RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FDA RISK MANAGEMENT FRAMEWORK

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FOREWORD

Over the recent years, managing risk has become an increasingly important aspect in supporting achievement of organizational objectives. This requires the adoption of risk management practices within a formal implementation framework.

Adherence to this framework will ensure successful implementation of institutional risk management and subsequently promote good governance.

It is anticipated that, this framework will be reviewed regularly in response to the experiences gathered from its utilization.

Dr. Charles KARANGWA
Ag. Director General

LIST OF ABBREVIATIONS

EAC	East African Community
ISO	International Organization for Standardization
RMC	Risk Management Coordinator
RMF	Risk Management Framework
SADC	Southern African Development Community
Rwanda FDA	Tanzania Food and Drugs Authority

DEFINITION OF KEY TERMS AND CONCEPTS

Risk refers to the possibility of an event occurring that will have an impact on the achievement of objectives. Risk is measured in terms of impact and likelihood.

Risk Management is a process of identifying, assessing, managing, and controlling potential events or situations to provide reasonable assurance regarding the achievement of organization's objectives.

Authority means Rwanda Food and Drug Authority.

Enterprise wide Risk Management is a systematic, integrated and continuous approach applied across the entire Organization for identifying, assessing, managing and controlling potential events or situations to provide reasonable assurance regarding the achievement of organizational goals.

Risk Appetite is the level of risk exposure or the amount of risk, or potential adverse impact from an event or a situation, that the Organisation is willing to accept in the course of performing its functions. When risk appetite limit is exceeded, appropriate actions shall be taken to bring the exposure level back within the accepted range.

Risk Management Coordinator (RMC) means a Management Personnel appointed by Director General who shall lead all Rwanda FDA efforts in Enterprise-wide Risk Management.

Heat Map is a graphical representation of data where the values taken by a variable in a two-dimensional map are represented in colours. It highlights risk universe coverage based on priority and groups of Organisation's defined risk based upon several criteria using Impact/Consequences of the risks and their Likelihood/Probability of occurrence.

Inherent Risk is the probability of loss arising out of circumstances or existing in an environment, in the absence of any action to control or modify the circumstances.

Risk Analysis is defined as the systematic process applied to determine the likelihood and impact on occurrence. It provides the basis for risk evaluation and decisions about risk treatment.

Residual Risk is the risk that remains after management action to treat the risk.

Risk Tolerance is the acceptable level or capacity to accept or absorb risk depending on the set risk appetite.

Risk Treatment is the process of responding to risk in which the negative impact of the risk is neutralized.

Risk Acceptance means taking no action. This is common to risks that are considered insignificant and/or too costly to treat.

Risk category is the organization of risks in the form of a hierarchical scale that identifies each risk and what that level of risk entails. The Rwanda FDA risks are categorised into Strategic, Operational, Financial and Systems and Compliance.

1.0 INTRODUCTION

Within the regulatory environment, which is continuously changing from time to time, there are inherent risks that make Rwanda FDA susceptible of becoming vulnerable to not achieving its strategic objectives. The long-term sustained growth, continued success and reputation of the institution is critically dependent on the effective risk management process which is amongst core focus areas of good governance and modern management.

Rwanda FDA has taken time to identify various risks and plans to incorporate risk management practices in their daily functions and to incorporate risk management concepts in its operations. To achieve this, Rwanda FDA developed this Framework document to guide the implementation of risk management practices across its activities and programs.

1.1 Objective of the Risk Management Framework

The main objective of this framework is to provide practical guidance to Rwanda FDA in developing and implementing standardized and customized risk management practices to be embedded in day-to-day activities.

1.2 Rationale for Risk Management at Rwanda FDA

Rwanda FDA operates in a dynamic regulatory and business environment which is not risk free, hence it is required to manage and control risks in order to achieve its goals.

The following are the potential benefits for managing risks at Rwanda FDA:-

a. Establishment of a reliable basis for decision making and planning (strategic and operational planning);

b. Effective use of organization's resources such as minimizing operational surprises, shocks or unexpected losses;

c. Enhanced communication on risk issues across all levels of management within the organization;

d. Assurance on achievement of organization's objectives and grasp new opportunities in a timely manner;

e. Ensure compliance with relevant legal and regulatory requirements and international standards; and

f. Increase stakeholders' confidence and trust that the organization is aware of the risks towards attaining its objectives.

