RWANDA FOOD AND DRUGS AUTHORITY
QUALITY MANUAL

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ADOPTION AND APPROVAL

In EXERCISE of the powers conferred upon the Board of Directors of Rwanda Food and Drugs Authority by Article N° 15 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, the Board of Directors adopted and approved the Quality Manual of Rwanda Food and Drugs Authority during the meeting held on 11th May 2021

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Chairman, Board of Directors

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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

In this Manual, the following verbal forms are used:

"shall" indicates a requirement;
"should" indicates a recommendation;
"may" indicates a permission; and
"can" indicates a possibility or a capability.

INTRODUCTION

BACKGROUND

This policy manual and its provisions shall be cited as the "Quality Manual", hereafter designated as "The Manual". "Procedure's manual" stipulated in Rwanda Food and Drugs Authority Law Nº. 003/2018 of 09/02/2018 shall be referenced to this Quality Manual.

One of the goals of Rwanda Food and Drugs Authority (FDA) is to have a functioning quality management system (QMS) in accordance with national and internationally recognized standards. The Manual describes how Rwanda FDA implements and evaluates its quality processes to ensure safety and quality of all regulated products. It also aims at achieving customer needs and expectations throughout the lifecycle of a product/service. The Manual provides practical guidance to quality management processes in meeting the requirements of the International Standard ISO 9001: 2015

The Manual defines the:
1. scope of the QMS, including details of, and justification for, any exclusions;
2. documented information established for the QMS, or reference to them; and
3. description of the interaction between the processes of the QMS.

OBJECTIVES OF THE MANUAL

1. To define and describe the QMS, authorities and responsibilities of the management 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.
2. 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 drug regulatory service to the population of Rwanda.

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 that determined 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.

QUALITY POLICY STATEMENT

Rwanda FDA is committed to providing the highest quality of regulatory services that meet customer requirements by implementing a QMS that complies with the requirements of ISO 9001:2015.

Regulatory services include assessment and registration, inspection and licensing, control of imports and exports, pharmacovigilance, post-marketing surveillance, oversight of clinical trials, control of promotional materials and advertisements, laboratory testing, and enforcement.

The Authority shall commit adequate financial, human, physical, and technological resources for implementing, maintaining, and continually improving the QMS to achieve set quality objectives, and to maintain an adequate workforce that is trained, motivated, facilitated, and empowered to achieve the intended results.

Quality objectives, processes, systems, and procedures that support this quality policy shall be established and reviewed periodically for continuing suitability.

QUALITY OBJECTIVES (STRATEGIC OBJECTIVES)

1. Regulatory and control systems that ensure safety, efficacy, quality, affordability, and accessibility of the products regulated by Rwanda FDA are established/strengthened.

2. Regulated products for which market authorisation is required are evaluated and a register maintained.

3. Clinical trials on drugs, vaccines, and other biological products, medical devices, and herbal medicines are regulated and inspected.

4. System of pharmacovigilance and post-marketing surveillance for effective regulation is strengthened.

5. Promotional materials, advertising, and marketing of the regulated products are controlled.

6. Effective and efficient customer service, dissemination, and publication of information on safety, efficacy, and quality of the regulated products to the public are promoted.

7. Collaboration and partnerships arrangement with national, regional, and international agencies on areas of mutual interest are harnessed.

8. Mechanisms for conducting operational research and innovation on regulated products that contribute to the investment promotion are established.

9. Human resources and administration for effective implementation of Rwanda FDA are established and strengthened.

10. Effective risk management, quality management system, and performance management system to monitor and measure effective regulation are developed.

11. Organisation structure, governance framework, infrastructure, and sustainable financial resources for effective institutional development are strengthened.

VISION OF RWANDA FDA

A world class regulatory Authority effectively protecting and promoting public health.

MISSION OF RWANDA FDA

To regulate medical products, processed food, household products, tobacco and tobacco products to ensure their quality and safety to protect the population of Rwanda from defective, falsified, and substandard products.

