Egyptian Drug Authority

هيئة الدواء المصرية

BIO INN Lot Release

Activity REPORT

2025

https://edaegypt.gov.eg

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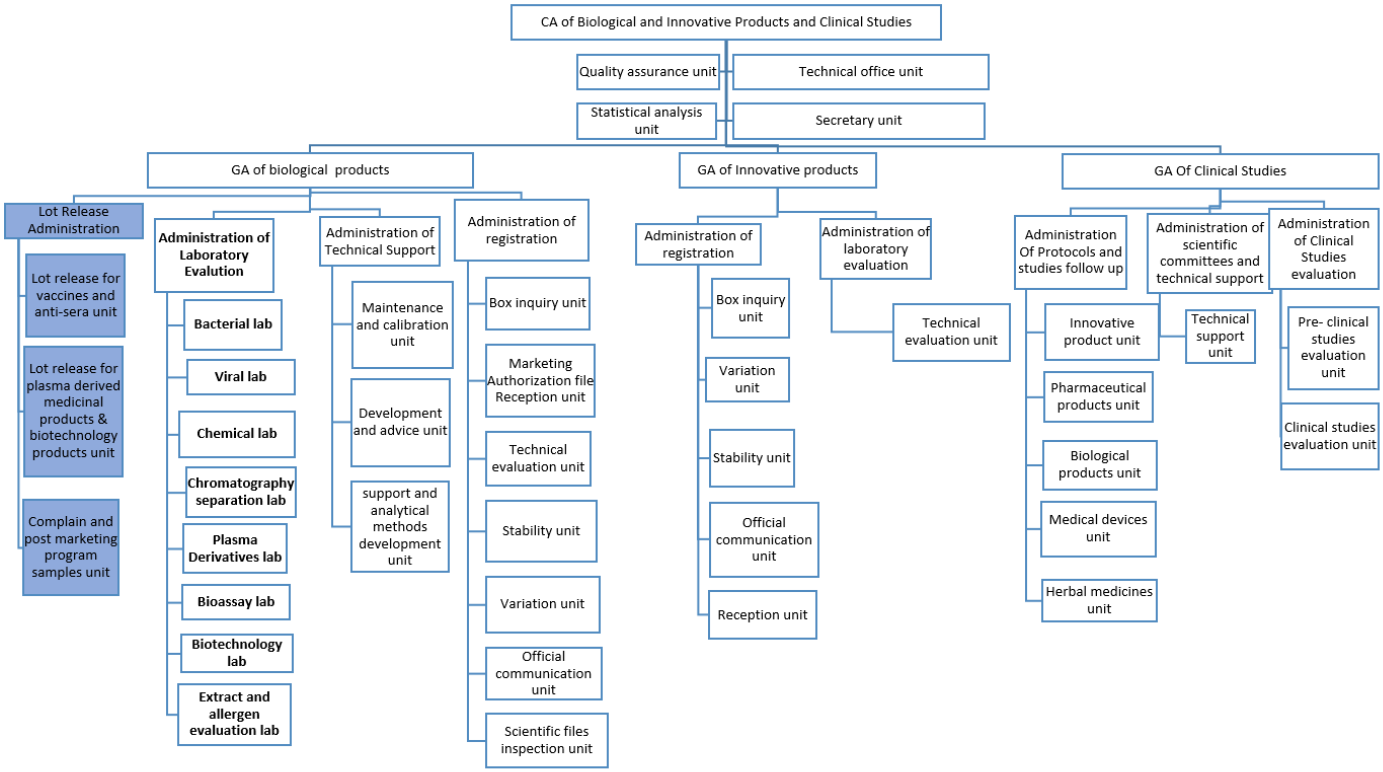
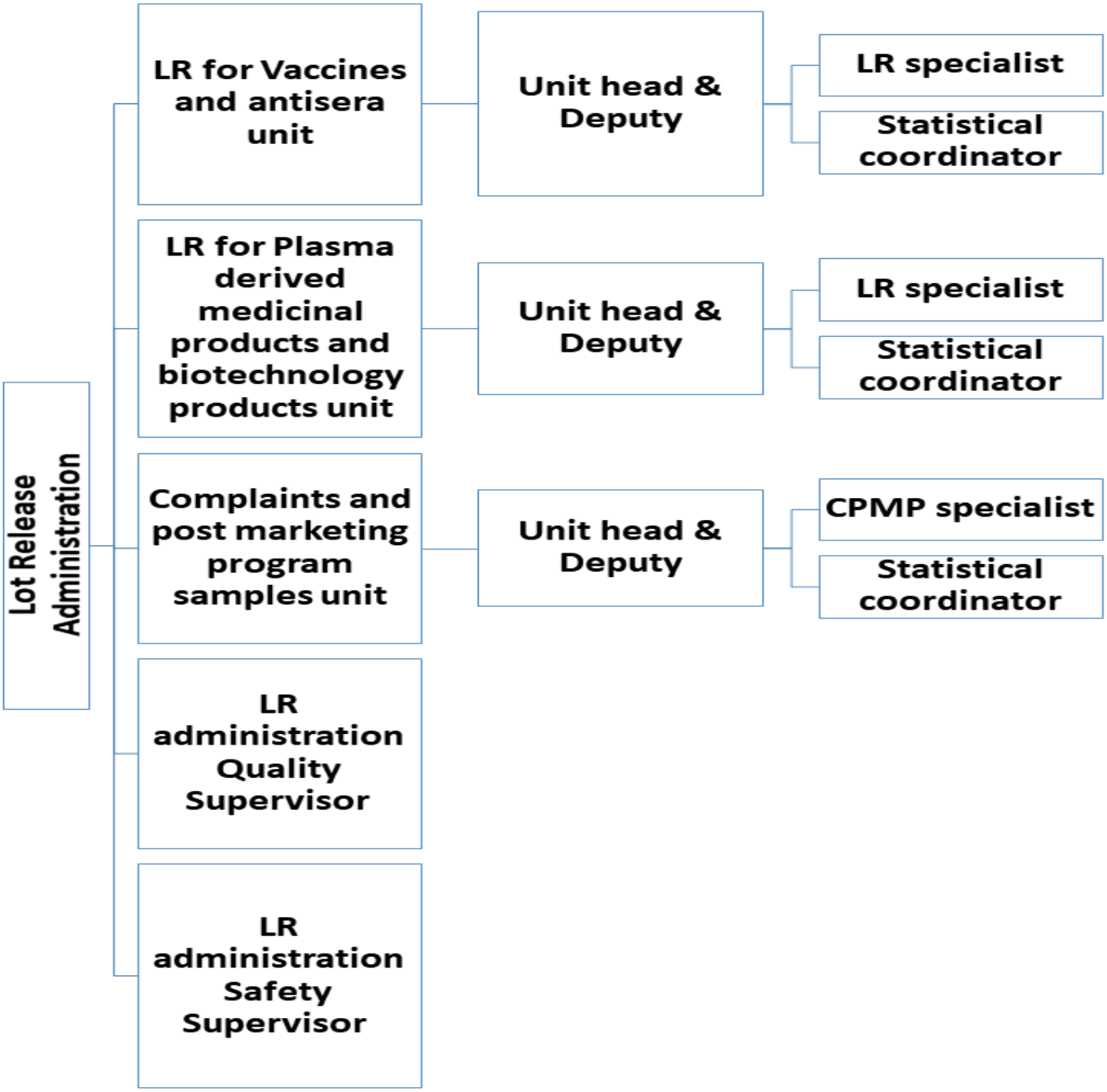
Organizational chart

