Egyptian Drug Authority

هيئة الدواء المصرية

BIO INN Laboratories

Activity REPORT

2023-2024

https://edaegypt.gov.eg

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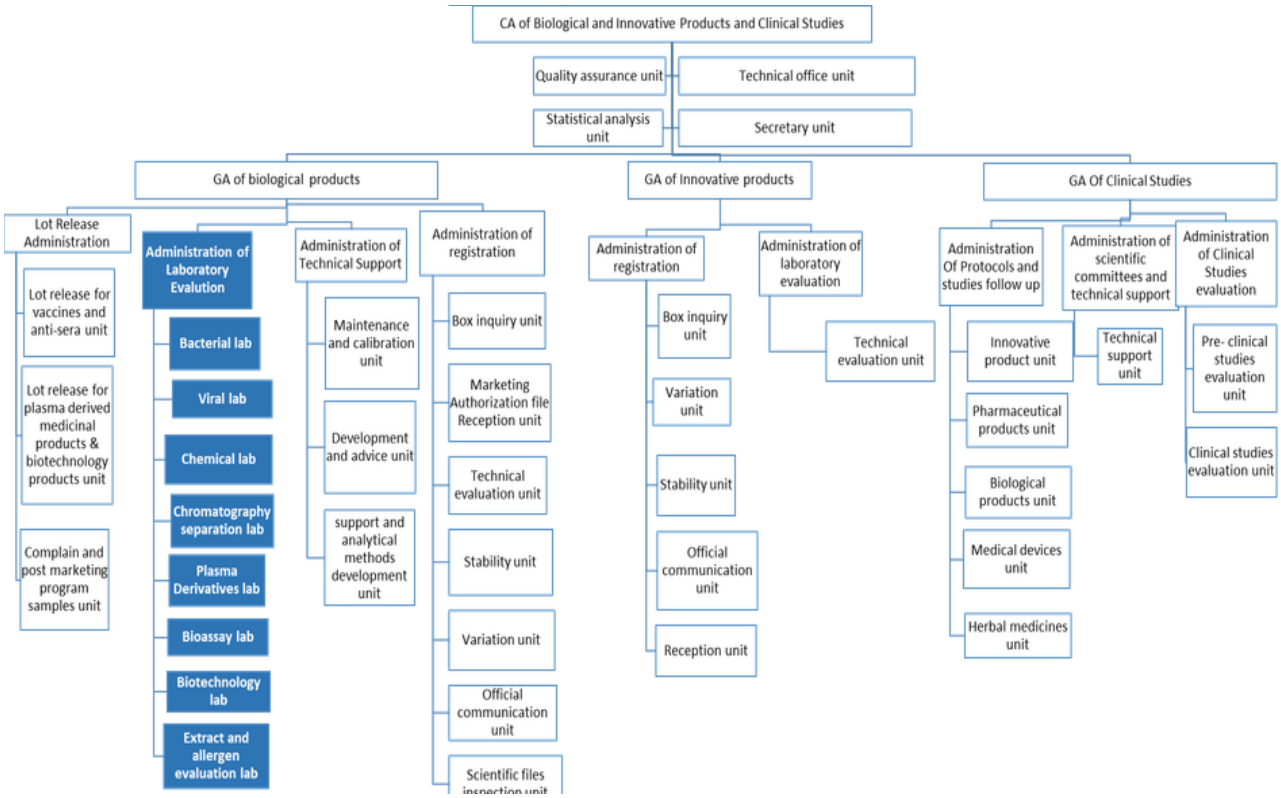
Organizational chart

BIOINN ORGANOGRAM



LAB EVALUATION ADMINISTRATION – OVERVIEW

The Lab Evaluation Administration is a constituent unit of the General Administration of Biological Products, operating under the Central Administration of Biological & Innovative Products and Clinical Studies (Bio-Inn) within the Egyptian Drug Authority (EDA).

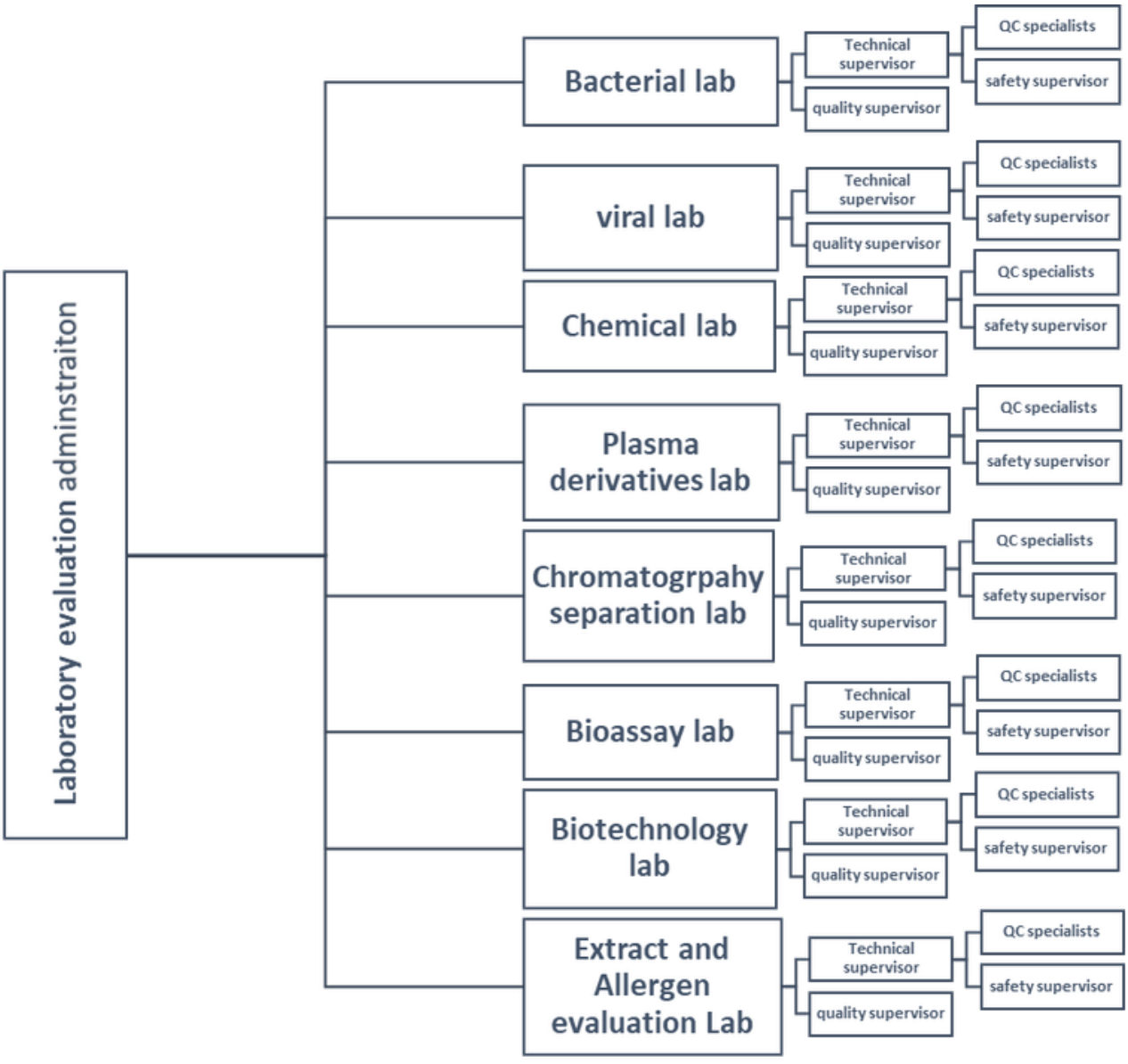
The Administration comprises eight specialized laboratories, each under the direction of an appointed Lab Manager.