CORE VALUES OF RWANDA FDA

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

1. Serving with **Professionalism** for excellent service delivery;
2. Continuously working with **Integrity;**
3. Promoting **Accountability** at all times;
4. Nurturing **Teamwork** to achieve common objectives;
5. Striving for **Innovation** to create value for our stakeholder and other interested parties.

QUALITY MANAGEMENT SYSTEM

1.0 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. These include key regulatory services, namely:

1. Assessment and registration of products (human and veterinary drugs, human and animal vaccines and other biological products; processed food for humans and animals, food supplements and fortified foods; poisonous substances; herbal medicines; medicated cosmetics;

human and veterinary medical devices; tobacco and tobacco products; laboratory and cleaning chemicals as well as pesticides).

2. Inspection and licensing of premises that manufacture, distribute, and sell regulated products for compliance to Good Manufacturing Practices (GMP); Good Dispensing Practices; Good Laboratory Practices (GLP); Good Hygienic Practices(GHP); and Hazard Analysis and Critical Control Point (HACCP) for human and veterinary drugs, human and animal vaccines and other biological products; processed food for humans and animals, food supplements and fortified foods; poisonous substances; herbal medicines; medicated cosmetics; human and veterinary medical devices; tobacco and tobacco products; laboratory and cleaning chemicals, and pesticides;
3. Control of import and export of the regulated products;
4. Pharmacovigilance (medicines, cosmetics, and medical devices);
5. Safety monitoring for processed food, food supplements, and fortified foods;
6. Post-marketing surveillance;
7. Authorization of clinical trials and inspection of clinical trial sites;
8. Control of advertisements and promotion materials; and
9. Quality control by testing regulated products.

The quality management system described in this Manual applies to the entire Authority's management.

All clauses of ISO 9001:2015 Quality management systems—Requirements apply except Section 8.3 (Design and development of products and services), which is excluded from this Manual because Rwanda FDA does not engage in design and development work. Rwanda FDA uses product regulatory guidelines described in both national and international guidelines including East African Community (EAC) Medicines Regulatory Harmonization (MRH); World Health Organization (WHO), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Codex Alimentarius, and other international bodies.

Clauses for impartiality, independence, and confidentiality have been included in this Manual as sections 7.5.2 and 7.5.3, respectively to fulfil the requirements for section 6.2.3 in the EAC MRH QMS Compendium 2014.

2.0 **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 9001:2015 Quality management systems—Requirements

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

1. ISO 9000:2015, Quality Management Systems – Fundamentals and vocabulary.
2. The Rwanda Food and Drugs Authority Law N°. 003/2018 of 09/02/2018.

3.0 TERMS AND DEFINITIONS

"Regulated products" means human and veterinary drugs, human and animal vaccines and other biological products, processed food for humans and animals, food supplements and fortified foods, poisonous substances, herbal medicine; medicated cosmetics, human and veterinary medical devices, tobacco and tobacco products, laboratory and cleaning chemicals, and pesticides.

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

4.0 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 2021-2024. Internal factors are those within the organization which may affect the implementation of the QMS. They include controls in decisions to employ, knowledge and skills of the employees, low employee morale, cultural changes, management, and financial changes.

External factors are events that take place outside the organization that are harder to predict and control such as emerging porous borders, rapid changes in technology, variations in (un-harmonized) regulatory systems in the EAC as regional economic bloc, and 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 QMS through development of a Client Service Charter and stakeholders' analysis in the strategic plan.

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 activities:

1. Assessment and registration of regulated products.

2. Inspection and licensing of premises that manufacture, distribute, and sell regulated products.
3. Control of imports and exports for regulated products.
4. Pharmacovigilance and post-marketing surveillance.
5. Food safety monitoring.
6. Clinical trials.
7. Control of promotional and advertisement relating to the regulated products.
8. Quality control laboratory testing of the regulated products.
9. Operational research for informed regulatory decisions.

It also includes Rwanda FDA's support functions such as finance and audit, procurement, information communication technology, legal services, human resources and administration, public relations, and others as applicable to the approved organizational structure of Rwanda FDA.