BIOINN ORGANOGRAM



LOT RELEASE ADMINISTRATION ORGANOGRAM



Responsibilities of Lot Release

· Manage and coordinate lot release activities for biological products to ensure appropriate regulatory control before market distribution.
· Apply risk-based approaches and reliance/recognition pathways to support efficient and proportionate regulatory oversight.
· Review batch documentation, testing outcomes, and quality-related information to support release and certification decisions.
· Coordinate with relevant laboratory, regulatory, inspection, and post-marketing stakeholders, including follow-up on quality issues and continuous improvement activities.

STATISTICAL DATA

Lot Release administration is intended to ensure the quality and efficacy of biological products. As a result, Key Performance Indicators (KPIs) are routinely monitored to ensure that lot release is conducted efficiently and in accordance with defined regulatory standards.

Risk-based Lot release system

Lot release administration

✓ National lot release is governed by:

- EDA establishment law 151/2019 and its executive regulation 777/2020
- Policy for lot release of biological products in Egypt
- EDA chairman decree 425/2022 for LR regulation in Egypt
- Guideline for Lot Release of Biological Products in Egypt

✓ Risk-based Lot release system

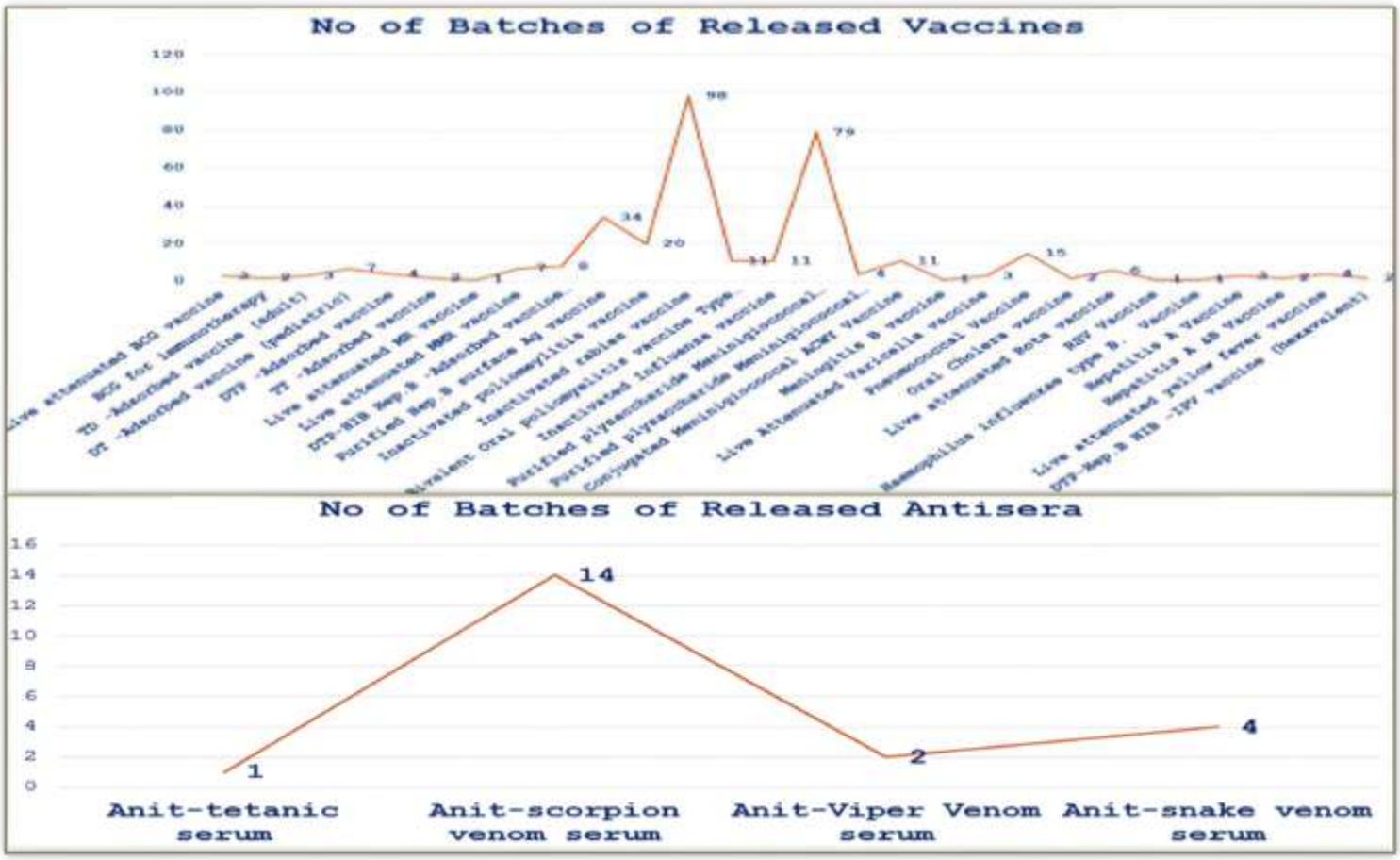
- The Egyptian Drug Authority (EDA) has adopted a Risk-Based Lot Release (RB-LR) system to enhance the efficiency and effectiveness of the lot release process for biological products. This approach aligns with international best practices and aims to ensure the timely availability of high-quality biological products in the Egyptian market.