1.3 Risk Regulatory Requirements

This Framework is developed based on the national and international standards and guidelines for developing and implementing institutional risk management in the public sector to comply with the following requirements: -

a. The requirement stipulated in ISO 9001:2015 (Quality Management Systems-Requirement) clause 6.1 that requires organizations to take action to address risks and opportunities.

1.4 Scope and Applicability

This framework focuses on providing guidance on commitment and approach in managing risks that affect the achievement of Rwanda FDA strategic and operational objectives at all levels (departments, divisions and units) of the Authority. It identifies responsibilities and activities of all employees of Rwanda FDA for applying risk management principles and practices in their work areas.

1.5 Structure of Framework Document

This Framework is comprised of five main chapters; these are:

a. Introduction;

b. Context of Rwanda FDA;

c. The risk management policy;

d. Risk management governance structure;

e. Risk management procedures; and

f. Annexes.

1.6 Review of the Framework Document

The Risk Management Framework review shall be done following changes in the strategic plan, laws and regulations and international standards relating to risk management or when the need arises.

2.0 CONTEXT OF Rwanda FDA

2.1 Background

Rwanda Food and Drugs Authority (Rwanda FDA) is the regulatory body established to regulate food and pharmaceutical. It was established under Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning. The Rwanda FDA as an autonomous regulatory agency started its operations of regulation of the quality, safety, efficacy and effectiveness of food, drugs, cosmetics and medical devices.

Internal and external factors are important in achieving Organizational objectives. These factors should be identified during the implementation of Rwanda FDA Risk Management Framework.

Internal factors are those within the Organization which may affect implementation of Risk Management. They include employment controls in doing decision to employ, low employee morale, culture change, management and financial changes.

External factors are events that take place outside the Organization that are harder to predict and control such as porous borders, fast change of technology, and unharmonised regulatory systems in the Regional Economic Communities such as EAC and overlap of Government Institutions responsibilities.

2.2 Mission

To protect and promote public health by ensuring quality, safety and effectiveness of food, medicines, cosmetics and medical devices.

2.3 Vision

To be a World Class Regulatory Authority ensuring Safe, Quality and Effective Food, Drugs, Cosmetics and Health Technologies.

2.4 Philosophy

Rwanda FDA strives to offer quality regulatory services in the pursuit of protecting public health and the environment by using competent and dedicated staff.

2.5 Quality Policy Statement

"Rwanda FDA is committed to providing the highest standard of regulatory service to all customers by implementation of a quality management system that complies with ISO 9001:2015.

Timely and reliable service, compliance to all applicable statutory and regulatory requirements, continual improvement of the processes, systems and procedures; and meeting customer requirements underlie all its efforts in ensuring quality, safety, efficacy, and wholesomeness of all regulated products used in Rwanda.

This is achieved through assessment and registration; inspection and licensing; control of imports and exports; pharmacovigilance; post-marketing surveillance; clinical and field trials; control of publications and advertisements; laboratory testing; and enforcement.

Rwanda FDA shall therefore commit adequate financial, human, physical and technological resources for implementing, maintaining and continually improving the quality management system to achieve set objectives; and maintain an adequate workforce that is trained, motivated, facilitated and empowered to achieve results.

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

2.6 Rwanda FDA Core values

The core values of Rwanda FDA are professionalism, excellent service delivery, integrity, transparency and accountability, teamwork, creativity and innovation.

2.7 Location of Rwanda FDA offices

The Rwanda FDA Head Offices is located on **Nyarutarama Plaza, KG 9 Ave**
P. Box: 1948 Kigali- Rwanda.

2.8 Functions of the Authority

The Authority is the regulatory body for the products regulated under the Law No. 003/2018 of 09/02/2018, and in particular:-

a) regulate pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs food supplements, food fortificants fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products, management of unfit pharmaceutical and food products and clinical trials on pharmaceutical products for human and veterinary use;

b) regulate compliance with quality standards relating to the manufacture, storage, sale, distribution, use, import and export, labels, packages and raw materials used in the manufacture of products regulated under this Law;

c) regulate laboratory and cleaning chemicals and pesticides as well as premises involved in the manufacture of products regulated under this Law;

d) establish, approve and publish the list of human and veterinary food and pharmaceutical products as well as other products regulated under this Law for which marketing

e) authorization has been granted;

f) establish and publish the list of prohibited cosmetics;

g) establish the quality assurance and quality control of products regulated under this Law through designated quality control laboratories when necessary;

h) to regulate and inspect clinical trials;

i) ensure that processed food, food supplements and fortified food meet the prescribed quality standards before they are placed on the market;