4.4 Quality management system and its processes

The sequence and interaction of the regulatory processes have been optimised through a Source of Inputs-Activities-Outputs-Receiver of Outputs (SIAOR) analysis. The interactions of these processes at macro-level are shown in Appendix 2 (Level 1 and 2).

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

The necessary resources needed have also been included in Rwanda FDA's approved annual budgets. The key performance indicators used to monitor and measure these 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.

5.0 LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

Rwanda FDA is committed to the implementation of QMS. The Board of Directors has approved the quality policy, vision and mission and the necessary human, financial, physical, technical, and technological resources for the successful implementation of the QMS.

5.1.2 Customer focus

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

1. customer and applicable statutory and regulatory requirements are determined, understood, and consistently met through annual work plans and budgets that are consistent with the strategic plan and Rwanda FDA mandate;

2. any risks and opportunities with the potential to impact Rwanda FDA's ability to provide regulatory services that conform with the requirements or that may affect customer satisfaction are being identified and addressed (risk register); and

3. the focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Establishing the quality policy Statement

The Board of Directors has approved a Quality Policy *(Doc. N^{o} QMS/POL/001)*.

5.2.2 Communicating the quality policy statement

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

5.3 Organizational roles, responsibilities, and authorities

It is the responsibility of Rwanda FDA to assign the responsibility and authority for ensuring that the integrity of the quality management system is maintained when changes to the QMS are planned and implemented and for ensuring the promotion of customer focus throughout the organization.

The overall in-charge of QMS 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 international standard and other relevant international standards and guidelines.
2. Providing leadership for effective performance of the QMS in the entire Rwanda FDA.
3. Reporting to top management on the QMS and on the opportunities for improvement.

A QMS implementation committee has been set up with representation from each division and chaired

by one of the heads of departments with the overall in-charge of QMS as the rapporteur.

The Board of Directors adopted and approved the organizational structure for Rwanda FDA that is available on the shared QMS folder on the Rwanda FDA server and on the website.

There are approved current job profiles and descriptions clearly stating the roles, duties, and responsibilities of each member of staff.

6.0 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.

The SIAOR analysis is used to identify the potential risks and opportunities during process planning and rationalisation in the different departments / units.

Rwanda FDA has also conducted an overall business risk analysis as per the risk identification and analysis and maintains a risk register, where monitoring and reporting on the progress of mitigating the risks is done by each department, division, and directorate.

6.2 Quality objectives and planning

Rwanda FDA has a strategic plan for the period 2021-2024. It 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.

7.0 SUPPORT

7.1 Resources

7.1.1 General

Necessary resources are determined for each financial year during the planning and budgeting period (between November and February). This results in recurrent and capital expenditure budget estimates for the entire Rwanda FDA that is approved by the Board of Directors.

7.1.2 People

Rwanda FDA establishment in terms of the required staffing levels is available and is in accordance with the approved current organizational structure (Appendix 2). Recruitment is progressively made with respect to the establishment.

7.1.3 Infrastructure

Rwanda FDA has offices at Nyarutarama Plaza KG 9 Avenue, Kigali. These offices have been provided with the necessary utilities; process equipment (both hardware and software); and supporting services (such as transport, communication, or information systems).

The infrastructure is continually improved and maintained to improve service delivery to customers.

7.1.4. Environment for the operation of processes

The offices, storage areas, and laboratory have been provided with adequate lighting, cold storage for samples, noise-protection, and air-conditioning, where necessary.

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, semi-annual, and annual performance reporting against the targets. Process data are captured and analysed to reveal any process trends that can be the basis for planning and improvement during the coming period.

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 jeopardising any future measurement results. Verification and/or calibration records are kept.

7.1.6. Organizational knowledge

Organizational knowledge specific to Rwanda FDA 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, guidelines, charters, manuals, procedures, reports, and records. These documents shall be controlled as per SOPs for control of documents and records.

An assessment of organizational knowledge is done prior to 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 in respect to the changes to the quality management system.

7.2 Competence

Competence is defined as the *"ability to apply knowledge and skills to achieve intended results"*.
The competence of the employees of Rwanda FDA is acquired through appropriate education and training or experience, as necessary. Requirements for education, skill, training, and experience are documented in the job specifications/description. Training of employees is done in accordance with the approved annual training plan.