The organizational structure is clearly defined and supports effective governance of laboratory activities. Overall leadership is provided by the Laboratory Evaluation Administration Manager, who is responsible for coordination, oversight, and supervise implementation of general policy and all work plans in compliance with the EDA strategic objective and plans.

Each laboratory is functionally supported by competent personnel with specific responsibilities essential to maintaining compliance with regulatory and quality requirements

This structured framework ensures that the Lab Evaluation Administration operates in a systematic, efficient, and quality-driven manner, thereby supporting the EDA’s mandate for regulatory oversight of biological products.

LABORATORY EVALUATION ADMINISTRATION ORGANOGRAM



Responsibilities of BioInn Labs

- Perform quality control testing on biological products to ensure compliance with regulatory and quality standards.
- Carried out validation and verification of analytical techniques used in the testing of biological substances.
- Participation in proficiency testing programs and inter-laboratory comparisons to assess testing accuracy and laboratory performance.
- Technical evaluation and assessment of documents related to the quality of product.
- Participation in GMP and licensing inspections for both domestic and international manufacturers of biological products and plasma collection facilities.
- Participating in internal quality audits to evaluate system compliance and support continuous quality improvement efforts.

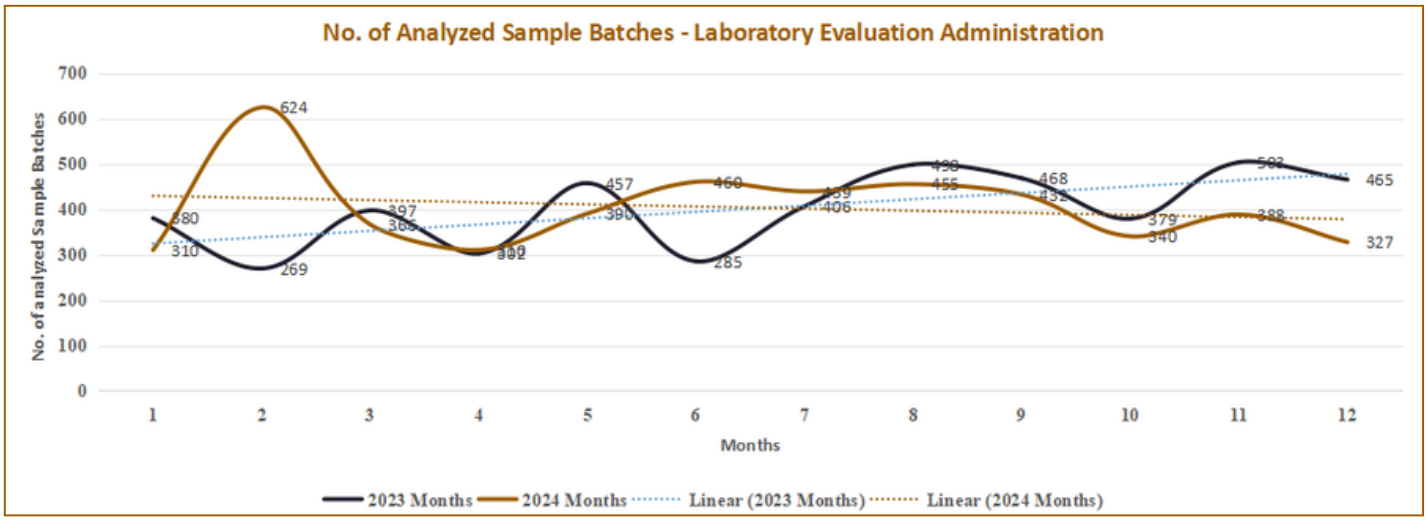
STATISTICAL DATA

Laboratory evaluation administration is intended to ensure the quality and safety of biological products. As a result, Key Performance Indicators (KPIs) are routinely monitored to ensure that laboratory testing is conducted efficiently and in accordance with defined regulatory standards.