Risk factors

Batch Release

Vaccines & antisera Unit

- The unit oversees the end-to-end Lot Release process for vaccines and antisera through electronic submission of batch documentation and risk-based laboratory testing at the National Control Laboratory (NCL), leading to final regulatory decisions and batch certification.
- It ensures efficient coordination with manufacturers and relevant EDA administrations, supports data-driven oversight through trend analysis, and supports product availability in the market..

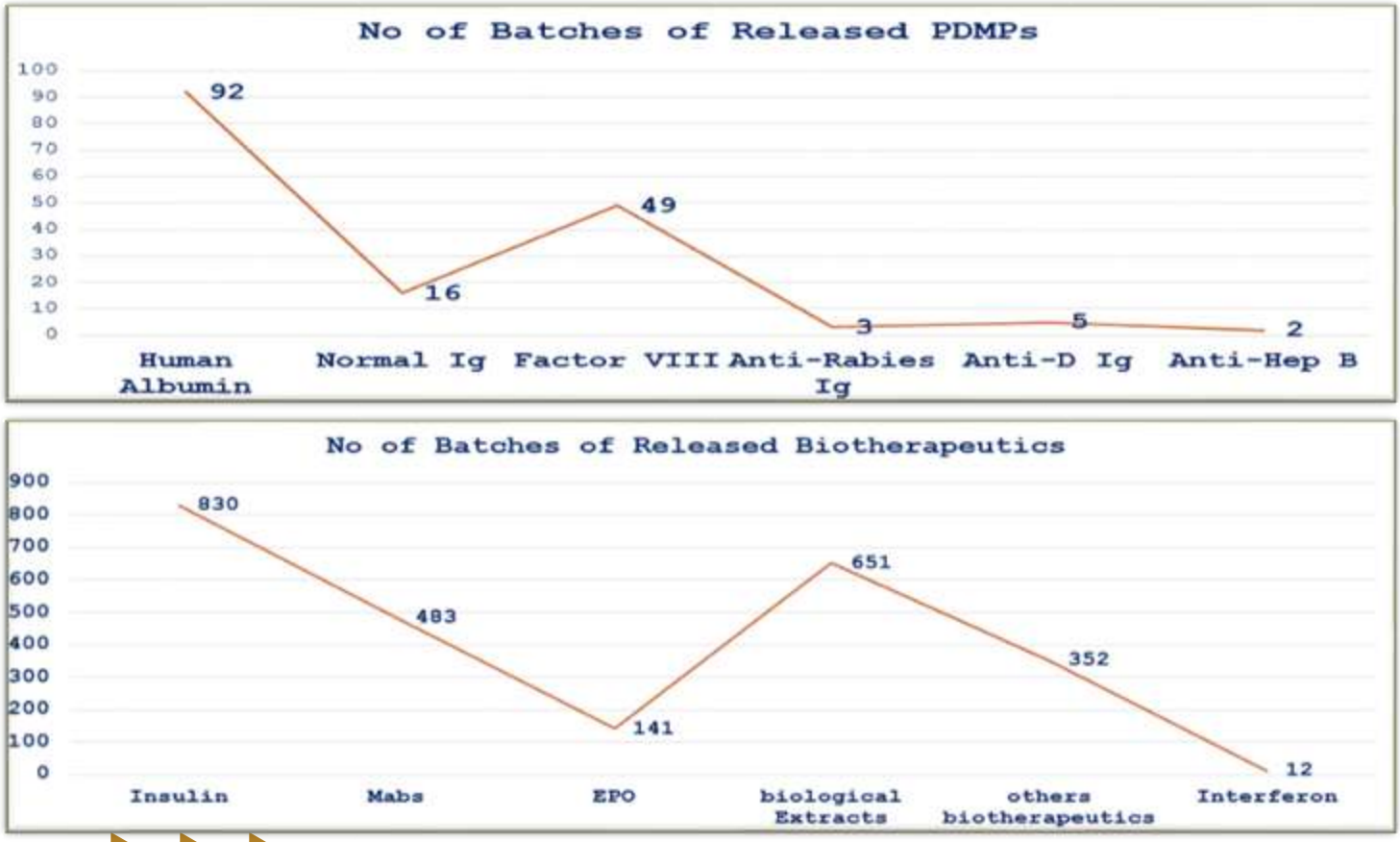


Statistical outcomes

Batch Release

Plasma & Biotechnology products unit

- The unit plays a critical role in ensuring that each manufactured batch of plasma derived medicinal products and other biologicals meets predefined quality, safety, and efficacy standards before being released to the market. This process follows a risk-based approach aligned with WHO guidelines, where batches may undergo full evaluation, partial review, or reliance-based exemption depending on product classification, manufacturing history, and certification from recognized reference authorities.

