
- Plasmid Design & Development
- Antigen Design
- Process Development (DS + DP)

Biotech Production (GMP)
- Master & Working Cell Banks
- Plasmid Manufacturing
- DS & Bulk DP Manufacturing

Analytics (GMP)
- Characterization Assays
- Drug Substance Release Assays
- Drug Product Release Assays

Aseptic Filling & Finishing (GMP)
- Sterile Filling Line
- Visual Inspection, Label & Pack
- Shipping

REGULATORY CHALLENGES ACROSS A VALUE CHAIN



Afrigen
Biologics & Vaccines

A Challenge to Concur

“Access to innovation is a primordial priority that cannot be disconnected from global health policies and emergencies response, as the quality of response will always depend on pre-existing regulatory systems and internationally agreed reliance procedures. Innovative technologies are certainly a challenge for regulatory systems as the forward looking of regulatory systems need to align regulatory science (and development of new innovative products) with regulatory systems (and organizational frameworks under commonly agreed and converging regulatory standards).

Global efforts are needed to build robust, resilient and reliable regulatory systems which will serve as enabler to access quality health products, especially life-course vaccines, to support tacking aging population, climate change, non-communicable diseases and emerging diseases.”

Dr. Rogerio Gaspar Director, Dept Regulation and Prequalification Division of Access to Medicines and Health Products Division, World Health Organization, Geneva, Switzerland

7 October 2024, AVMI Regulatory Consultation, Cape Town, SA

Afrigen Biologics: Africa Case Study
End-to-end R&D and GMP Manufacturing

Regulatory Pre-requisite requirements (SAHPRA) : IT STARTS AT HOME!

- Afrigen as first applicant need to deeply understand SAHPRA requirements -need a GMP certified facility with production process (GMP batches) before commencing manufacturing of an investigational new product for Phase 1 – mRNA-LNP vaccine (pre-commercialization);
- Requires ethical approval of clinical trial protocol by registered Research Ethics Committee prior to Clinical trial application submission;
- Good Quality complete IMPD – missing data can result in CTA rejection.

Afrigen Biologics: Africa Case Study

Enabling regulatory framework within Afrigen to ensure compliance:

- Keeping abreast and adapting to new SAHPRA processes and Regulatory Information Mngt System and Global trends;
- Workforce development in the regulatory arena – require a multidisciplinary integrated workforce team from Regulatory Affairs, CMC, non-Clinical Development, Clinical, R&D; Pharmacovigilance; Quality and projects;
- Charter effectively through fragmented material and equipment import and export landscape;
- Digitalization and enhancing regulatory compliance and reduce risk – a must do;
- Aligning internal processes and systems with SAHPRA's strengthened regulatory expectations and the WLA Framework – future ready;
- Continuous benchmarking against Global Best Practices, contribute to pilot studies to enhance efficiencies, system innovation without transfer of risk – such as GMP certification and WHO PQ.

Afrigen Biologics: Africa Case Study

Core Strategy: **Strengthened Partnerships and Collaboration**:

- Engage with SAHPRA early in the product development process to clarify requirements (such as clinical material production and commercial batches), address potential issues and align expectations;
- Foster strong transparent relationship with SAHPRA;
- Forming collaborations with our fellow industry role players in SA and the continent to enhance knowledge sharing and compliance to global standards;
- Participating in regulatory working group initiatives across boundaries;
- Continuous development and training of staff – USP and other regulatory expert Institution partnerships;
- Integrated approach to regulatory compliance and efficiency – from raw material qualification, procurement and supply chain right through to safe and effective use.

Improving vaccine approval navigation

Twinning ⟷ **Global**

Advance holistic and cross-cutting expertise

- Specifically designed curriculum with opportunity practicums
- Open-door cooperation promoting common understanding
- Secondments, sabbaticals and work placements

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- Develop consensus on science, technology, interventions or regulatory actions

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- Regional pool of experts supporting decentralized regulatory review and approval processes
- Guidance from WLA and ML4 designated countries

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Transforming knowledge development opportunities through adaptation and collaboration

We build solutions through collaboration

Collaborating with
industry

including DCVMN

Collaborating with
global regulatory bodies

including WHO, NRAs and regional initiatives

Collaborating with
stakeholders

including donors, governments and other Pharmacopeias

Collaborating with
strategic partners

including other TA providers and regional initiatives

Our work in global health

USP's global health programs strengthen health systems at local, regional, and global levels and deliver end-to-end pharmaceutical services that champion **equitable access to quality medical products**.

USP across the vaccine ecosystem

Bridging needs and catalyzing solutions: a holistic approach to implementation

Regulatory Authorities

- GBT maturation – systems strengthening
  - Regulatory review and approval (including EUA)
  - Inspection and licensing
  - Lot release (LSS)
  - Post-marketing surveillance
  - Vigilance
- Regional reliance and network frameworks

Vaccine Access

- International vaccine handling toolkits
- Dose optimization
- Standards *
- USP Education program

Manufacturers

- Quality systems
- GMP
- QA/QC
- Qualification, validation
- Dossier preparation and registration
- Vaccine quality assessment toolkits

* 17 October Session 6: Novel Technologies “Supporting the vaccine product lifecylce through standards”, K. Carrick

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The standard of trust