SAMPLE ANALYSIS

Laboratory evaluation administration

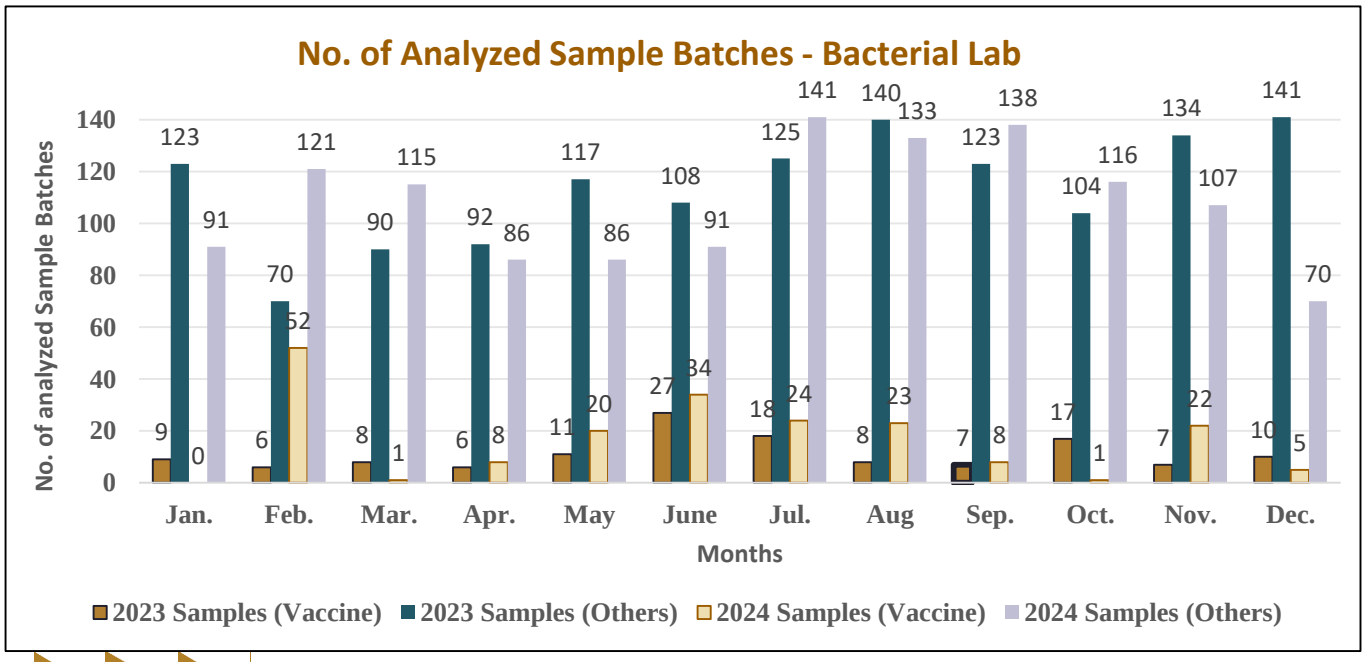
- Sample analyses are conducted by qualified analysts in accordance with validated and standardized procedures, under the supervision of designated laboratory management at multiple levels.
- The testing covers a wide range of biological products - including vaccines, plasma-derived medicinal products, recombinant biological products, and extracted or allergenic substances - in line with applicable regulatory guidelines.
- Laboratory testing is carried out across the eight laboratories listed in the organogram provided above, with each laboratory responsible for its own specific testing procedures.
- The following chart presents the number of analyzed sample batches in 2023 and 2024, totaling 4809 and 4841 batches, respectively.



SAMPLE ANALYSIS

The Bacterial Laboratory

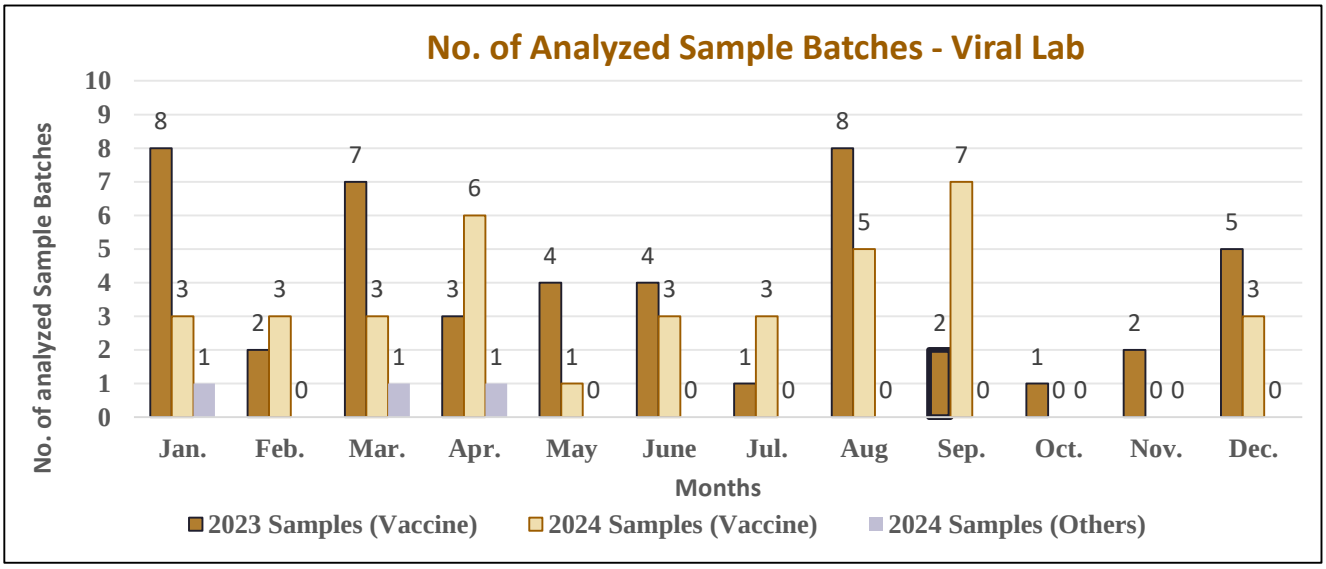
- The Bacterial Laboratory plays a central role within the Laboratory Evaluation Administration by conducting comprehensive microbiological quality control testing for all biological products.
- The laboratory specializes in performing critical assays such as endotoxin and sterility testing for biological products, in addition to conducting identification and potency testing for bacterial vaccines.
- The following chart presents the number of analyzed sample batches across the Bacterial Laboratory for 2023 and 2024. In 2023, the laboratory processed a total of **1,484 analyzed sample batches**, which included **134 vaccine samples** and **1,367 other biological product samples**. In 2024, the laboratory processed a total of **1,493 analyzed sample batches**, which included **198 vaccine samples** and **1,295 other biological product samples.**