j) conduct pharmacovigilance and post marketing surveillance for safety and quality of products regulated under this Law;

k) follow up and analyse information on the use of pharmaceutical products that are subject to global drugs safety monitoring;

l) regulate and analyse information used in the promotion, advertising and marketing of products regulated under this Law;

m) regulate the use of unregistered products regulated under this Law for clinical trial purposes or compassionate use;

n) disseminate information on quality and safety of products regulated under this Law to health professionals and to other concerned persons;

o) conduct research and studies on food and pharmaceutical products and publish the findings in order to promote investment;

p) build cooperation and partnership for harmonization of practices with regional and international bodies with similar missions;

q) to advise the Government on matters regarding the products regulated under this Law;

2.9 Corporate Governance

The Board of Directors of the Rwanda FDA is responsible for oversight of Rwanda FDA performance and also to ensure that a comprehensive system of internal control policies and procedures is operative and in compliance with sound corporate governance principles.

The day-to-day management of the business is vested in the Director General. The Management forms the secretariat of the Board meetings. The Authority is committed to the principles of effective corporate governance (integrity, transparency and accountability).

2.10 Rwanda FDA Management

The Management is comprised of Director General and other staff members.

2.10.1 Office of the Director General

Under the office of the Director General there are two main departments, namely Drug and Food Assessment and Registration and Food and Drug Inspection and Safety Monitoring as well as the Chief Finance Office.

2.10.2 Department of Drug and Food Assessment and Registration

The department is responsible for pre-market evaluation and registration of products regulated under the Law.

2.10.3 Department of Food and Drug Inspection and Safety Monitoring

The department is responsible for the inspection and enforcement of standards for medicines, cosmetics, medical devices and diagnostics.

2.10.4 Chief Finance Office

It is responsible for planning, finance, human resources and administration, marketing and management information systems.

Annex 1: Shows Rwanda FDA Organization Structure.

2.11 Rwanda FDA Strategic Objectives

Currently Rwanda FDA is pursuing eleven (11) strategic objectives in the next six (6) years as described below: -

a) Establish the regulatory and control systems to ensure; Safety, Efficacy, quality, affordability and accessibility of the products regulated by Rwanda FDA.

b) Evaluate and maintain a register of regulated products for which market authorisation is required.
c) Regulate and inspect clinical trials on drugs, vaccines and other biological products, medical devices and herbal medicines.
d) Strengthen the system of pharmacovigilance and post market surveillance for effective regulation.
e) Control the promotional materials, advertising and marketing of the regulated products.
f) Promote effective and efficient dissemination and publication of information on Safety, Efficacy, and Quality of the regulated products to the public.
g) Harness collaboration and partnerships arrangement with national, Regional and international agencies on areas of mutual interest.
h) Establish mechanisms for conducting operational research and innovation on the regulated products to contribute to the investment promotion.
i) Establish and strengthen the organisation Human resources and administration for effective implementation of the Rwanda FDA.
j) Develop an effective Risk, Quality management system and performance management system to monitor and measure effective regulation.
k) Strengthen the organisation structure, Governance framework, infrastructure and sustainable financial resources for effective institutional development.

Detailed information on the Strategic Objectives can be found in the Rwanda FDA Strategic Plan for the period of 2018 – 2024.

2.12 Risk Category and Appetite

Rwanda FDA risks are in the form of a hierarchical scale that identifies each risk and what that level of risk entails. They are categorized into Strategic, Operational, Financial and Systems and Compliance. When the Rwanda FDA risk appetite limit is exceeded appropriate actions shall be taken to bring the exposure level back within the accepted range. Rwanda FDA risk categories and appetite has been set as shown in table 1:

Table 1: Risk category and tolerance levels

S/No	Risk category	Risk appetite level statement
1.	Strategic	Rwanda FDA will accept maximum degree of calculated risk in pursuing new strategic initiatives which are in strategic plan. However, Rwanda FDA will accept low degree of risk if the

S/No	Risk category	Risk appetite level statement
		initiative is not within the Rwanda FDA strategic plan.
2.	Operation	Rwanda FDA will tolerate minimum level of risk associated with deliberate misuse of existent ICT equipment, technical personnel, inspections and enforcement, evaluation and registration, staff turnover, poor service delivery and physical damage to assets.
3.	Financial and Systems	Rwanda FDA will not tolerate any level of risk associated with financial controls systems.
4.	Compliance	Rwanda FDA will not tolerate any level of non-compliance with any legal or regulatory requirement.

