



## **THE QUALITY MANAGEMENT SYSTEMS OF FOOD AND DRUGS AUTHORITY - GHANA**

The Food and Drugs Authority (FDA)-Ghana was established in 1992 as the Food and Drugs Board (FDB) on the basis of the 1992 Food and Drug Law (PNDCL 305B), later amended by the Food and Drugs ACT of 1996. The Food and Drugs legislation was revised in 2012 and integrated into a new Public Health ACT 851, 2012 that gave birth to the Food and Drugs Authority.

The FDA's legal mandate is found in Part 6 (Tobacco Control Measures), Part 7 (organization and responsibilities of the FDA), and Part 8 (Clinical trials) of the Public Health Act, 2012 Act 851.

It is the National Regulatory Body responsible for the regulation of food, drugs, food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products, blood and blood products as well as the conduct of clinical trials protocols.

The Governing Board with the responsibility of ensuring the effective implementation of the functions of the Authority has mission and vision statements which seek to protect the health and safety of people in Ghana and to be a global centre of excellence for food and medical product regulation.

The FDA executive committee headed by the Chief Executive Officer (CEO) has responsibility for the daily operational management, service delivery and strategic issues

of the organization. The committee, conscious of this mandate has established a Quality Management Systems to ensure operational consistency, improved productivity, reduced costs, increased efficiency, better service delivery, and enhanced reputation ultimately leading to customer satisfaction.

FDA's quality management system (QMS) is a formalized system that has documented processes, procedures, and responsibilities for achieving quality policies and objectives. It coordinates and direct the organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continual basis. This has led to the creation of a Quality Management Systems Department (QMSD) with a responsibility to establish, implement and maintain a quality management system in line with international standards like; ISO 9001, ISO 17025, WHO-Prequalification and WHO-Global Benchmarking Tool (WHO-GBT).

The CEO in consultation with the Executive Committee members, established, implemented and maintains a quality policy for the organization as follows:

***“THE FOOD AND DRUGS AUTHORITY WILL CONTINUALLY ENSURE QUALITY, SAFE AND EFFICACIOUS / EFFECTIVE / WHOLESOME PRODUCTS THROUGH REGISTRATION, INSPECTIONS, LICENSING, SURVEILLANCE AND CLINICAL TRIAL ACTIVITIES IN CONFORMITY WITH THE APPLICABLE NATIONAL AND INTERNATIONAL STANDARDS TO MEET CUSTOMER SATISFACTION”.***

The FDA's QMS is certified to ISO 9001:2015 ([click to view certificate](#)) for all its operations. These operational functions include:

- Import Control Department
- Export Control Department
- Data Management Department
- Financial Audit and Compliance
- Revenue Department
- Expenditure & Reporting Department

- Strategy, Partnerships & International Collaboration Department
- Quality Management System Department
- Planning, Monitoring and Evaluation Department
- Technical Support Department
- Capacity Strengthening Department
- Intelligence Department
- Operations Department
- Investigations Department
- Manufacturing Facilities
- Storage Facilities Department
- Volta Regional Office
- Ashanti Regional Office
- Career Development Department
- Staff Welfare Department
- Supply Chain Department
- Administration Department
- Legal Department
- Communication & Public Education Department
- Information Management & Technology Solutions Department
- Drugs & Nutraceuticals Department
- Herbal & Homeopathic medicine Department
- Medical Devices Department
- Cosmetics & Household Chemical Substance Department
- Safety Monitoring Department
- Clinical Trial Department
- Vaccines & Biological Products Department
- Substances of Abuse Department
- Tobacco and Tobacco Products Department
- Food Evaluation Registration Department
- Applied Nutrition, Research and Advertisement Review Department

- Food Service Establishment Department
- Food Safety Coordination & Consumer Education Department

Regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes and innovation.

The Global Benchmarking Tool (GBT) represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. It incorporates the concept of 'maturity level' or ML, allowing WHO and regulatory authorities to assess the overall 'maturity' of the regulatory system on a scale of 1 (existence of some elements of regulatory system) to 4 (operating at advanced level of performance and continuous improvement).

The FDA's regulatory quality management system has been assessed and awarded a Maturity-Level 3 status (<https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4>) which means the organization's regulatory oversight commensurate to a stable, well-functioning and integrated regulatory system.

The organization has a laboratory as required by the Public Health Act which is known as Centre for laboratory services and research (CLSR). The Centre has six (6) testing Laboratories operating under an integrated quality management systems of ISO 17025 and WHO-GPPQCL requirements.

The Testing Laboratories include (<http://www.fdaghana.gov.gh/qc-labs.php>):

- Drug Physicochemical
- Food Physicochemical
- Pharmaceutical Microbiology
- Food Microbiology
- Cosmetic / Household Chemical Substances
- Medical Devices

The Centre's Quality Management System (QMS) is an organizational structure tailored according to the ISO/IEC 17025 and WHO-GPPQCL standards, which consists of policies, procedures, processes, and resources used for quality management. The QMS is designed to plan, control and improve the elements that impact on the achievement of accurate and reliable test results and customer satisfaction.

The Quality Policy of the Centre, as approved by the Chief Executive and prominently displayed on the premises, is as stated below:

***"IT IS THE POLICY OF THE LABORATORY SERVICES OF THE FOOD AND DRUGS AUTHORITY TO MAINTAIN GOOD PROFESSIONAL LABORATORY PRACTICES MEETING INTERNATIONAL STANDARDS OF TESTING WITH THE HIGHEST ACHIEVABLE ACCURACY. PERSONNEL FAMILIARIZE THEMSELVES WITH THE POLICIES/PROCEDURES AND PROVIDE TRACEABLE, HIGH-QUALITY SERVICES TO THE SATISFACTION OF THE CUSTOMERS IN CONFORMITY WITH THE APPLICABLE REQUIREMENTS OF ISO/IEC 17025:2017 INTERNATIONAL STANDARD AND WHO-GPPQCL."***

All the 6 laboratories under the CLSR have been accredited to ISO 17025:2017 requirements with a total scope of accreditation currently at 58 ([click to view certificate](#)). The Drug Physicochemical Laboratory, a unit under the Drug Laboratory Department is additionally prequalified by WHO to WHO-GPPQCL requirements (<https://extranet.who.int/pqweb/medicines/prequalified-lists/sf-quality-control-labs>).