SAMPLE ANALYSIS

The Viral Laboratory

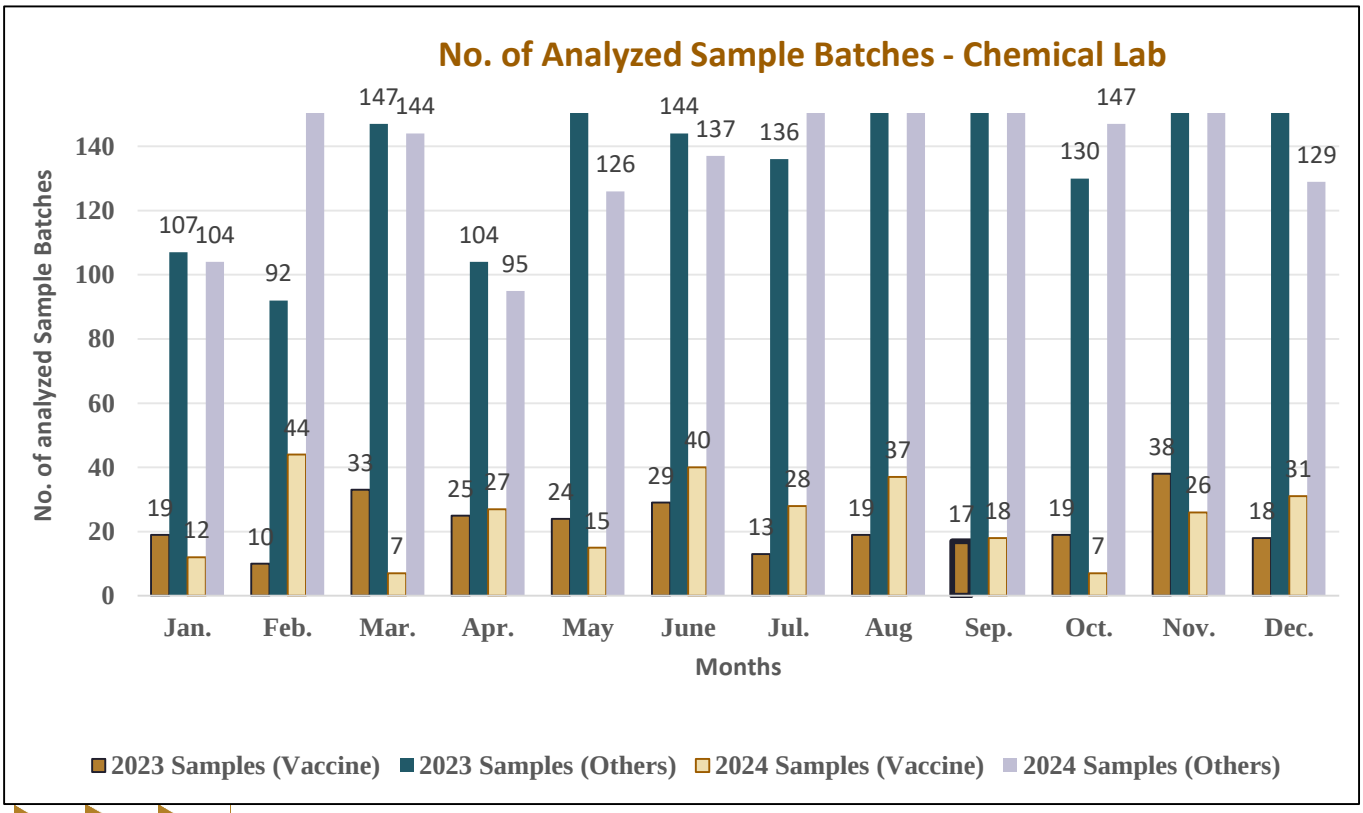
- The Viral Laboratory plays a key role within the Laboratory Evaluation Administration by conducting specialized quality control testing for viral vaccine products.
- The laboratory specializes in performing critical assays such as identification and potency testing for viral vaccines, as well as for the viral components of combined vaccines.
- The figure presents the number of analyzed sample batches in 2023 and 2024, totaling 47 and 37 batches, respectively.
- The following chart presents the number of analyzed batches across the Viral Laboratory for 2023 and 2024. In 2023, the laboratory processed a total of 47 analyzed Vaccine batches. In 2024, the laboratory processed a total of 40 analyzed sample batches, which encompassed 37 vaccine samples.



SAMPLE ANALYSIS

The Chemcial Laboratory

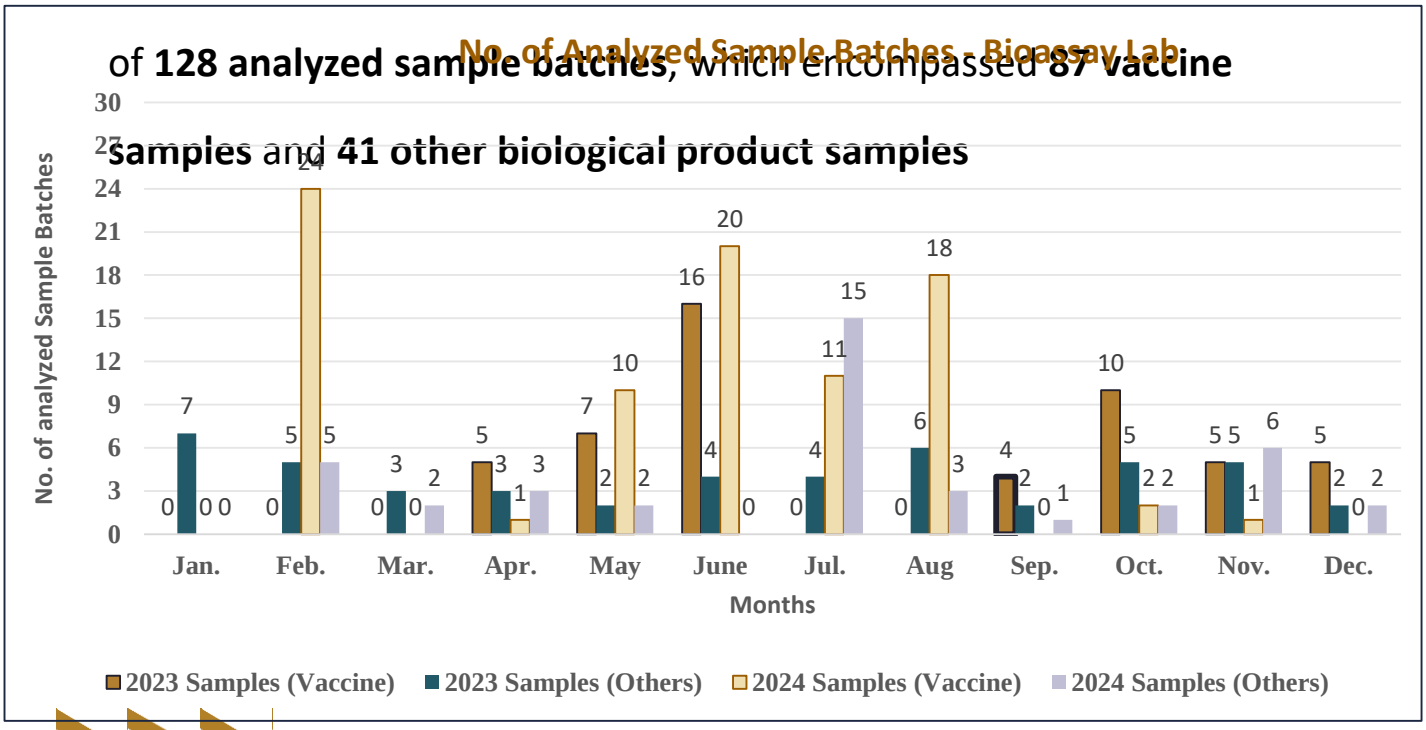
- The Chemical Laboratory plays an essential role within the Laboratory Evaluation Administration by conducting comprehensive analytical quality control testing for all biological products.
- The following chart presents the number of analyzed sample batches in 2023 and 2024. In 2023, the laboratory processed a total of 1,484 analyzed sample batches, which included 264 vaccine samples and 1,697 other biological product samples. In 2024, the laboratory processed a total of 2,013 analyzed sample batches, which included 198 vaccine samples and 1,295 other biological product samples.