3.0 RISK MANAGEMENT POLICY

Rwanda FDA is prone to encounter various risks at different levels of its operations, some of which have detrimental effects if not managed. This Risk Management Policy establishes the guidelines to be applied consistently and effectively by the Authority in the management of its risks. The policy statement on risk management is given to communicate the organization's mission, commitment and adopted standards towards managing its risks. It is also aimed at charging Organization officials with responsibilities for effective risk management in their areas of responsibilities. The policy creates an enabling environment to all departments, divisions and units at Rwanda FDA to implement risk management.

3.1 Adoption of Risk management procedure

Rwanda FDA has set ISO 9001 certification as one of its organizational goals and thus has committed to incorporate risk management in its operations and processes. It is in this line that the Authority developed this Risk Management Framework in compliance with requirements of the International Organization for Standardization (ISO 31000:2009).

3.2 Objective of the policy

The main objective of the Rwanda FDA Risk Management Policy is to provide guidance and direction in minimizing all risks that are likely to deter the Authority in achieving its objectives.

3.2.1 The specific objectives of the Policy are to:-

a. establish risk management as an integral part of Rwanda FDA planning and management processes;

b. ensure Rwanda FDA risks are comprehensively identified, analysed, evaluated and treated, monitored and reviewed;

c. facilitate compliance with RMF;

d. build up risk management cultures to Rwanda FDA staff at all levels;

e. ensure Rwanda FDA key performance indicators include attributes of the risk management processes; and

f. ensure that the knowledge, skills and attitudes required for successful implementation of risk management are properly communicated to all Rwanda FDA staff and stakeholders.

3.3 Risk Policy statement

Rwanda FDA is committed to provide resources for establishment and implementation of risk management while fulfilling its mission and vision. The implementation shall begin at the management and be applied consistently throughout all levels of operations.

4.0 RISK MANAGEMENT GOVERNANCE STRUCTURE

A fully integrated enterprise wide risk management requires roles and responsibilities to be clearly defined and assigned to designated individuals and organs. In this stance, Rwanda FDA has established a clearly defined risk management structure to be integrated into existing management systems for easy implementation. This section presents clearly defined structure, individual and collective risk management responsibilities at all levels of the Authority.

4.1 Risk management roles and responsibilities

The implementation of risk management is assigned to different levels in the Authority. The specific roles and responsibilities for individuals and organs involved in risk management process, as well as reporting levels and performance relationship are as described hereunder:-

4.1.1 Board of Directors

The Rwanda FDA Board of Directors is ultimately responsible for oversight of internal and external risks that may impact Rwanda FDA in achieving its strategic objectives. The Board is responsible for:-

a. understanding the Rwanda FDA risk policy;

b. review of the Rwanda FDA portfolio of risk and consider it against the Authority's risk appetite;

c. approve risk management performance reports as per QMS FOM 011 from management and make appropriate resolutions; and

d. approve recommendations of the Audit Committee regarding the effectiveness of the risk management processes.

4.1.2 Audit Committee of the Board

The Audit Committee of the Board shall have the following roles and responsibilities:

a. assist the Board to review and promote Rwanda FDA Risk Management objectives, strategy and policy;

b. monitor and evaluate the risk management process at strategic, managerial and operational levels;

c. deliberate and advice the Board on risk management reports on quarterly basis;

d. commission and review assessment of the Risk Management Framework and advice the Board accordingly;

e. provide for a standing agenda item on risk at every meeting held and receive feedback from Internal Audit, Departments, Divisions and Units on the effectiveness of the implementation of risk management; and

f. advise the Board on all relevant matters relating to risk management arising from the annual and audit reports.

4.1.3 Director General

The Director General is accountable for the overall governance of the risk management practice in Rwanda FDA. This includes overseeing the development and implementation of Risk Management Framework that align to Rwanda FDA operations, structure and context. Specifically, the Director General has the following responsibilities:-

a. setting an appropriate tone by supporting the adoption and implementation of effective risk management;

b. design, implement and enhance Appropriate Risk Management Framework;

c. delegate responsibilities for risk management to risk owners and internal formations so that it aligns to the existing organization structure, processes, culture and context;

d. provide assurance to relevant stakeholders that key risks are properly identified, assessed and mitigated;

e. report risk management issues on annual risk report as per TFRS 1;

f. supervise the implementation of appropriate and approved risk policies, procedures and guidelines throughout the Authority;

g. approve Rwanda FDA risk register and recommend submission to the Audit Committee;

h. implement risk management governance mechanisms established by the Risk Management Framework for effective monitoring of risks and their management;.

i. ensure that the risk management function is availed with appropriate and sufficient resources; and

j. ensure appropriate action in respect of the recommendations of audit committee, internal audit, and external audit with regard to issues of risk management.

