RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FOOD AND DRUGS AUTHORITY QUALITY MANUAL

(Rwanda FDA Law N° 003/2018 of 09/02/2018, Article 15)

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23/05/2021	1	First Issue
19/01/2026	2	1. To align the new version of the quality manual with the updated Quality Policy statement and Quality Objectives to reflect the updated Rwanda FDA's Strategic Plan 2025-2029. 2. Integration of ISO/IEC 17025 on general requirements for the competence of testing and calibration laboratories, ISO/IEC 17020 on conformity assessment – Requirements for the operation of various types of bodies performing inspection, and ISO/IEC 27001:2022 on Information Security Management Systems within the QMS scope. 3. Overall fine tuning to ensure clarity, consistency, and compliance with Rwanda FDA's regulatory documentation.

ADOPTION AND APPROVAL OF THE QUALITY MANUAL

In exercise of the powers conferred upon the Board of Directors of Rwanda Food and Drugs Authority by Article No. 15 of the Law No. 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, the Board of Directors adopted and approved Rwanda Food and Drugs Authority Quality Manual.

Dr. Etienne KARITA
Chairman, Board of Directors

ARRANGEMENT OF THE QUALITY MANUAL

ABBREVIATIONS AND ACRONYMS

CAR Form	Corrective Action Request Form
CTD	Common Technical Document
EAC MRH	East African Community Medicines Regulatory Harmonization
GHP	Good Hygienic Practices
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ISO	International Organization for Standardization
PIC/S	Pharmaceutical Inspection Co-operation Scheme
QMS	Quality Management System
SIAOR	Source of Inputs-Inputs-Activities-Outputs-Receiver of Outputs
SOP	Standard Operating Procedure
WHO	World Health Organization

CHAPTER.I GENERAL INTRODUCTION

I.1 Background

This manual and its provisions shall be cited as the "Quality Manual", hereafter designated as “The Manual”. The “Procedures manual” stipulated in article 15.4 of the Law N°. 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (Rwanda FDA) and determining its mission, organization, and functioning shall be referenced in this Quality Manual.

One of the goals of Rwanda FDA is to establish, implement, and maintain an effective Quality Management System (QMS) in accordance with national and internationally recognized standards. The Manual describes how Rwanda FDA manages, implements, and evaluates its quality processes to ensure the safety, efficacy, and quality of all regulated products.

This Manual also aims to achieve customer needs and expectations throughout the entire lifecycle of a product/service. It provides practical guidance to quality management processes in meeting the requirements of the International Standard ISO 9001: 2015.

I.2 Scope of the Manual

This Manual serves as the foundational framework for ensuring compliance with international standards, including but not limited to ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories), ISO/IEC 17020 (Conformity assessment – Requirements for the operation of various types of bodies performing inspection), and ISO/IEC 27001:2022 (Information Security Management Systems). Additionally, it underpins the institution’s adherence to the applicable Global Benchmarking Tools (GBT) and food system assessment tools for regulatory system strengthening and in alignment with the current regulatory ecosystem and landscape.

The Manual sets the core quality standards and compliance framework applicable across the entire Rwanda FDA. It also guides the development of specific quality manuals for institutional structures, which shall be approved by Rwanda FDA and reviewed periodically to ensure compliance and consistency.

I.3 Key elements

The Manual defines the following critical components of the QMS:

a. The **scope** of the QMS, including details of, and justification for, any exclusions;
b. The **documented information** established for the QMS, or reference to them; and
c. The **description of the interactions** between the processes of the QMS.

I.4 Objectives of the Manual

The following are the objectives of the Manual:

a. To define and describe the QMS, authorities, and responsibilities of all the personnel involved in the operation of the system and to provide references to the general procedures for all activities

comprising the quality system of the entire Rwanda FDA, based on ISO 9001:2015 Quality Management Systems—Requirements.

b. To communicate the QMS to the Rwanda FDA staff, members of the Board of Directors, customers, stakeholders, development partners, and other interested parties, and to inform them of the specific controls that are implemented by Rwanda FDA to assure the highest standard of regulatory services to the public.

CHAPTER.II MANDATE OF RWANDA FOOD AND DRUGS AUTHORITY

Rwanda FDA, hereafter designated as the "Authority", was established by Law Nº 003/2018 of 09/02/2018 determining its mission, organization, and functioning. The mandate of the Authority is to protect public health through the regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco, and tobacco products.

The scope of regulated products may be subject to changes in accordance with applicable laws, regulations, and emerging public health needs.

II.1 Vision of Rwanda FDA

The vision of Rwanda FDA is **"to become a World-class Regulatory Authority effectively protecting and promoting public health".**

II.2 Mission of Rwanda FDA

The mission of Rwanda FDA is to protect and promote public health by ensuring quality and safety of regulated products.

II.3 Core Values of Rwanda FDA

The conduct and performance of the Authority is underpinned by the following five core values:

a. Serving with **Professionalism** for excellent service delivery;
b. Continuously working with **Integrity**;
c. Promoting **Accountability** at all times;
d. Nurturing **Teamwork** to achieve common objectives;
e. Striving for **Innovation** to create value for our stakeholders and other interested parties.

CHAPTER.III QUALITY POLICY STATEMENT AND QUALITY OBJECTIVES

III.1 Quality Policy Statement

Rwanda FDA is committed to providing the highest quality of regulatory services that consistently meet customer requirements and expectations through the implementation of a robust Quality Management System (QMS) that complies with ISO 9001.

This is achieved through assessment and registration, inspections and licensing, control of imports and exports, vigilance, post-market surveillance, oversight for clinical trials, control of promotional materials and advertisements, laboratory testing and lot release. These functions are implemented to ensure the quality, safety and efficacy of regulated products, through enforcement of applicable laws and regulations.

Rwanda FDA, therefore, commits adequate financial, human, physical, and technological resources to efficiently implement, maintain and continually improve the QMS. We strive to attract and retain a competent, motivated, facilitated, and empowered workforce to achieve our quality objectives and mission.

The objectives, processes, systems, and procedures supporting this policy are established and regularly reviewed to ensure continuous improvement of the QMS.

III.2 Quality objectives/Strategic objectives

In accordance with the requirements of ISO 9001:2015, Rwanda FDA has established quality objectives that are consistent with our Quality Policy and aligned with our overall strategic direction. These quality objectives are documented in the current institutional strategic plan, which provides detailed, measurable targets to drive continual improvement in the effectiveness of our Quality Management System and to ensure the consistent delivery of products and services that meet customer and regulatory requirements.

The current strategic plan was communicated to all relevant personnel and is reviewed periodically to ensure the quality objectives remain relevant and achievable. Progress toward these objectives is regularly monitored and evaluated during management reviews to support ongoing quality improvement.

CHAPTER.IV QUALITY MANAGEMENT SYSTEM REQUIREMENTS

This chapter on the Quality Management System (QMS) follows the structure and clause numbering of ISO 9001:2015 to facilitate ease of navigation, alignment, and cross-referencing with the international standard.