SAMPLE ANALYSIS

The Bioassay Laboratory

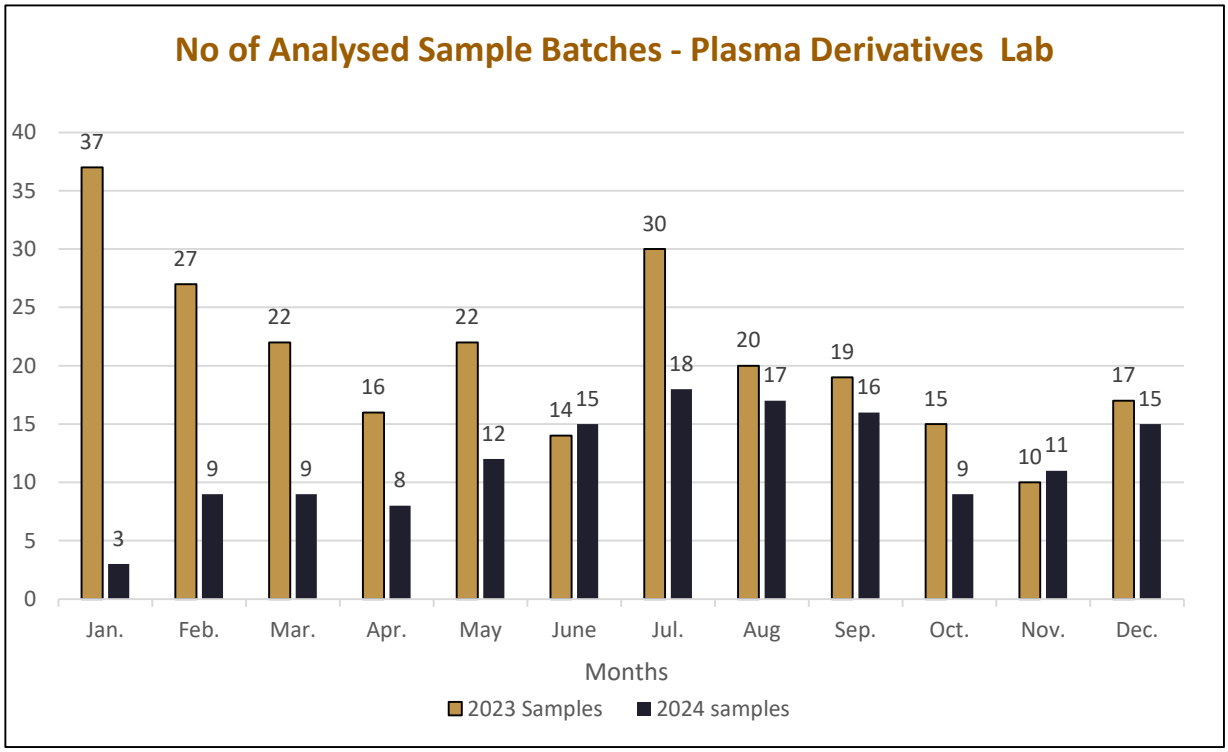
- The Bioassay Laboratory is responsible for performing safety and pyrogen tests on all biological products to ensure their safety, and compliance with regulatory standards.
- The following chart presents the number of analyzed sample across the Bioassay Laboratory for 2023 and 2024.
- .In 2023, the laboratory processed a total of **100 analyzed sample batches**, which encompassed **52 vaccine samples** and **48 other biological product samples**. In 2024, the laboratory processed a total of **128 analyzed sample batches**, which encompassed **87 vaccine samples** and **41 other biological product samples**