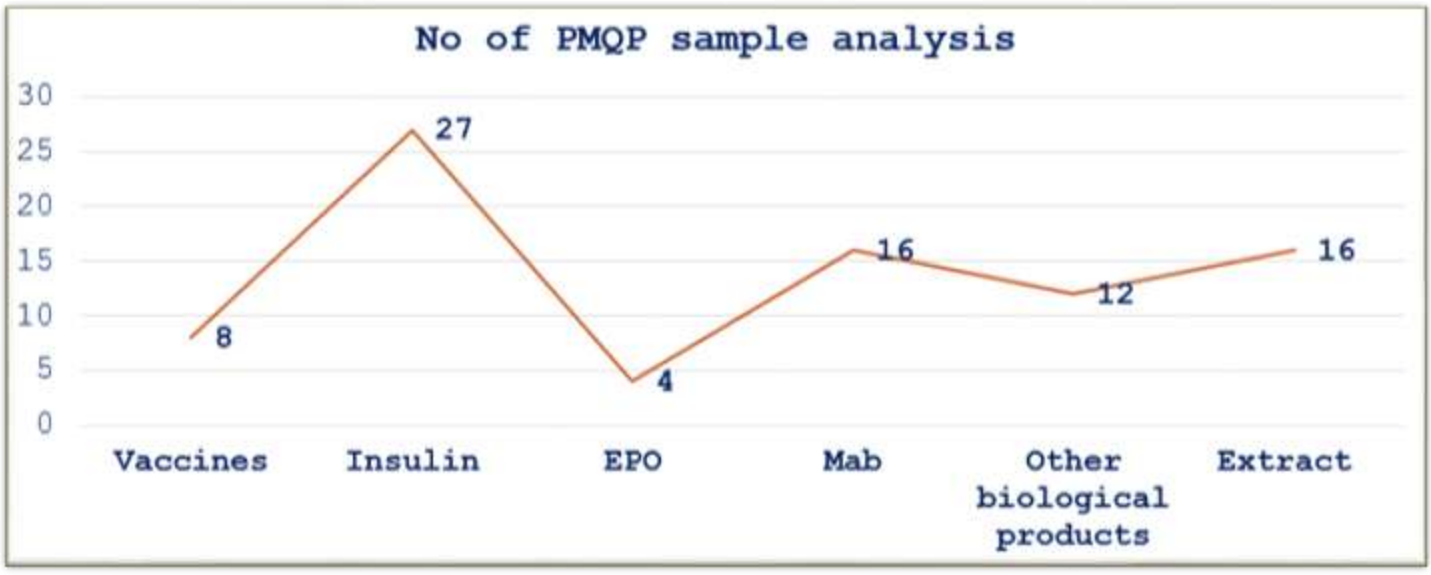


Statistical outcomes

SAMPLE ANALYSIS

Complaints & PMP unit

- The unit operates as a core component of the national post-marketing surveillance system applying a risk-based approach to ensure the ongoing quality and safety of biological products after market entry. It combines proactive monitoring (planned sampling and laboratory testing) with reactive investigation of complaints related to suspected product defects. Findings are assessed in coordination with the National Control Laboratory and inspection teams to detect quality issues, identify trends, and trigger appropriate regulator actions such as recalls or corrective measures. Through this integrated system, EDA maintains continuous lifecycle oversight of biological products and safeguards public health.



International Activities

African Regulators platform- PTB/PEI/AMRH

Paul-Ehrlich-Institut

Physikalisch-Technische Bundesanstalt Braunschweig und Berlin

AMRH

Lot release administration manager participated in the Vaccine Regulatory Workshop held in Dakar, Senegal, from 25 to 27 March 2025. The workshop was organized within the framework of the African Medicines Regulatory Harmonization initiative and the African Medicines Quality Forum, with the support of regional and international partners including PEI, PTB, EDQM, WHO, GIZ, USP and AUDA-NEPAD.
EDA's participation contributed to regional discussions on strengthening and harmonizing vaccine regulation across Africa, with a particular focus on vaccine lot release, reliance mechanisms, mutual recognition of test results, and the operationalization of the Network of African Reliance Laboratories.
During the country input session, LR administration manager shared Egypt's regulatory experience, highlighting that EDA is the first African National Regulatory Authority to achieve WHO Maturity Level 3 for medicines and vaccines-producing functions. EDA also emphasized its role as a Regional Centre of Regulatory Excellence for vaccine oversight and expressed its commitment to supporting collaboration and capacity-building among sister African NRAs.