1. SCOPE OF THE QUALITY MANAGEMENT SYSTEM

This Manual meets the requirements of the International Standard ISO 9001:2015 Quality management systems—Requirements and applies to all services provided by Rwanda FDA as

mandated by the Law N° 03/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organization, and functioning.

Clauses for impartiality, independence, and confidentiality have been included in this Manual as sections 7.5.3 and 7.5.4, respectively, to fulfil the requirements for section 6.2.3 in the EAC MRH QMS Compendium 2014.

2. NORMATIVE REFERENCES

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

The ISO 9000:2015 Quality management systems—*Fundamentals and vocabulary*

In addition, the following referenced documents are indispensable for the application of the QMS at Rwanda FDA:

a. The Rwanda Food and Drugs Authority Law N°. 003/2018 of 09/02/2018.
b. WHO Global Benchmarking Tool.

3. TERMS AND DEFINITIONS

"Regulated products" human and veterinary pharmaceutical products, vaccines and other biological products, diagnostics, medical devices including in-vitro diagnostics, processed and genetically modified food products, and cosmetics and other health related products. The scope of regulated products may be subject to change in accordance with applicable laws, regulations, and emerging public health needs.

The terms and definitions given in ISO 9000: 2015 Quality management systems—Fundamentals and vocabulary shall apply for the purposes of this Manual.

Furthermore, the glossary of terms and definitions to be used in Rwanda FDA documentation is regularly updated for harmonization purposes.

In accordance with ISO standards and regulatory terminology, the following verbal forms are used throughout this Manual:

a. "Shall" indicates a requirement;
b. "Should" indicates a recommendation;
c. "May" indicates a permission; and
d. "Can" indicates a possibility or a capability.

4. CONTEXT OF RWANDA FOOD AND DRUGS AUTHORITY

4.1. Understanding the context of Rwanda FDA

Rwanda FDA has determined the external and internal issues that affect its ability to achieve the intended result(s) of its quality management system in its Strategic Plan 2025-2029. Internal factors are those within the organization that may affect the implementation of the QMS. They include controls in decision-making, the knowledge and skills of employees, low employee morale, cultural changes, management, and financial changes.

External factors include issues arising from legal, technological, competitive market, cultural, social, and economic environments, whether international, regional, national, or local. They take place outside Rwanda FDA, and they are harder to predict and control, such as emerging porous borders, rapid changes in technology, variations in regulatory systems within the EAC as a regional economic bloc, and the overlap of government institutions' responsibilities.

Monitoring and reviews are done through periodic performance reviews as per the strategic plan.

4.2. Understanding the needs and expectations of interested parties

Rwanda FDA has determined its interested parties and their requirements that are relevant to the scope of Rwanda FDA work through development of a Client Service Charter and stakeholders' analysis in the strategic plan, which employed a risk-based approach, and was documented in the strategic plan. Furthermore, the management communicates with interested parties to ensure that the information from them is well monitored and reviewed.

4.3. Determining the scope of the quality management system

This Manual applies to all activities that affect the quality of services delivered by Rwanda FDA. These include the following key regulatory functions:

1. Registration and market authorization of regulated products;
2. Licensing establishment (premises that manufacture, wholesale, distribute, retail, repackage, and relabel regulated products);
3. Regulatory inspection to verify compliance with applicable legal provisions, standards and GxPs;
4. Import and export control of regulated products;
5. Post-marketing surveillance of regulated products;
6. Vigilance of regulated products;
7. Clinical trials oversight;
8. Control of promotional and advertisement relating to the regulated products;
9. Laboratory testing of regulated products;
10. Lot release.

It also includes Rwanda FDA's support functions such as finance and audit, procurement, information communication technology, legal services, human resources and administration,

Planning, Monitoring & Evaluation, public relations and communication, and others as applicable to the approved organizational structure.

4.4. Quality Management System and Processes

The sequence and interaction of the regulatory processes have been optimised through a Source of Inputs-Activities-Outputs-Receiver SIAOR) analysis as per applicable process flow charts and/or process operational planning controls. The interactions of these processes at the macro-level are shown in Appendix 2 (Level 1 and 2).

The criteria and methods required to ensure that the operation and control of the processes are effectively documented in regulations, manuals, guidelines, guidance, standard operating procedures (SOPs), forms, formats, checklists, aide memoires, flow charts, registers, records, and other controlled documents.

Necessary resources required are included in Rwanda FDA's approved annual budgets. Key performance indicators used to monitor and measure the processes are established and contained in the Monitoring and Evaluation Framework of Rwanda FDA.

There are controls over externally provided processes, products, and services that include specialised quality control testing for product samples (outsourced where necessary); cleaning and security services for office and laboratory premises; and expert reviewers.

The processes are regularly reviewed to maintain and continually improve the QMS, and each procedure defines the responsible person and assigns accountability for efficiency. Risk and opportunities are identified and recorded to ensure adequate monitoring of activity.

5. LEADERSHIP

5.1. Leadership and Commitment

5.1.1. General

Rwanda FDA's top management demonstrates leadership and commitment with respect to quality management system. The Board of Directors approves the institutional quality policy statement with a commitment to accomplish its mandate as per the Law No. 03/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organization, and functioning. This is in line with ISO 9001:2015 principles, and it ensures the necessary human, financial, physical, technical, and technological resources for the successful implementation of the QMS with impartiality in decision making. In addition, the strategic objectives of Rwanda FDA are adopted as quality objectives for maintaining the quality management system.

Rwanda FDA achieves the mission through the promotion of a process approach defined in the document control and risk-based thinking defined in the risk management policy. The quality policy of the institution clearly states the management's commitment to the availability of resources to

efficiently implement, maintain, and continually improve the QMS. This aims to provide the highest quality of regulatory services that consistently meet customer requirements and expectations.

Rwanda FDA considers an appropriate opportunity for improvement and delegates the power to responsible managers to ensure that they demonstrate their leadership as it applies to their area. This is further demonstrated through a well-established chain of command, which provides room for applying the leadership skills at each level. Furthermore, the Authority has committed to regularly communicating to staff and other interested parties the importance of effective quality management and of conforming to the quality management system requirements.

5.1.2. Customer focus

Rwanda FDA demonstrates leadership and commitment with respect to customer focus by ensuring that:

1. The services of the Authority as defined in the Law N° 03/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and other regulatory requirements are determined, understood, and consistently provided. To achieve this, a strategic plan aligned with the Health Sector Strategic Plan (HSSP) V and National Strategy for transformation 2 (NST2) has been developed. The strategic plan considers regulatory environment from which annual work plans are derived, and budget allocations are availed to support their effective implementation.

2. Customer complaints and appeals guidelines and procedures are established to ensure that the customers have the right to complain and/or appeal on regulatory decisions. Risks and opportunities with the potential impact on customer satisfaction are being identified and addressed in accordance with risk management policy. Rwanda FDA has put in place different platforms for customers to request additional information/queries, complaints, and appeals.

3. The relevant guidelines to Rwanda FDA mission detail regulatory requirements that are considered in the provision of services. The legal team advises Rwanda FDA and communicates to the staff the required legal matters, while the heads of departments are responsible for technical matters.