SAMPLE ANALYSIS

The Plasma Derivative Laboratory

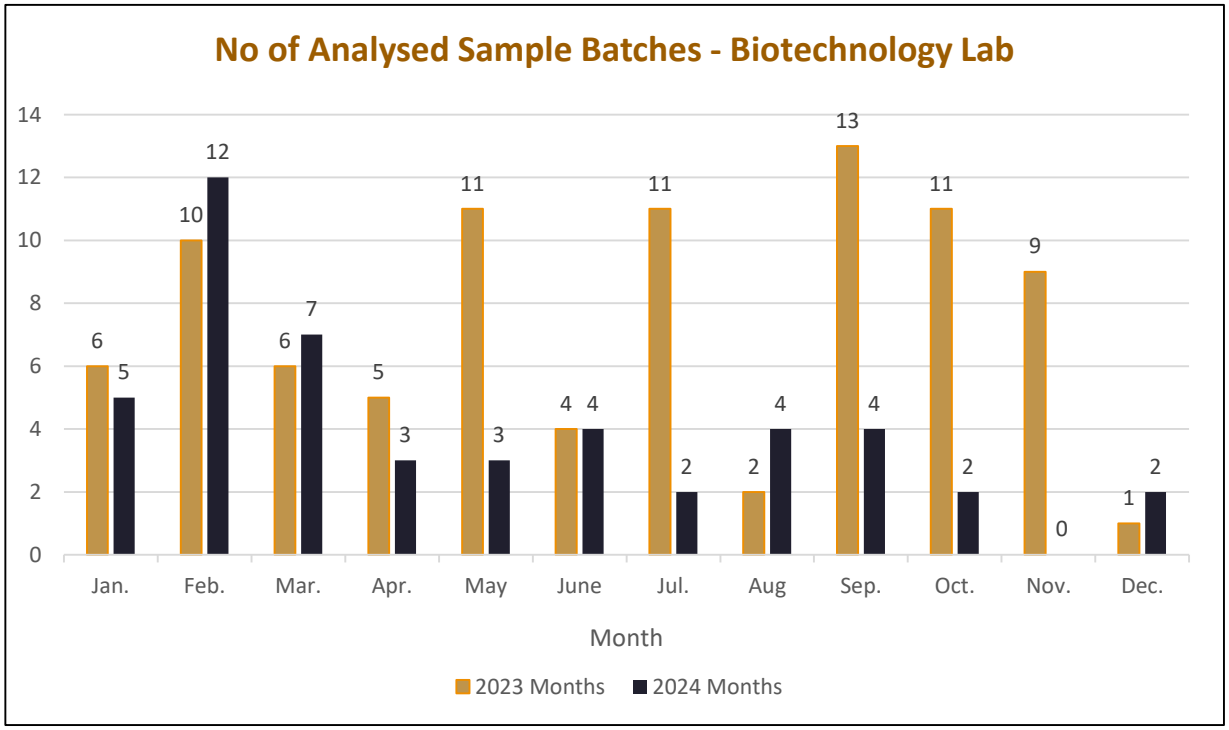
- The Plasma Derivatives Laboratory plays a key role within the Laboratory Evaluation Administration by conducting comprehensive quality control testing for plasma-derived medicinal products.
- The following chart presents the number of analyzed sample batches in 2023 and 2024, totaling 249 and 142 batches, respectively.



SAMPLE ANALYSIS

The Biotechnology Laboratory

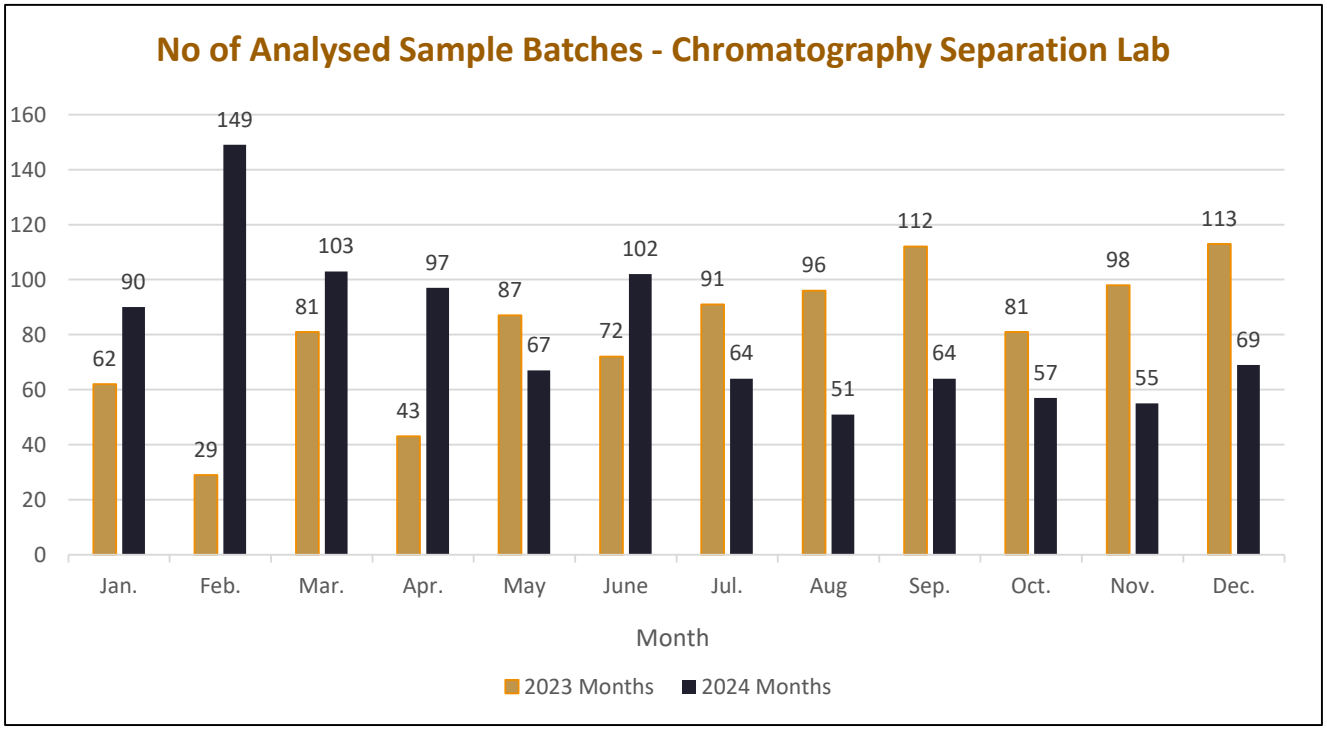
- The Biotechnology Laboratory plays a key role within the Laboratory Evaluation Administration by conducting comprehensive quality control testing for recombinant, monoclonal, and biosimilar products.
- The laboratory specializes in performing critical assays, including identification, and potency testing of these products.
- The following chart presents the number of analyzed sample batches in 2023 and 2024, totaling 89 and 48 batches, respectively.