The necessary competence for specific tasks is determined for employees and for contracted external experts that are required to perform work affecting conformity to product and/or service requirements (refer to scheme of service, job profiles, job descriptions, competence matrix, and terms of references for committees and for outsourced external experts).

A training plan is developed on annual basis and training records are maintained.

7.3 Awareness

Staff awareness on the quality policy, objectives, and their contribution to the effectiveness of the QMS, and implication of not conforming to the requirements (ISO 9001:2015 Quality management systems—Requirements) is ensured through the provision of QMS trainings and staff directorates meetings. New recruited staff are also oriented immediately after recruitment and at specified periods. Minutes and training records are retained in the files of the respective directorates.

7.4 Communication

The communication policy and strategy for both internal and external stakeholders have been established and implemented. The strategy shows information such as what will be communicated, when to communicate, with whom to communicate, how to communicate, and who communicates.

Communication channels that are organised mainly for external stakeholders include: press conferences and press releases, radio and television talk shows, emails, circulars, public alerts, seminars, and workshops and consultative meetings. Channels for internal stakeholders (staff and members of Board of Directors) include emails, WhatsApp, meetings, and retreats.

7.5 Documented information

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 described in the SOP for document control *(Doc. Nº QMS/SOP/001).*

Rwanda FDA has established the following categories of documents of internal origin for the quality management system:

	Document Type	Code
1)	Chart	CHT
2)	Checklist	CKL
3)	Concept note	CNT
4)	Contract	CTC
5)	Form	FOM
6)	Format	FMT
7)	Guideline	GDL
8)	Internal rules & regulations	IRR
9)	Job description	JOD
10)	Job specification	JBS
11)	Manual	MAN
12)	Memorandum of understanding	MoU
13)	Policy	POL
14)	Press release	PR

	Document Type	Code
15)	Process flow outline	PRF
16)	Protocol	PTC
17)	Report	REP
18)	Standard operation procedure	SOP
19)	Standard test procedure	STP
20)	Technical regulation	TRG
21)	Terms of Reference	TOR
22)	Work instruction	WOI

Document registers for internal documents and external documents are maintained.

7.5.1 Creating, updating and control of documented information

The SOP for document control describes the procedure for creating, updating, and controlling documents that are maintained, while the control of internal and external documents and a documented SOP for control of records describes controls for records (i.e., documents that are retained).

7.5.2 Impartiality and independence

Rwanda FDA is bound by the Internal Rules and Regulations on Human Resources. Each member of staff is required to sign the Annual Declaration of Interest form.

7.5.3 Confidentiality

The members of the Advisory Committee and the staff of Rwanda FDA are required to sign confidentiality commitments using the Confidentiality form.

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

8.0 OPERATION

8.1 Operational planning and control

Rwanda FDA has a legal mandate to ensure that all human and veterinary drugs, vaccines, and other biological products used in clinical settings as drugs; processed food for human and animal use, food supplements, and fortified foods; poisonous substances; herbal medicines; medicated cosmetics; human and veterinary medical devices; tobacco and tobacco products; poisonous substances; and herbal medicines used in Rwanda are of good quality, safe, and effective through the following processes:

1. Inspection and licensing of wholesale and retail pharmacies.

2. Inspection and licensing of pharmaceutical manufacturing and food processing facilities (GMP and HACCP).
3. Assessment and registration of all regulated products.
4. Control of imports and exports *(verification of pro-forma invoices, inspection of consignments at ports of entry into Rwanda).*
5. Enforcement *(seizure and confiscation of any product, imposing administrative sanctions, and withdrawal of authorization).*
6. Post-marketing surveillance process *(sampling of suspect, spurious, and random samples from drug outlets).*
7. Pharmacovigilance *(Monitoring of adverse drug events [safety and efficacy of drugs]).*
8. Safety monitoring for regulated food products.
9. Authorization of clinical trials and inspection of clinical trial sites.
10. Control of publications and advertising relating to regulated products (including promotional materials).
11. Quality control testing of regulated products (*testing of suspected defective, and random samples from ports of entry and from drug outlets).*

Process flows, in terms of SIAOR analysis 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 (as a document) and retained (as a record).