5.2. Policy

5.2.1. Establishing the quality policy Statement

The Board of Directors has approved Rwanda FDA Quality Policy Statement *(Doc. Nº ODG/QMS/POL/001)*.

5.2.2. Communicating the quality policy statement

The Quality Policy statement has been made available to the staff through the shared folder and on the website of Rwanda FDA and displayed at visible locations at the main office Rwanda FDA and other designated offices.

5.2.3. Organizational roles, responsibilities, and authorities

Rwanda FDA management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood. It ensures that the integrity of the quality management system is maintained when changes to the QMS are planned and implemented with regard to promotion of customer focus throughout the organization.

The QMS division is responsible for the following:

1. Ensuring that processes, systems, and procedures needed for the QMS for the entire Rwanda FDA are established, implemented, maintained, and continually improved in conformity with ISO 9001:2015 and other relevant standards and guidelines;
2. Providing leadership for the effective performance of the QMS in the entire Rwanda FDA;
3. Reporting to top management on the QMS and on the opportunities for improvement.

The Board of Directors adopts the draft organizational structure of Rwanda FDA before it is approved in accordance with national legal provisions.
There are approved current job profiles and descriptions clearly stating the roles, duties, and responsibilities of each staff member.

6. PLANNING

6.1. Actions to address risks and opportunities

Rwanda FDA has, through its strategic plan, determined the risks that need to be mitigated and opportunities to be harnessed. A SWOT analysis was conducted to identify potential risks and opportunities.

Rwanda FDA also conducts an overall business risk analysis in accordance with the risk management policy. It also updates and maintains a risk register, where monitoring and reporting on the progress of control measures are conducted regularly.

6.2. Quality objectives and planning to achieve them

Rwanda FDA has a 5-year strategic plan, which details quality objectives that are in line with the strategic objectives that have been developed for each of the regulatory and support processes of Rwanda FDA.

6.3. Planning of changes

An SOP for change control is used to control changes within Rwanda FDA.

7. SUPPORT

7.1. Resources

7.1.1 General

Rwanda FDA determines necessary resources for each financial year, for the establishment, implementation, maintenance, and continual improvement of the quality management system. This results in recurrent and capital expenditure budget estimates for the entire Rwanda FDA that is approved by the Board of Directors. By doing this, Rwanda FDA considers the capabilities of, constraints on, existing internal resources, and what needs to be obtained from external providers.

7.1.2 People

Rwanda FDA implements the gazetted organizational structures (Appendix 2), for the effective implementation of its quality management system and for the operation and control of its processes. Recruitment and capacity building are made with respect to the applicable national legal provisions.

7.1.3. Infrastructure

Rwanda FDA has offices in Gasabo and Kicukiro Districts, with Head Office at Nyarutarama Plaza KG 9 Avenue, and the Laboratory Services Department at KK 15 Rd. Necessary utilities and support infrastructure (hardware and software equipment, transportation resources, information & communication technology, among others).

All infrastructure of Rwanda FDA is tagged and identifiable to Rwanda FDA and recorded in assets registers system. Continuous improvement and maintenance of infrastructure are conducted in order to improve service delivery to customers.

7.1.4. Environment for the operation of processes

Rwanda FDA has defined adequate environmental conditions necessary for the operation of processes as per the relevant international and national legal provisions and institutional regulatory documents. Environmental, occupational health, and safety are maintained in accordance with applicable international standards.

Rwanda FDA is committed to maintaining an enabling environment that upholds the social, psychological, and physical well-being of all personnel. This includes, but is not limited to, promoting non-discriminatory, respectful, and non-confrontational social interactions; supporting psychological health through measures aimed at stress reduction, burnout prevention, and emotional resilience; and maintaining optimal physical conditions with respect to temperature, humidity, lighting, airflow, hygiene, and noise control. Furthermore, Rwanda FDA ensures that all waste management activities are conducted in strict compliance with applicable national policies and procedures.

7.1.5. Monitoring and measuring resources

7.1.5.1.General

Rwanda FDA determines and provides the resources needed to ensure valid and reliable results. Approved annual work plans are the basis for the quarterly, and annual performance reporting against the targets and the recording is done through the performance management systems that are in place.

Process data are systematically collected, analysed, and interpreted to reveal any process trends and inform evidence-based decision-making. These insights serve as a basis for continuous improvement and for enhancing future planning and operational planning

7.1.5.2. Measurement traceability

Measuring equipment used in Rwanda FDA is verified and/or calibrated against international or national measurement standards, at specified intervals or prior to their use, in order to provide confidence in the measurement results.

Measuring instruments are identified with calibration stickers to determine their calibration status and are protected to prevent them from being adjusted, damaged, or subjected to deterioration or anything that would invalidate their correct calibration status, therefore jeopardise any future measurement results. Rwanda FDA retains the records for evidence of verification and/or calibration.

7.1.6. Organizational knowledge

Rwanda FDA continuously determines and manages the organizational knowledge required to meet the present and future needs. Talent acquisition and development are maintained for improved organizational knowledge through implementation of the talent acquisition and development strategy.

Organizational knowledge is gained through experience of the staff; through specialized on-the-job training and mentoring over the years; from surveys, studies, operational research; and from conferences, seminars, workshops, benchmarking study visits, and meetings with stakeholders, interested parties, and regional and international bodies. Records and reports of organizational knowledge attained are kept within the organization.

Organizational knowledge is determined through developed process mapping, regulations, strategic plans, guidelines, guidance, charters, manuals, procedures, working instructions, reports, and records, among others. These documents are controlled as per SOPs for control of documents and records.

An assessment of organizational knowledge is done before making any changes to the quality management systems (as part of change control) in response to changing needs or trends in the operational environment. This is to ensure that informed decisions are made with respect to the changes to the quality management system.

7.2. Competence

Rwanda FDA recruits its staff in compliance with the Law No. 017/2020 of 07/10/2020 establishing the General Statute governing Public Servants and the Presidential Order No. 128/2020 of 04/12/2020 relating to Recruitment of Public Servants and Induction Programme.

Rwanda FDA ensures that all employees performing tasks affecting the performance and effectiveness of the Quality Management System (QMS) are competent based on appropriate education, training, skills, and experience. Rwanda FDA staff can also serve as trainers to other national regulatory authorities (NRAs) or organizations that may require skills from them under existing partnerships or collaboration.

To achieve this, the organization has developed and implemented a Competency Framework that defines the required competencies for each role. These requirements are established in alignment with regulatory responsibilities, organizational goals, and applicable statutory or quality standards.

Where necessary, individual competencies are assessed and recorded using a competency matrix, which enables the identification of gaps between required and actual competence levels. Based on these gaps, Rwanda FDA conducts a structured Training Needs Assessment (TNA) annually, which incorporates inputs from performance appraisals, internal and external audit findings, evolving regulatory requirements, and organizational goals.

Findings from the TNA inform the development of the Annual Training Plan, which outlines both technical and soft skills development activities required to close competency gaps and support staff progression.