The workshop provided an opportunity for EDA to exchange experience with other African regulatory authorities on current vaccine regulatory challenges, recent achievements, benchmarking opportunities, and areas for technical collaboration. EDA also actively contributed to the discussions on the development of harmonized product-specific guidelines for vaccine lot release and the roadmap for operationalizing continental reliance-based laboratory testing under NARL.

Vaccine regulatory workshop –
25-27 March, 2025, Senegal

Summary report

Group picture, 25 March 2025

International Activities

AUDA-NEPAD/ RCORE

Ghana FDA

The Lot Release Administration participated in EDA's regional capacity-building activities for Ghana FDA trainees through specialized training programs on vaccine lot release and biological product quality control.
Its contribution focused on explaining the practical implementation of the lot release process, including batch documentation review, quality data assessment, lot-to-lot consistency, temperature excursion handling, integration of PMS testing results into release decisions, quality management system requirements, and EDA's experience in lot release automation.
The Administration also supported training activities related to vaccine batch release regulatory policies, documentation practices, and the link between laboratory testing and regulatory decision-making.
This participation reflects EDA's commitment to strengthening regulatory capacity, promoting knowledge exchange and reliance among African regulatory authorities, and ensuring the availability of safe, effective, and quality-assured biological products.

WHO Rotational Fellowship

LR staff participation in the WHO RCN Rotational Fellowship Mission at WHO Headquarters in Geneva supported capacity building in regulatory system strengthening, reliance, harmonization, and lot release-related functions.

The mission provided exposure to WHO regulatory teams and networks, including Regulatory Convergence and Networks, Laboratory Networks and Services, Regulatory System Strengthening, Pharmacovigilance, Inspection, Prequalification, Norms and Standards, and other relevant technical units. Through these engagements, LR staff contributed to discussions on regulatory convergence, good reliance practices, risk-based approaches, quality management systems, and strengthening of regulatory functions within EDA and the wider North African region.