Quality control and quality assurance measures at different stages of service provision have been established; for example, first and second assessors for the evaluation of product dossiers; peer review of assessment reports and of GMP reports; and acceptance criteria based on applicable standards to be met, (e.g., 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 products and services

8.2.1 Customer Communication

Rwanda FDA communicates to its customers about specific service requirements (e.g., annual licensing requirements for pharmacies, product registration requirements in the Common Technical Document dossiers, requirements for amendments to a registered product, etc.) 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 electronic media.

Feedback from clients, customers, stakeholders, and interested parties is through customer satisfaction surveys and a market complaint handling system.

8.2.2 Determining the requirements for products and services

Requirements specified by the customer have been determined through consultative meetings with customers (e.g., manufactures, importers, exporters, wholesalers and retail operators, practitioners, consumer organizations) and from feedback mechanisms. This mainly affects the information to be included in new or revised regulations and guidelines.

In developing such guidance documents, Rwanda FDA also takes into account national, regional (EAC MRH), and international guidelines and best practices.

A service delivery timeline showing the regulatory area, action, and timelines has been developed for the regulatory functions of Rwanda FDA. It is posted on the website to communicate it to clients and other interested parties.

8.2.3 Review of requirements for products and services

When applications are received for inspection of local and foreign manufacturers; processors of regulated products; inspection for suitability of premises for manufacturing, wholesale, and retail; inspection of a clinical trial, application for market authorisation, etc., they are screened for completeness before they are accepted.

Inspection schedules are developed and communicated to the applicants for consent before the inspection takes place. However, un-announced inspections are also done under special circumstances.

8.2.4 Changes to requirements for products and services

Changes to inspection schedules are made whenever justified and mutually agreed upon between Rwanda FDA and the applicants.

Applicants and the general public are notified of changes in the requirements for licensing, inspection, product registration, sample size, etc. for any regulated products.

8.2.5 Complaints and appeals

Rwanda FDA has established a documented procedure (complaint handling and dispute resolution) for investigation and handling of market complaints and appeals from customers.

8.3 Design and development of products and services

This section is not applicable because Rwanda FDA is not involved in design and development work as justified under section 1.0 (Scope of the quality management system) of this Manual.

8.4 Control of externally provided processes, products, and services

Externally provided processes, products, and services include cleaning of office and security of premises.

Outsourcing of laboratory testing is done for tests that cannot be done by the Rwanda FDA laboratory. The necessary controls for the latter are described in the Laboratory Quality Manual.

Procurement of all externally provided processes, products, and services is governed by Law N° 62/208 of 25/08/2018 Governing Public Procurement in Rwanda.

Records arising from the procurement process, including product/service specifications, procedures, evaluation of suppliers and selection criteria, are maintained by the Office of Chief Finance.

8.4.1 Type and extent of control

A list of prequalified suppliers of services, works, and supplies was developed in accordance with the procurement laws and regulations. Rwanda FDA ensures that purchased products are inspected and verified against the purchase order before they are accepted. Goods Receipt Notes are kept as evidence of inspection and verification of the purchased product.

8.4.2 Information for external providers

Rwanda FDA develops and maintains purchasing information describing the product, service, or works to be procured. This information includes specifications, procedures, and acceptance criteria.

8.5 Production and service provision

8.5.1 Control of production and service provision

Rwanda FDA carries out service provision under controlled conditions following Rwanda FDA law, regulations, guidelines, SOPs, checklists/aide memoires, and qualified equipment.

Additional controls include quality assurance measures such as peer review of reports, first and second assessors for product dossier evaluation, checking by supervisors at different levels, or by a relevant technical committee, and approval by the Director General, where required.

8.5.2 Identification and traceability

Rwanda FDA uses unique identification numbers for customer property (e.g., product dossiers, product samples) and outputs (e.g., marketing authorization number, permit number, license number, GMP certificate number, adverse event report number, test report number).