All planned trainings are implemented accordingly, and their effectiveness is systematically evaluated through methods such as pre- and post-training assessments, supervisor feedback, performance monitoring, and staff feedback. This Evaluation of Training Effectiveness ensures that learning objectives are met and applied in the workplace.

Rwanda FDA maintains up-to-date records of education, training, skills, and experience as objective evidence of staff competence. These records are reviewed regularly to ensure compliance with ISO 9001:2025 requirements.

The organization promotes continuous professional development (CPD) and learning to ensure sustained competence, adaptability to change, and continuous improvement in regulatory performance and service delivery.

7.3. Awareness

Staff awareness on the quality policy, objectives, and their contribution to the effectiveness of the QMS, and implications of not conforming to the requirements (ISO 9001:2015 Quality management systems—Requirements) is ensured through the provision of QMS training and staff meetings. Newly recruited staff are also oriented immediately after recruitment and at specified periods.

Minutes and training records are retained in the files of the respective Offices/Departments/Divisions/units.

7.4. Communication

Rwanda FDA has determined, implemented, and documented internal and external communication strategy and procedures within the QMS. They clearly describe "what" to communicate, and define responsibilities and authorities for communication to the assigned competent personnel. Depending on the context, nature, and intent of the communication, the policy describes the level, audience, and frequency of the communication, including the format and medium (including but not limited to verbal, letter, mail, website, or SharePoint). Social media and mobile applications are additional tools for communicating with interested parties.
The communication strategy and procedures are implemented within the institutional legal framework and related national procedures and practices.

7.5. Documented information

7.5.1. General

Documented information is information that Rwanda FDA is required to control, to maintain (to document), and to retain (to keep records). Control of documentation is done as described in the SOP for document control *(Doc. Nº ODG/QMS/SOP/001).* Document registers for internal documents and external documents are maintained

7.5.2. Creating and updating

Rwanda FDA ensures the implementation of the SOP for document control *(Doc. Nº ODG/QMS/SOP/001)* for all created or updated information taking into consideration the following:

a) appropriate identification and description (e.g. Title, date and reference number);
b) format and media;
c) review and approval for suitability and adequacy.

7.5.3. Control of documented information

7.5.3.1. Internal and external documented information required by QMS is controlled in accordance with the SOP for document control *(Doc. Nº ODG/QMS/SOP/001).*

7.5.3.2. The distribution, access retrieval, use storage and preservation are controlled in accordance with the SOP for control of records describes controls for records, while SOP on change control describes the effective management of changes for continuous conformity with requirements.

The members of the Advisory Committee, the staff of Rwanda FDA are required to sign confidentiality agreement using the available confidentiality agreement forms.

Rwanda FDA is bound by the Internal Rules and Regulations on Human Resources, which govern the integrity and accountability of the staff. Each member of staff is required to sign the declaration of Interest form to ensure their impartiality in decision-making.

Subcontracted personnel, experts, and interns are also required to sign the confidentiality agreement and Conflict of Interest Declaration form before the commencement of their assignments.

8. OPERATION

8.1. Operational planning and control

Rwanda FDA has a legal mandate to ensure that all regulated products used in Rwanda are of good quality, safe, and effective through the following core processes:

1. Registration and market authorization of regulated products;
2. Licensing establishment (premises that manufacture, wholesale, distribute, retail, repackage, and relabel regulated products);
3. Regulatory inspection to verify compliance with applicable legal provisions, standards and GxPs;
4. Import and export control of regulated products;
5. Post-marketing surveillance of regulated products;
6. Vigilance of regulated products;
7. Clinical trials oversight;
8. Control of promotional and advertisement relating to the regulated products;
9. Quality control of regulated products;
10. Lot release

Process flows have been developed, outlining the activities involved at each stage and the required controls and associated risks in terms of documented information that should be maintained and retained.

Quality control and quality assurance measures at different stages of service provision have been established; for example, first and second assessment for the evaluation of product dossiers; peer review of assessment and GMP inspection reports; and acceptance criteria based on applicable standards to be met, (including but not limited to pharmacopeia specifications, requirements by WHO, ICH, EAC MRH, Codex Alimentarius, and other national, regional, and international standards that related to the regulation and control of the regulated products).

Operational planning and control are addressed in the guidelines, strategic plan and quality manual on processes and procedures.

8.2. Requirements for services

8.2.1. Customer Communication

Rwanda FDA communicates to its customers about specific service requirements (including but not limited to annual licensing requirements for pharmacies, product registration requirements in the Common Technical Document dossiers, and requirements for amendments to a registered product.) by sharing the information in draft regulations and guidelines with the respective customer/clients for consultation and input before they are finalised and approved.

Channels used for communication with the clients (importers, manufacturers, distributors, wholesalers, and retailers of all the regulated products); stakeholders; other interested parties; and the general public include the following:

1. The website of Rwanda FDA where the following are posted: laws, relevant policies, regulations, guidelines, forms and registers for approved regulated products, confiscated products, banned products, closed premises, recalled products, and other enforcement actions;
2. Face-to-face consultative and awareness meetings, workshops, and seminars; and
3. Print and digital media.

Feedback from clients, customers, stakeholders, and interested parties is received through customer satisfaction surveys and customer support tools, and is addressed in set timelines. Evidence is retained in the system and handled as per the procedure of archiving information. Other channels used for communication by Rwanda FDA are monitored for any inquiries and dealt with. Each client's inquiry is given a unique identification number. Contingency actions are established based on the Risk Management Framework, and regular review is conducted to ensure their relevance.

8.2.2. Determining the requirements for services

The requirements for the services offered to Rwanda FDA stakeholders are determined through the formulation of regulations and guidelines for all regulatory functions.

In developing those regulations and guidelines, Rwanda FDA takes into account all applicable statutory and regulatory requirements, including national, regional, and international guidelines and best practices. Stakeholders' engagement is also considered with reference to the relevant procedures. A service charter for the services of Rwanda FDA, with timelines, has been established and published on the website. The Authority ensures that the set requirements are defined and can be met.

8.2.3. Review of the requirements for services

During the review of requirements for services, Rwanda FDA ensures that requests from customers are considered. Rwanda FDA included in relevant guidelines the procedure for screening the applications on the fulfilment of the pre-requisite for service provision to ensure that Rwanda FDA will meet the set requirements. The Authority grants feedback to the services based on the established mechanisms in the specific regulations governing the provision of the service.

Rwanda FDA may also consider, under specific circumstances to issue a conditional authorization or an emergency use authorization based on risk-benefit analysis as detailed in the specific regulations and guidelines. When the requirements for products and services are changed for any reason, Rwanda

FDA takes measures to inform all relevant interested parties. It also ensures that evidence of the results of the revisions to the service requirements, and any new requirements for the services are retained.

8.2.4. Changes to requirements for services

When changes to requirements for services provided are deemed necessary, the authority follows the procedure for change control and prepares the draft of the revised changes. If it engages stakeholders, it follows the procedure of engaging stakeholders during development, review, and validation of documents, and documented information is retained accordingly. Applicants and the general public are notified of changes in the requirements for service provision of any regulated service through established procedures for internal and external communication.