SAMPLE ANALYSIS

The Chromatography separation Laboratory

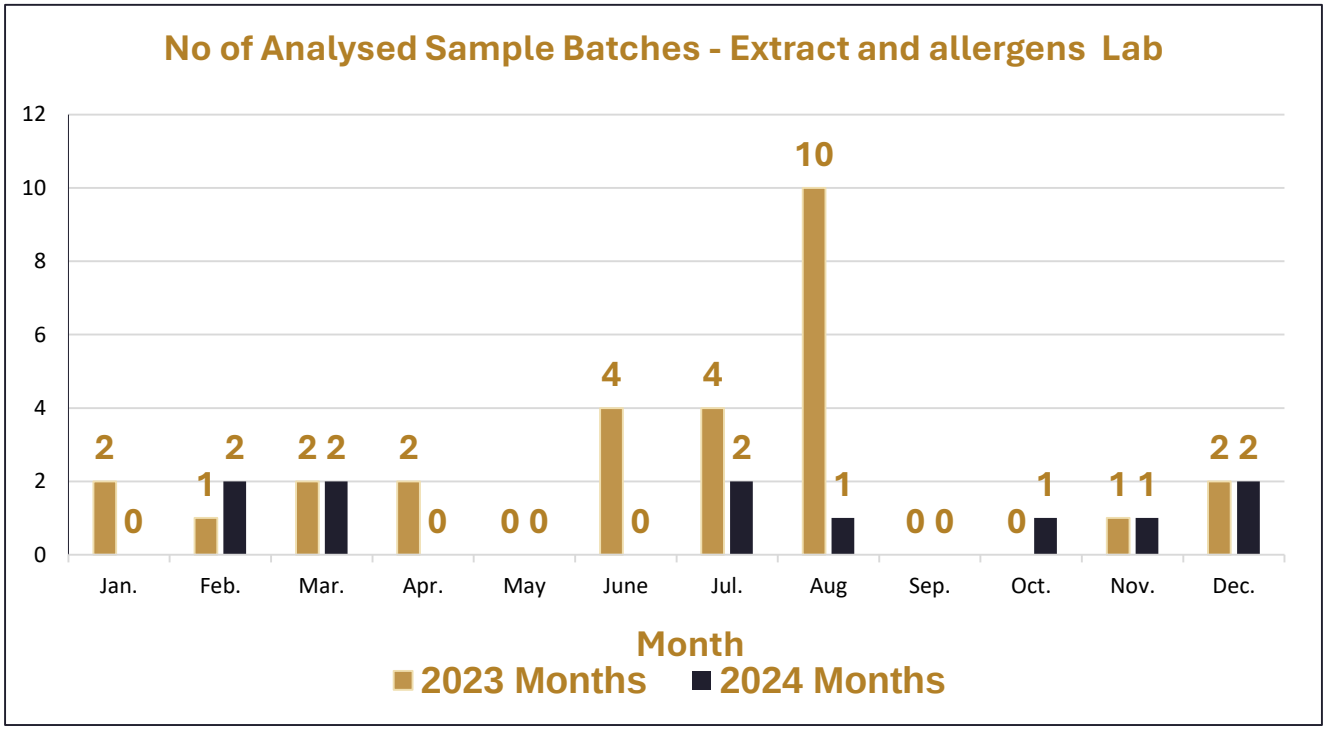
- The Chromatography Separation Laboratory plays a key role within the Laboratory Evaluation Administration by conducting quality control testing using various chromatographic separation methods for recombinant products.
- The laboratory specializes in performing critical assays and assessing the purity profiles of recombinant products.
- The following chart presents the number of analyzed sample batches in 2023 and 2024, totaling 965 and 968 batches, respectively.



SAMPLE ANALYSIS

The Extract and allergens Laboratory

- The Extracts and Allergens Laboratory plays a key role within the Laboratory Evaluation Administration through In vivo testing to ensure the quality and safety of extractable biological products.
- The following chart presents the number of analyzed sample batches in 2023 and 2024, totaling 28 and 11 batches, respectively.

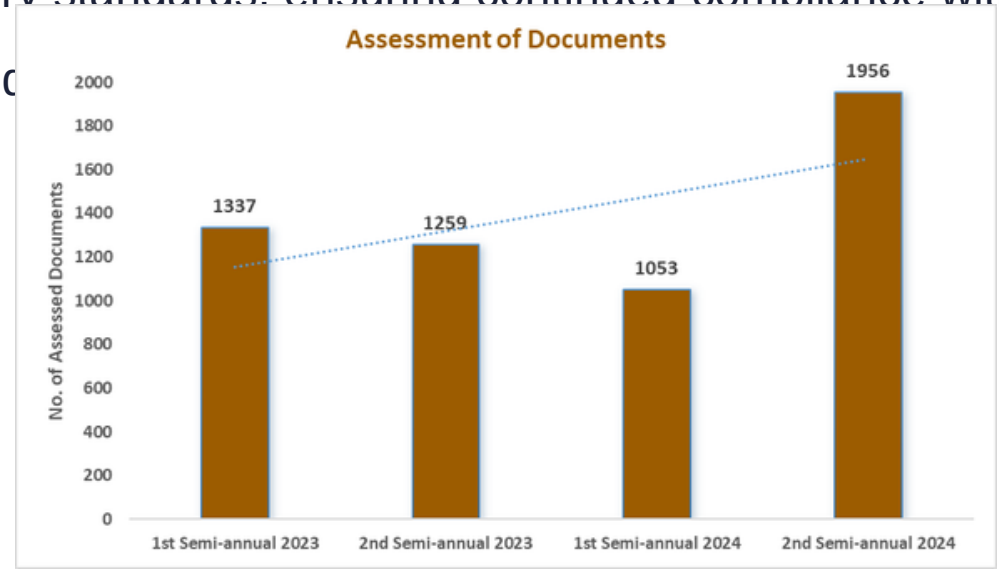


DOCUMENT ASSESSMENT

As part of routine quality and regulatory oversight, technical assessment of quality and manufacturing data were conducted throughout the year. These reviews include:

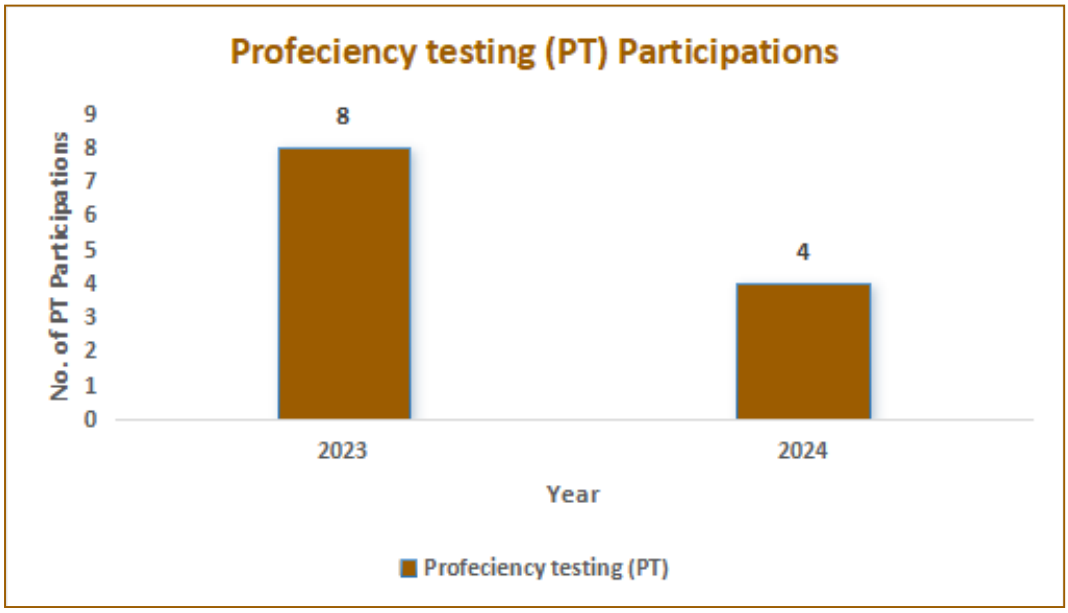
- The technical evaluation of Summary Protocols/Certificate of analysis.
- The assessment of the Quality Module of the Marketing Authorization file for biological products including Advanced therapy medicinal Products
- The technical evaluation of quality module of Investigational medicinal products
- The technical assessment of post-approval changes.

The chart presents the number of assessed documents across four semi-annual periods, with recorded values of 1337 in the first half of 2023, 1259 in the second half of 2023, 1053 in the first half of 2024, and 1956 in the second half of 2024. All evaluations were completed in accordance with predefined timelines and regulatory standards, ensuring continued compliance with product c



PROFECIENCY TESTING (PT)

- The Laboratory Evaluation Administration participates in a wide range of proficiency testing (PT) schemes and inter-laboratory comparisons to verify the accuracy, consistency, and reliability of analytical results. Since the first successful PT participation in 2010, the administration has continued involvement across various test categories.
- PT Participation Areas for years 2023 & 2024
    - Water: semi-micro determination
    - Seasonal inactivated influenza vaccine: potency (HA content)
    - Osmolality
    - subvisible particles
    - Sterility testing
    - tetanus and diphtheria toxoid content by flocculation
    - Human Factor VIII potency
    - Liquid chromatography
    - pH determination
    - Protein content by biuret method
    - Bacterial endotoxins



Accreditation/Recognition/ membership

ISO 9001/2015

- The Laboratory Evaluation Administration obtained ISO 9001 certification in 2008. Since then, all laboratory operations have been conducted in accordance with ISO 9001 and its subsequent revisions. Certification has been maintained through regular surveillance and periodic full recertification, ensuring ongoing conformity and continuous improvement of our quality management system

ISO 17025/2017

- The Laboratory Evaluation Administration first obtained ISO/IEC 17025 accreditation in 2010 for certain test scopes. Since that time, all activities under those scopes have been carried out in full compliance with the ISO/IEC 17025 standard and its subsequent revisions. Our accreditation has been maintained each year through regular assessments, surveillance audits, and full reassessments, ensuring that technical competence and quality remain at the highest standard.
- On 16 January 2024, the Laboratory Evaluation Administration expanded its ISO/IEC 17025 accreditation to include three additional test scopes. As a result, the total number of accredited scopes now stands at nine, which are:
  - Determination of Hepatitis B Surface Antibodies using ELISA Method
  - Identification and determination of Influenza heamagglutinin content SRID assay
  - Determination of prekallikrein activator by chromogenic assay
  - Determination of Total Protein in Anti-sera & Erythropoietin (Biuret Assay)
  - Determination of bacterial endotoxin
  - Determination of Tetanus and Diphtheria toxoid content with Flocculation method procedure.
  - In vivo Pyrogen test.
  - Impurities with molecular mass greater than that of insulin.
  - Sterility testing by direct inoculation.

WHO

- In March 2022, the Egypt Drug Authority (EDA) was accredited by the World Health Organization (WHO) for its ability to regulate and evaluate vaccines, both locally produced and imported. EDA's National Regulatory Authority reached Maturity Level 3 (ML-3)—the second-highest level in WHO's global regulatory system. Egypt became the first country in the Eastern Mediterranean Region and the ninth worldwide to achieve this level for vaccine regulation
- In April 2024, EDA also joined the WHO National Control Laboratory Network for Biologicals (WHO-NNB), reinforcing its role in ensuring the quality and safety of biological products in line with international standards.

ICH IPRP International Pharmaceutical Regulators Programme usp

- Staff members of the Laboratory Evaluation Administration actively participate in numerous international initiatives, including ICH Expert Working Groups and internal task forces focused on revising and updating ICH guidelines.
- Moreover, they involved in IPRP working groups and contribute to USP scientific programs, playing a key role in advancing global regulatory standards and scientific collaboration.

Strengthening Regulatory Capacity in Africa

NEPAD-AMRH

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

- EDA has officially announced in August 2023 to be one of NEPAD-AMRH Regional Centers of Regulatory Excellence (RCOREs) in the following functions: LT that focus on promoting and enhancing regulatory standards practices, strengthen the regulatory capacity and development in Africa

- As one of the NEPAD–AMRH Regional Centers of Regulatory Excellence (RCOREs), Laboratory evaluation administration administration submitted two training programs targeted at several African countries in the East Africa region, as part of ongoing collaboration with African Union member states to strengthen regulatory capacity and harmonize practices across the continent.

- In corporation with lot release, lab evaluation administration concluded a specialized training program (27-Oct. 2024 - 7 Nov. 2024) focusing on enhancing participants' skills in laboratory testing and lot release.

- In corporation with lot release & registration administrations , lab evaluation administration concluded a second training program provided to the Food and Drugs Authority of Ghana. Entitled "Best Practices in Batch Release and Control Laboratories for Vaccines" from 01 December 2024 to 03 December 2024

- Participation in AMQF Laboratory twining program: - 3rd round from 09/12/2024 to 13/12/2024.

EGYPTIAN PHARMACOPEIA

- Laboratory evaluation provided Experts for participating in issuing multiple Biological Products Monographs in Egyptian pharmacopeia starting in 2021/2022
- Total Issued monographs for Active biological substance are 13 monographs, while the total Issued monographs for pharmaceutical biological products are 12 monograph in Egyptian pharmacopeia 5th edition during 2024.

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