8.5.3 Property belonging to customers or external providers

Rwanda FDA identifies, verifies, protects, and safeguards customer property provided for use during provision of services while it is under its control.

Customer property includes product dossiers for marketing authorization, samples, site master files for manufacturing facilities, pro-forma invoices for importers of or regulated products, samples collected/taken for quality control laboratory testing, confiscated products, promotional materials, and certificates.

8.5.4 Preservation

Rwanda FDA preserves the conformity of product during internal processing and delivery to the intended destination, including preservation of samples taken during post marketing surveillance or exhibit samples taken during inspection.

Preservation includes identification, handling, storage, and protection. Preservation of product includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

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 monitors product safety, quality, and efficacy/effectiveness with respect to regulated products that are used by the public by carrying out safety monitoring of food products, pharmacovigilance, and post-marketing surveillance activities.

8.5.6 Control of changes

Rwanda FDA follows the SOP for control of change No QMS/SOP/033 to ensure that changes made do not adversely affect the specifications and quality of the services delivered. Records of change controls are maintained as per SOP on control of Records No QMS/SOP/034.

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 senior officers authorised by him. The list of authorised persons to release outputs to customers is updated from time to time.

The release of reports, certificates, licences, permits, and delivery to the customers (applicants) does not proceed until the requirements have been satisfactorily met (e.g., GMP certificates are not issued until the evidence of corrective and preventive actions by the manufacturer are submitted and evaluated by Rwanda FDA and found to be satisfactory).

8.7 Control of non-conforming outputs

Whenever a non-conforming output is identified, it is registered by the relevant unit and Complaint Investigation In-Process form (in case of market/customer complaints) or Corrective Action Request form, (for others e.g., arising out of quality audits), is raised for investigation to be initiated in order to find out the root cause or assignable cause. Corrective action is then taken by the unit.

Non-conforming outputs can include but not limited to any of the following:

1. Error or omission on a certificate, permit, or licence.
2. Error on 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 advertisement relating to drugs processes).
5. Out-of-specification test results.

9.0 PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis, and evaluation

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

9.1.1. 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 will be conducted at least once a year.

The Customer Complaint Report form is available on the Rwanda FDA website and at the office reception area for interested parties to fill and submit to Rwanda FDA.

Inquiries are also received via social media accounts of the Authority: email (info@rwandafda.gov.rw); and on the Rwanda FDA website (www.rwandafda.gov.rw).

9.1.2. 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, and department.

9.2 Internal audit

Internal quality audits are conducted according to an approved schedule. 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 for QMS and the requirements of International Standard (ISO 9001:2015) and whether the QMS is effectively implemented and maintained.

The frequency and scope of the audits are determined based on the significance/sensitivity of a process and the results of previous audits.

An SOP for internal quality audit is established to define the responsibilities and requirements for planning and conducting quality audits, establishing records, and reporting results.

Reports of internal quality audits are submitted to the Authority and to the auditee. The auditee also receives the corresponding Corrective Action Request (CAR) forms. The audit is considered closed when the implementation and effectiveness of corrective actions have been verified and recorded.

Audit results become part of the quality records and are presented at management review.

9.3 Management review

Management reviews the QMS 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 specialist as the rapporteur. The records of management reviews are maintained.

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. 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.

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 market complaints, licensing complaints, and appeals. When nonconformity occurs, the Authority:

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.

The actions that relate to the registered product can include suspension or deletion of the product from the register and/or direct the affected batches of product for quarantine and recall by the license holder, applicant, or local technical representative.

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 Authority shall retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action.