8.3. Design and development of products and services

8.3.1. General

Rwanda FDA implements new regulatory function(s) in cases where a national legal framework is amended or there is a need to introduce new regulatory products or services.

Processes are designed and developed in accordance with the guidance on QMS organization and implementation to ensure the efficient provision of the service.

8.3.2. Design and development planning

Rwanda FDA determines and documents the process(es) that will form part of the new function, including the stages, steps, and control measures needed through an implementation roadmaps or projects. The determination includes reviews, verifications and validations to ensure that the processes are sufficiently robust for the intended function.

Prior to establishment of an implementation roadmap or project, a designated focal person and/or responsible office/division/unit are assigned to coordinate the project and an initial plan is developed with documented competencies, responsibilities and authorities of the project development team.

The resources needed for implementing the project are determined earlier. The need to engage stakeholders is evaluated with reference to the procedure on engaging stakeholders during development, review and validations of documents. The established team should evaluate the existing requirements that are affected by the new regulatory function, or whether there is a need to establish additional ones. All documents used and generated out of these roadmaps are retained in an appropriate format.

8.3.3. Design and development inputs

Rwanda FDA determines and documents requirements essential for specific types of products and services to be designed and developed by considering performance indicators, national legal requirements for compliance, codes of ethics and professional conduct, as well as the potential consequences of failure for the established roadmap using a risk-based approach.

8.3.4. Design and development controls

Rwanda FDA applies controls to the design and development process by conducting intermediate reviews, verification, and validation steps to ensure that the resulting function or service meets the requirements for the intended use.

8.3.5. Design and development outputs

The requirements for design and development outputs are defined in the regulatory documents, such as regulations, guidelines, standard operating procedures, or service provision manuals that give the information necessary for all the processes required to provide intended products and services, including information to be provided by the customers. They are aligned to the inputs and reflect the processes required for the service provision. All outputs are retained to support product safety, quality, and efficacy

8.3.6. Design and development changes

Rwanda FDA identifies, reviews, and controls changes to be made during, or subsequent to, the design and development of products or service(s), as per the relevant internal procedures to ensure that there is no adverse impact on conformity to requirements. Rwanda FDA also retains documented information related to changes.

8.4. Control of externally provided processes, products, and services

8.4.1. General

Procurement of all externally provided processes, products, and services is governed by national legal provisions. Records arising from the procurement process, including product/service specifications, procedures, evaluation of suppliers, and selection criteria, are maintained.

8.4.2. Type and extent of control

Rwanda FDA ensures that externally provided products and services remain within the control of its quality management system. It also ensures that purchased products or services are inspected and verified against the purchase order specifications before they are accepted.

8.4.3. Information for external providers

Rwanda FDA prepares and maintains technical specifications describing the product or service to be procured before publication of the tender.

8.5. Production and service provision

8.5.1. Control of production and service provision

Rwanda FDA provides services under controlled conditions by following regulations, guidelines, and procedures that provide services that meet the defined requirements. Quality assurance measures include peer reviews at different hierarchical organizational levels.

Where measuring equipment is used in providing regulatory services, technical requirements and recommendations are established and documented with reference to applicable international requirements to the necessary extent.

8.5.2. Identification and traceability

Rwanda FDA uses unique identification numbers for customer property (including but not limited to application dossiers, product samples) and outputs (such as but not limited to certificates, licenses, reports, letters, among others.)

8.5.3. Property belonging to customers or external providers

Rwanda FDA identifies, verifies, protects, and safeguards customer property provided for use during the provision of services in accordance with national legal provisions and internal procedures for confidentiality and impartiality.

Customer property includes product dossiers for marketing authorization, samples, site master files for manufacturing facilities, invoices for imported/exported regulated products, samples collected/taken for quality control laboratory, confiscated products, product advertisement and promotional materials, and certificates.

8.5.4. Preservation

Rwanda FDA preserves the conformity of products or services during internal processing and delivery to the intended destination, including preservation of samples taken during inspections. Preservation includes identification, handling, storage, and protection.

Where applicable in accordance with product specifications and/or applicable regulations, provisions for preserving product(outputs) include:

1. Prevention from contamination and deterioration;
2. Marking and labelling, including safety warnings; and
3. Special handling and storage for temperature-sensitive materials and products.

8.5.5. Post-delivery activities

Rwanda FDA regularly monitors the post-service delivery activities through the customer support tool for feedback from customers. It also manages complaints in line with the Guidelines for

complaints and appeals against Rwanda FDA Regulatory Decisions. There are procedures established to guide the implementation.

8.5.6. Control of changes

Rwanda FDA reviews and controls changes following the SOP for control of change to the extent necessary to ensure the continuing conformity with QMS requirements. Documented information related to changes is also retained in accordance with the relevant procedures.

8.6. Release of products and services

Reports, certificates, licenses, permits, and authorization letters are checked by the respective supervisors and signed by the Director General or by other authorised senior officers. The list of authorised persons to release outputs to customers is updated from time to time. The release of reports, certificates, and licences to customers does not proceed until the requirements have been satisfactorily met.

8.7. Control of non-conforming outputs

Whenever a non-conforming output is identified, the relevant unit/division/department/office documents, corrects and communicates it to the concerned customer.

The Authority takes appropriate actions based on the nature of the nonconformity and its effect on the on the products and services, and this also applies to nonconforming outputs identified after delivery.

Non-conforming outputs can include any of the following:

1. Error or omission on a certificate, permit, or licence.
2. Error in published adverse event report.
3. Error on a clinical/field trials assessment monitoring report.
4. Error on promotional material vetting report (from the control of publications and advertisements relating to drug processes).
5. Out-of-specification test results.

9. PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1. General

A monitoring and evaluation framework that tracks process activities, targets, performance indicators, and outputs is used to monitor the progress of processes. Performance reports (quarterly and annual) are made, and their information is analysed and used as input in management reviews.

9.1.2. Customer satisfaction

Customers' perceptions of the degree to which their needs and expectations have been fulfilled with respect to the services they receive from Rwanda FDA are monitored using customer complaint analysis and customer satisfaction surveys using a structured questionnaire that is administered to stakeholder groups through different channels, including meetings and workshops. Customer satisfaction surveys are conducted at least once in three years.

Inquiries are also received through an online Customer Support Tool, social media platforms, and Rwanda FDA email (info@rwandafda.gov.rw).

9.1.3. Analysis and evaluation

Rwanda FDA analyses and evaluates appropriate data and information for a variety of pre-defined purposes such as to demonstrate that its services conform to requirements, to assess customer satisfaction, to ensure the conformity and effectiveness of the quality management system, to evaluate the performance of external providers, to determine the need for improvements within the quality management system, and to demonstrate that planning has been successfully implemented. This is done by each unit, division, department or office.

9.2 Internal audit

Internal quality audits are conducted according to an approved programme. Audit plans are developed to ensure that all aspects of the QMS are addressed. Audits provide information on whether the QMS conforms to Rwanda FDA's own requirements and International Standards to ensure the QMS is effectively implemented and maintained.