The participation included technical contributions directly relevant to lot release and laboratory testing, such as engagement with the LNS team on targeted vaccine testing risk assessment, review of the practical implementation manual for lot release, contribution to lot release guideline updates, and support for preparations related to WHO laboratory networks. The mission also included a study visit to Swissmedic, with discussions on reliance, work-sharing, batch release of plasma derivatives, hemovigilance, and handling of OOS/OOT results.

This participation enhanced LR staff understanding of WHO regulatory frameworks, international reliance mechanisms, laboratory network operations, and risk-based decision-making. It also supported EDA's strategic priorities related to strengthening lot release, laboratory testing, PMS, regulatory harmonization, and preparation toward higher regulatory maturity and WHO-Listed Authority status.

International Activities

WHO NNB/GNP

LR staff participation at the WHO laboratory network meetings provided an important opportunity to engage with global experts from national control laboratories, regulatory authorities, WHO networks, and international partners.

The participation included the 7th General Meeting of the WHO National Control Laboratory Network for Biologicals (WHO-NNB), held from 26 to 28 November 2025 at the WHO Academy in Lyon, France. The meeting focused on safeguarding vaccine quality, strengthening collaboration among national control laboratories, and avoiding duplication of efforts during the official lot release process.

LR staff also participated in activities linked to the 2nd Annual Meeting of the WHO Global Network of National Quality Control Laboratories for Pharmaceuticals (WHO-GNP), held from 24 to 26 November 2025, as well as the joint WHO-GNP/WHO-NNB session under the theme “Advancing Laboratory Excellence Through Collaboration, Innovation and Regulatory Agility.”

This participation supported knowledge exchange, international collaboration, and alignment with global best practices in biological product testing, vaccine lot release, quality control, and market surveillance.

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International Activities

The China-Africa International Training Course on Testing Technology of Biological Products

LR staff participation in the International Training Course on Testing Technology of Biological Products, held from 12 to 26 October 2025 in Beijing, China, supported capacity building in biological product quality control, vaccine lot release, and regulatory decision-making.

The training covered key technical and regulatory topics relevant to lot release activities, including laboratory quality management systems, overview of biologics lot release, production and quality control of viral and bacterial vaccines, blood products, therapeutic biologics, seed lot control, vaccine GMP, and technical review considerations for vaccines and other biological products.

The program also included practical and hands-on sessions on routine testing of biological products, such as HPLC, visual inspection, ELISA identification testing, sterility testing, animal potency testing, titration of live attenuated vaccine virus, rapid testing technologies, physicochemical testing, spectroscopic testing, and reference material development and management.

This participation enhanced LR staff technical knowledge and practical understanding of biological product testing, supported alignment with international practices, and strengthened the link between laboratory testing, quality assessment, and lot release decision-making.

International Activities

Seventh Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA VII)

LR team participation in the Seventh Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA VII) was reflected through abstract and poster presentations addressing key priorities for strengthening regulatory systems, harmonization, reliance, and local manufacturing across Africa.

The team contributed three scientific topics: “Enabling Local Production Through Regulatory Agility: Insights from African National Authorities,” “Strengthening Harmonized Regulatory Oversight Across African Countries: Pathways and Benefits,” and “Advancing Regulatory Harmonization and Local Manufacturing in Africa through Laboratory Twinning Programs: A Case Study under the AMRH Framework.”

Through these presentations, the LR team highlighted the importance of agile and risk-based regulatory approaches in supporting local production, promoting harmonized regulatory oversight among African countries, and strengthening laboratory capacity through twinning and work-sharing models. The contributions also emphasized the role of regulatory convergence, reliance, laboratory networks, and capacity building in improving access to quality-assured medical products and supporting sustainable manufacturing in Africa.

This participation demonstrated the LR team’s active role in regional regulatory science, knowledge sharing, and advancing AMRH objectives, while supporting the broader SCoMRA VII theme of unlocking Africa’s potential in health product manufacturing and trade through regulatory harmonization.

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