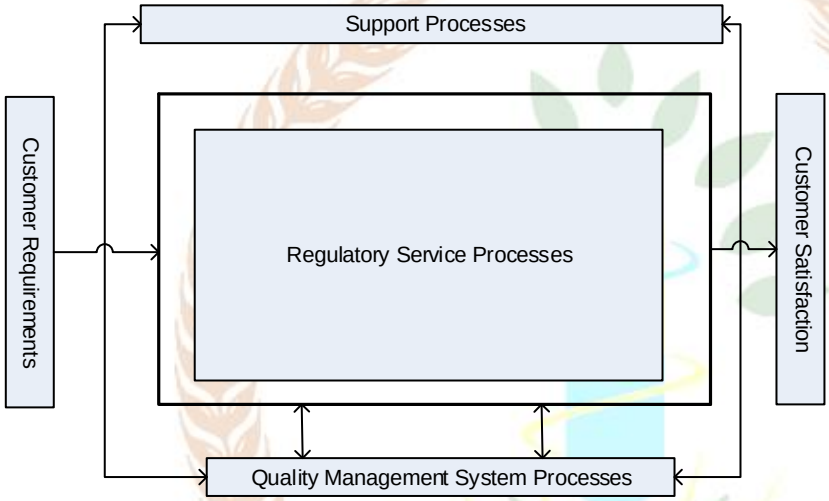
10.2 Continual improvement

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.

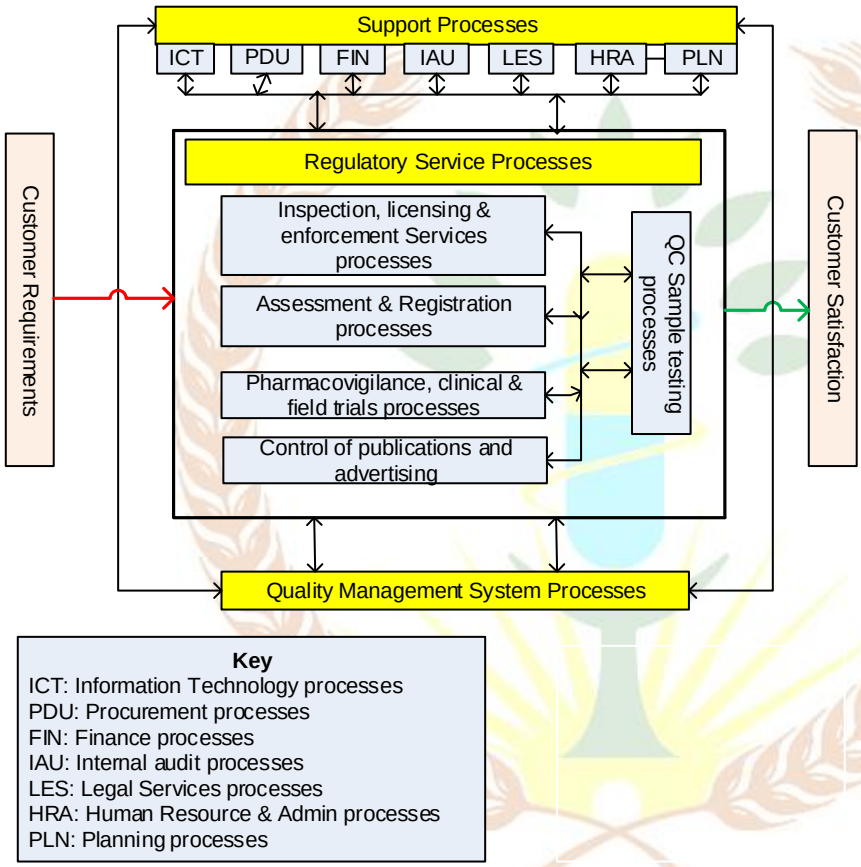
As part of continual improvement, Rwanda FDA uses the results of analysis and the evaluation of data from key processes and management review to determine areas of underperformance and to identify any opportunities for improvement.