The frequency is determined based on the significance/sensitivity of a process and the results of previous audits, and the scope of audits is aligned with the quality management system of the institution defined in clause 4.4.

Internal quality audit procedures are established to define the responsibilities and requirements for planning and conducting quality audits, generating records, and reporting results.
Audit results become part of the quality records and are presented at the management review meetings.

9.3 Management review

9.3.1. General

Management reviews are conducted to ensure that the quality management system achieves its intended results. Management reviews for the QMS occur at least once a year to ensure its continuing suitability, adequacy, and effectiveness. Management review meetings are chaired by the Director General and the QMS division manager as the rapporteur. The records of management reviews are maintained.

9.3.2. Management review inputs

Management review inputs include the following:

1. Review of the status of any actions identified at previous reviews.
2. Consideration of any changes in the organization's context.
3. Consideration of the QMS performance and effectiveness. Here, specific reference is made to the need for trends relating to nonconformities and corrective action, monitoring and measurement results, audit results, customer satisfaction, relevant interested parties' feedback, process performance, and conformity of the services. The review also includes external providers' performance and how well quality objectives are being achieved.
4. Information on opportunities for improvement.
5. The adequacy of resources.
6. Whether the actions to address risks and opportunities have been effective.

9.3.3. Management review outputs

The outputs of the management review include decisions and actions related to the opportunities for improvements, any need for changes to the quality management system, and required resources and documented information are retained.

10. IMPROVEMENT

The effectiveness and performance of the respective processes and the resulting services are reviewed to identify and address unwanted effects, whatever they are and whatever the cause. Improvements can then be pursued by correction, prevention, or reduction, as appropriate.

10.1 Nonconformity and corrective action

Rwanda FDA investigates and takes action towards nonconformity that has occurred, including those resulting from audits, complaints, and appeals. When nonconformity occurs, Rwanda FDA:

1. Reacts to the nonconformity;
2. Evaluates the need for action to eliminate the cause (s) of the nonconformity, so that it does not recur or occur elsewhere;
3. Implements any action needed;
4. Reviews the effectiveness of any corrective action taken;
5. Updates risks and opportunities determined during planning, if necessary; and
6. Makes changes to the QMS, if necessary.

Corrective action can also be required internally within the concerned processes. The needs for corrective action are documented on a Corrective Action Request form and submitted to the process owner to identify the root cause and to prevent recurrence.

The documented information as evidence of nonconformities and any subsequent actions taken and the results of any corrective action, are retained.

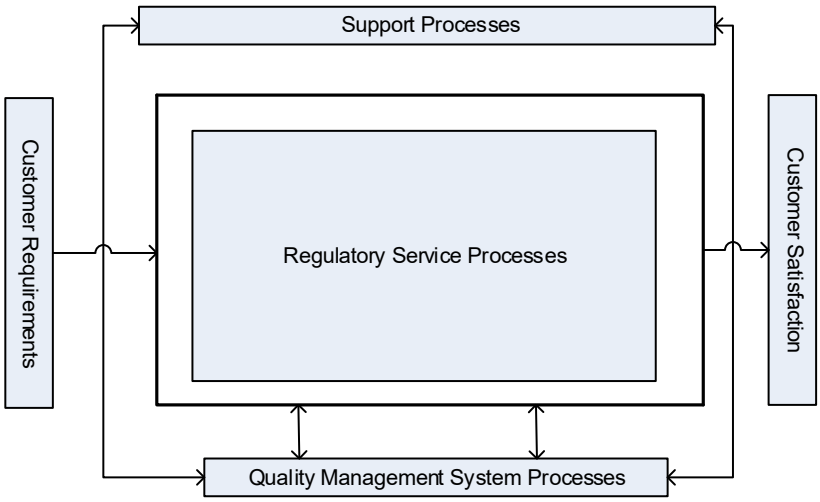
10.2 Continual improvement

Rwanda FDA adopts various forms of improvement, such as correction, corrective action, preventive action, breakthrough change, innovation, and reorganization. Other approaches include addressing both risks and opportunities associated with its context, objectives, and strategic direction and enhancing customer satisfaction.

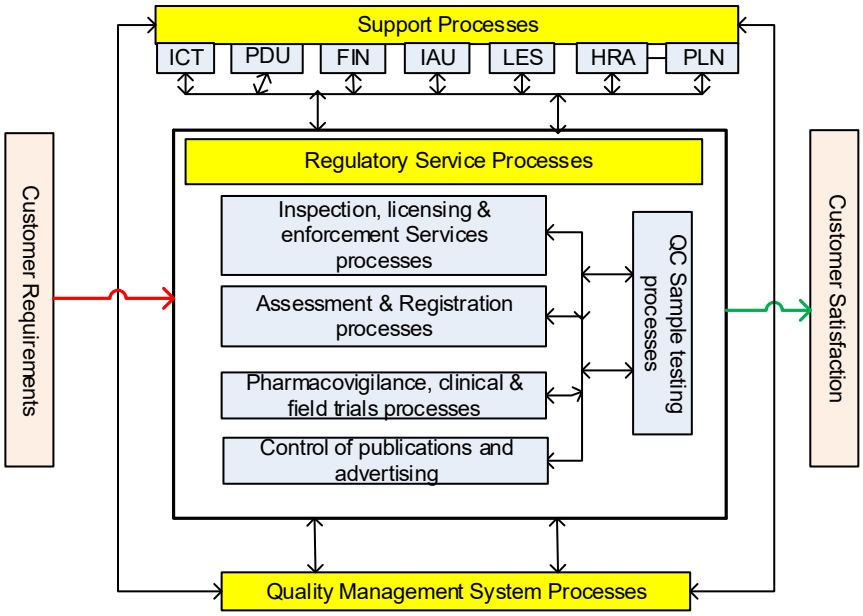
As part of continual improvement, Rwanda FDA uses the results of analysis and the evaluation of data from key processes and management review to determine areas of underperformance and to identify any opportunities for improvement.

APPENDIX 1: INTERACTION OF PROCESSES

Level 1: Rwanda FDA Interaction of Processes

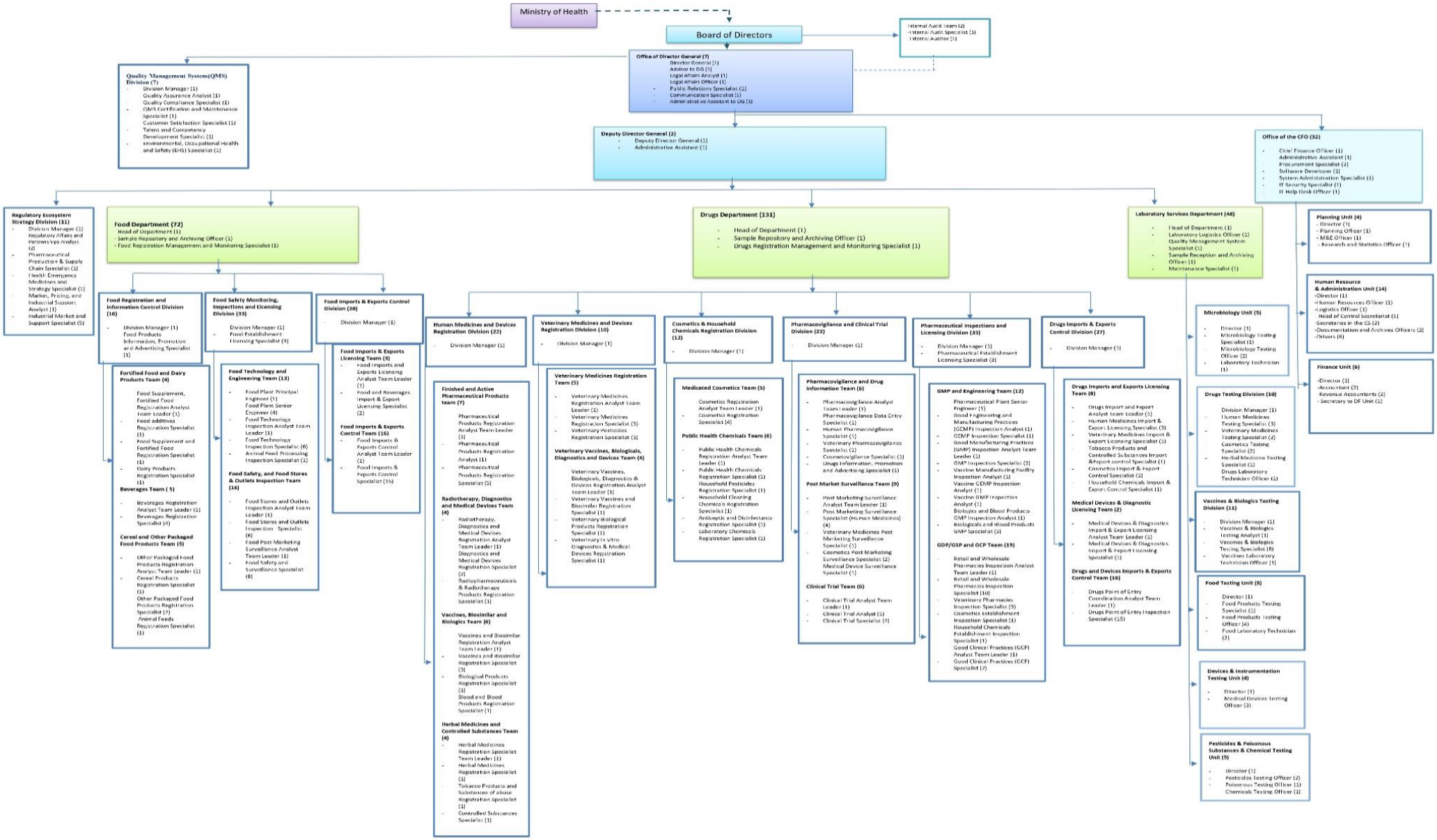


Level 2: Detailed Interaction of Processes



Key
ICT: Information Technology processes
PDU: Procurement processes
FIN: Finance processes
IAU: Internal audit processes
LES: Legal Services processes
HRA: Human Resource & Admin processes
PLN: Planning processes