Appendix 1: Interaction of Processes

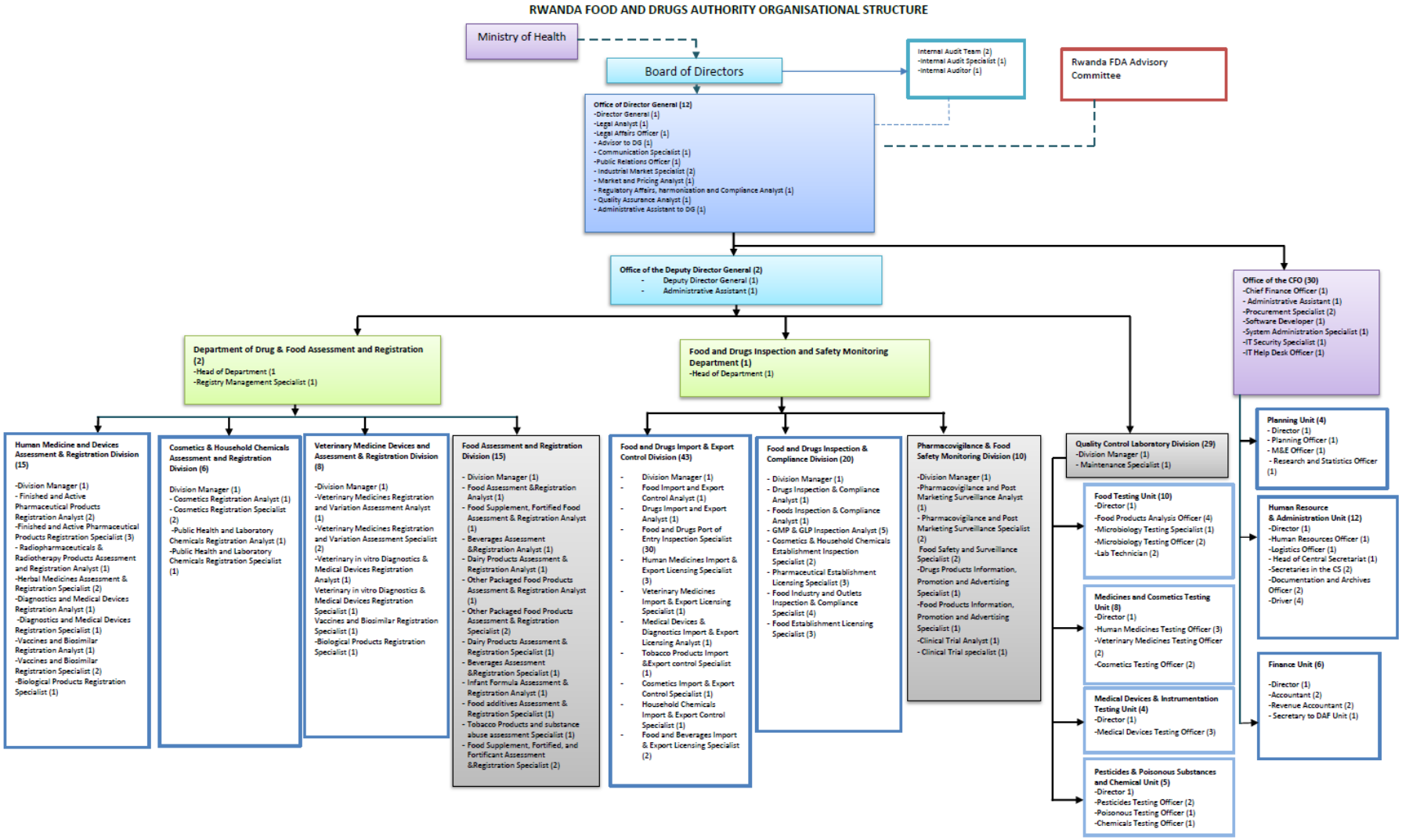
Level 1: Rwanda FDA Interaction of Processes



Level 2: Detailed Interaction of Processes



Appendix 2: Rwanda FDA Organizational Structure



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2. ISO 9000:2015, "Quality management systems – Fundamentals and vocabulary", ISO Geneva.
3. ISO 9001:2015 "Quality management systems—Requirements"
4. Law N° 62/2018 of 25/08/2018 Governing Public Procurement, The Republic of Rwanda.
5. Pharmaceutical Inspection Convention Scheme (PIC/S), pi 002-3 2007, "*Recommendations on quality system requirements for pharmaceutical inspectorates".*
6. The Law No. 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (Rwanda FDA) and determining its mission, organization, and functioning.

Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
26 October 2020	0	First issue

End of Document