APPENDIX II: ORGANIZATIONAL STRUCTURE


Ministry of Health
Board of Directors
Internal Audit team (2)
-Internal Audit Specialist (1)
-Internal Auditor (1)
Office of Director General (7)
Director General (1)
Advisor to DG (1)
Legal Affairs Analyst (1)
Legal Affairs Officer (1)
Public Relations Specialist (1)
Communication Specialist (1)
Administrative Assistant to DG (1)
Quality Management System(QMS) Division (7)
Division Manager (1)
Quality Assurance Analyst (1)
Quality Compliance Specialist (1)
QMS Certification and Maintenance Specialist (1)
Customer Satisfaction Specialist (1)
Talent and Competency Development Specialist: (1)
environmental, Occupational Health and Safety (EHS) Specialist (1)
Deputy Director General (2)
Deputy Director General (1)
Administrative Assistant (1)
Office of the CFO (32)
Chief Finance Officer (1)
Administrative Assistant (1)
Procurement Specialist (2)
Software Developer (1)
System Administration Specialist (1)
IT Security Specialist (1)
IT Help Desk Officer (1)
Regulatory Ecosystem Strategy Division (11)
Division Manager (1)
Regulatory Affairs and Partnerships Analyst (4)
Pharmaceutical Production & Supply Chain Specialist (1)
Health Emergency Medicines and Strategy Specialist (1)
Market, Pricing, and Industrial Support Analyst (1)
Industrial Market and Support Specialist (5)
Food Department (72)
Head of Department (1)
Sample Repository and Archiving Officer (1)
Food Registration Management and Monitoring Specialist (1)
Drugs Department (131)
Head of Department (1)
Sample Repository and Archiving Officer (1)
Drugs Registration Management and Monitoring Specialist (1)
Laboratory Services Department (48)
Head of Department (1)
Laboratory Logistics Officer (1)
Quality Management System Specialist (1)
Sample Reception and Archiving Officer (1)
Maintenance Specialist (1)
Planning Unit (4)
- Director (1)
- Planning Officer (1)
- M&E Officer (1)
- Research and Statistics Officer (1)
Human Resource & Administration Unit (14)
-Director (1)
-Human Resources Officer (1)
-Logistics Officer (1)
Head of Central Secretariat (1)
-Secretaries in the CS (2)
-Documentation and Archives Officers (2)
-Drivers (6)
Finance Unit (6)
-Director (1)
-Accountant (2)
-Revenue Accountants (2)
- Secretary to DF Unit (1)
Food Registration and Information Control Division (16)
Division Manager (1)
Food Products Information, Promotion and Advertising Specialist (1)
Food Safety Monitoring, Inspections and Licensing Division (33)
Division Manager (1)
Food Establishment Licensing Specialist (8)
Food Imports & Exports Control Division (20)
Division Manager (1)
Human Medicines and Devices Registration Division (22)
Division Manager (1)
Veterinary Medicines and Devices Registration Division (10)
Division Manager (1)
Cosmetics & Household Chemicals Registration Division (12)
Division Manager (1)
Pharmacovigilance and Clinical Trial Division (22)
Division Manager (1)
Pharmaceutical Inspections and Licensing Division (35)
Division Manager (1)
Pharmaceutical Establishment Licensing Specialist (3)
Drugs Imports & Exports Control Division (27)
Division Manager (1)
Microbiology Unit (5)
Director (1)
Microbiology Testing Specialist (1)
Microbiology Testing Officer (2)
Laboratory Technician (1)
Drugs Testing Division (10)
Division Manager (1)
Human Medicines Testing Specialist: (3)
Veterinary Medicines Testing Specialist (2)
Cosmetics Testing Specialist (2)
Herbal Medicine Testing Specialist (1)
Drugs Laboratory Technician Officer (1)
Vaccines & Biologics Testing Division (11)
Division Manager (1)
Vaccines & Biologics Testing Analyst (1)
Vaccines & Biologics Testing Specialist (8)
Vaccines Laboratory Technician (1)
Food Testing Unit (8)
Director (1)
Food Products Testing Specialist (1)
Food Products Testing Officer (4)
Food Laboratory Technician (2)
Devices & Instrumentation Testing Unit (4)
Director (1)
Medical Devices Testing Officer (3)
Pesticides & Poisonous Substances & Chemical Testing Unit (5)
Director (1)
Pesticides Testing Officer (2)
Poisonous Testing Officer (1)
Chemicals Testing Officer (1)
Fortified Food and Dairy Products Team (4)
Food Supplement, Fortified Food Registration Analyst Team Leader (1)
Food additives Registration Specialist (1)
Food Supplement and Fortified Food Registration Specialist (1)
Dairy Products Registration Specialist (1)
Beverages Team (5)
Beverages Registration Analyst Team Leader (1)
Beverages Registration Specialist (4)
Cereal and Other Packaged Food Products Team (5)
Other Packaged Food Products Registration Analyst Team Leader (1)
Cereal Products Registration Specialist (1)
Other Packaged Food Products Registration Specialist (2)
Animal Feeds Registration Specialist (1)
Food Technology and Engineering Team (13)
Food Plant Principal Engineer (1)
Food Plant Senior Engineer (4)
Food Technology Inspection Analyst Team Leader (1)
Food Technology Inspection Specialist: (6)
Animal Feed Processing Inspection Specialist (1)
Food Safety, and Food Stores & Outlets Inspection Team (16)
Food Stores and Outlets Inspection Analyst Team Leader (1)
Food Stores and Outlets Inspection Specialist: (6)
Food Post Marketing Surveillance Analyst Team Leader (1)
Food Safety and Surveillance Specialist (8)
Food Imports & Exports Licensing Team (3)
Food Imports and Exports Licensing Analyst Team Leader (1)
Food and Beverages Import & Export Licensing Specialist (2)
Food Imports & Exports Control Team (16)
Food Imports & Exports Control Analyst Team Leader (1)
Food Imports & Exports Control Specialist (15)
Finished and Active Pharmaceutical Products team (7)
Pharmaceutical Products Registration Analyst Team Leader (1)
Pharmaceutical Products Registration Analyst (1)
Pharmaceutical Products Registration Specialist (5)
Radiotherapy, Diagnostics and Medical Devices Team (4)
Radiotherapy, Diagnostics and Medical Devices Registration Analyst Team Leader (1)
Diagnostics and Medical Devices Registration Specialist (2)
Radiopharmaceuticals & Radiotherapy Products Registration Specialist (1)
Vaccines, Biosimilar and Biologics Team (6)
Vaccines and Biosimilar Registration Analyst Team Leader (1)
Vaccines and Biosimilar Registration Specialist (3)
Biological Products Registration Specialist (1)
Blood and Blood Products Registration Specialist (1)
Herbal Medicines and Controlled Substances Team (4)
Herbal Medicines Registration Specialist Team Leader (1)
Herbal Medicines Registration Specialist (1)
Tobacco Products and Substances of abuse Registration Specialist (1)
Controlled Substances Specialist: (1)
Veterinary Medicines Registration Team (5)
Veterinary Medicines Registration Analyst Team Leader (1)
Veterinary Medicines Registration Specialist: (3)
Veterinary Pesticides Registration Specialist (1)
Veterinary Vaccines, Biologicals, Diagnostics and Devices Team (4)
Veterinary Vaccines, Biologicals, Diagnostics & Devices Registration Analyst Team Leader (1)
Veterinary Vaccines and Biosimilar Registration Specialist (1)
Veterinary Biological Products Registration Specialist (1)
Veterinary In vitro Diagnostics & Medical Devices Registration Specialist (1)
Medicated Cosmetics Team (5)
Cosmetics Registration Analyst Team Leader (1)
Cosmetics Registration Specialist (4)
Public Health Chemicals Team (6)
Public Health Chemicals Registration Analyst Team Leader (1)
Public Health Chemicals Registration Specialist (5)
Household Pesticides Registration Specialist (1)
Household Cleaning Chemicals Registration Specialist (1)
Antiseptic and Disinfectants Registration Specialist (1)
Laboratory Chemicals Registration Specialist (1)
Pharmacovigilance and Drug Information Team (6)
Pharmacovigilance Analyst Team Leader (1)
Pharmacovigilance Data Entry Specialist (1)
Human Pharmacovigilance Specialist (1)
Veterinary Pharmacovigilance Specialist (1)
Cosmetovigilance Specialist: (1)
Drugs Information, Promotion and Advertising Specialist (1)
Post Market Surveillance Team (9)
Post Marketing Surveillance Analyst Team Leader (1)
Post Marketing Surveillance Specialist (Human Medicines) (4)
Veterinary Medicines Post Marketing Surveillance Specialist (1)
Cosmetics Post Marketing Surveillance Specialist (2)
Medical Device Surveillance Specialist (1)
Clinical Trial Team (6)
Clinical Trial Analyst Team Leader (1)
Clinical Trial Analyst (1)
Clinical Trial Specialist (4)
GMP and Engineering Team (12)
Pharmaceutical Plant Senior Engineer (1)
Good Engineering and Manufacturing Practices (GEMP) Inspection Analyst (1)
GEMP Inspection Specialist (1)
Good Manufacturing Practices (GMP) Inspection Analyst Team Leader (1)
GMP Inspection Specialist: (2)
Vaccine Manufacturing Facility Inspection Analyst (1)
Vaccine GEMP Inspection Analyst (1)
Vaccine GMP Inspection Analyst (1)
Biologics and Blood Products GMP Inspection Analyst (1)
Biologicals and Blood Products GMP Specialist (2)
GDP/GSP and GCP Team (19)
Retail and Wholesale Pharmacies Inspection Analyst Team Leader (1)
Retail and Wholesale Pharmacies Inspection Specialist (10)
Veterinary Pharmacies Inspection Specialist (5)
Cosmetics establishment Inspection Specialist (1)
Household Chemicals Establishment Inspection Specialist (1)
Good Clinical Practices (GCP) Analyst Team Leader (1)
Good Clinical Practices (GCP) Specialist (7)
Drugs Imports and Exports Licensing Team (8)
Drugs Import and Export Analyst Team Leader (1)
Human Medicines Import & Export Licensing Specialist: (3)
Veterinary Medicines Import & Export Licensing Specialist (2)
Tobacco Products and Controlled Substances Import &Export control Specialist (1)
Cosmetics Import & Export Control Specialist (1)
Household Chemicals Import & Export Control Specialist (1)
Medical Devices & Diagnostic Licensing Team (2)
Medical Devices & Diagnostics Import & Export Licensing Analyst Team Leader (1)
Medical Devices & Diagnostics Import & Export Licensing Specialist (1)
Drugs and Devices Imports & Exports Control Team (16)
Drugs Point of Entry Coordination Analyst Team Leader (1)
Drugs Point of Entry Inspection Specialist (15)

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5. Pharmaceutical Inspection Convention Scheme (PIC/S), pi 002-3 2007, "*Recommendations on quality system requirements for pharmaceutical inspectorates"*;
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End of Document