4.1.4 Risk Management Coordinator

This is a primary risk champion appointed by the Director General to assist him to fulfil risk management roles and to coordinate efforts in reviewing and updating the Authority's Risk Management Framework and its implementation. The Risk Coordinator has the following responsibilities;

a. coordinate efforts for developing and enhancing appropriate risk management policies and procedures;

b. coordinate and monitor the implementation of risk management initiatives within the Authority;

c. work with risk owners to ensure that the risk management processes are implemented in accordance with approved Risk Management Framework;

d. review all risk registers for consistency and completeness;

e. provide advice and tools to staff and management on risk management issues, including facilitating workshops in risk identification;

f. promote understanding and support for risk management including delivery of risk management training;

g. oversee and update organization-wide risk profiles, with input from risk owners;

h. ensure that relevant risk information is reported and escalated or cascaded, as the case may be, in a timely manner that supports organizational requirements; and

i. ensure Board members, management and staff receive support and training to fulfill their responsibilities on risk management.

4.1.5 Risk Owners

Risk owners (Appointed person in Director General's office, Department Heads, Division Managers and Unit Directors) are the ones who assume responsibility for designing, implementing, and/or monitoring risk treatments and shall be responsible for the following:-

a. manage the risk within their area of jurisdiction;

b. review the risk on a regular basis;

c. update risk register information;

d. prioritize the risk that is increasing in likelihood or consequences;

e. provide information about the risk when it is requested. This includes giving cooperation to auditors (both internal and external) in the course of audit of risk management activities within their departments or divisions;

f. prepare and submit quarterly risk management implementation reports and risk treatment action plans;

g. annual review of their risk registers and related controls;

h. maintain risk register and other documents/ reports relating to risk management in a systematic manner;

i. cascade down to subordinates Rwanda FDA risk appetite and make sure that it is well understood;

j. receive directives from Director General regarding risk management activities and ensure that the directives are acted upon by respective individuals within each department; and

k. manage, monitor and review risks from planning to implementation level for all projects, activities and operation being undertaken at their areas.

4.1.6 Risk Champions

Risks champions are appointed by the Director General from each Department, Division and Directorate, and the Director General`s office and will collaborate with the Risk Management Coordinator in promoting risk management culture across Rwanda FDA. The key functions of risk champions are:

a. be aware of Authority`s risk management requirement and liaise with coordinator in embedding risk management practices into other systems and processes;

b. assist in ensuring implementation of risk management process in functional and operational areas consistently across the Authority;

c. work with department and division heads, directors and unit managers within their functional areas to identify, capture the key business risks and regularly review, update and monitor their respective risk registers;

d. act as point of contact for risk management enquiries in their respective departments/divisions/directorates;

e. facilitate dissemination of risk information to their respective directors/managers;

f. regularly updating the risk owners regarding progress in implementing risk management programs; and

g. document and update risk register in their areas.

4.1.7 Chief Internal Auditor

The Chief Internal Auditor in the Director General's Office has the responsibility of providing overall assurance regarding adequacy and effectiveness of risk management process by conducting the following activities:

a. prepare risk based audit plans;

b. review and evaluate the effectiveness of the risk management process in mitigating risks facing the Authority;

c. advise the Director General and Audit Committee on the effectiveness of the risk management;

d. perform quarterly reviews on compliance with Risk Management Framework; and

e. participate in audit committee meetings where risk management issues are discussed.

4.1.8 Rwanda FDA Staff

Every individual staff shall have the following roles and responsibilities:-

a. recognise the integrated Risk Management Framework approved by the Board;

b. adhere to and apply the risk management process in their respective work undertakings;

c. implement the recommendations and directives of their supervisors as far as Risk Management is concerned; and

d. identify and report risk to immediate supervisor and use appropriate documentation procedures to record them.

5.0 RISK MANAGEMENT PROCEDURES

This section describes the procedures to be followed in carrying out risk management activities. It outlines the risk management rules, procedures, methodologies, tools and techniques to be employed in implementing the risk management process.

5.1 The Risk Management Process

The risk management approach shall be in line with the International Standards for Risk Management recommended for use in Tanzanian public sector context as stipulated in ISO 31000:2009. The figure below summarizes the process.

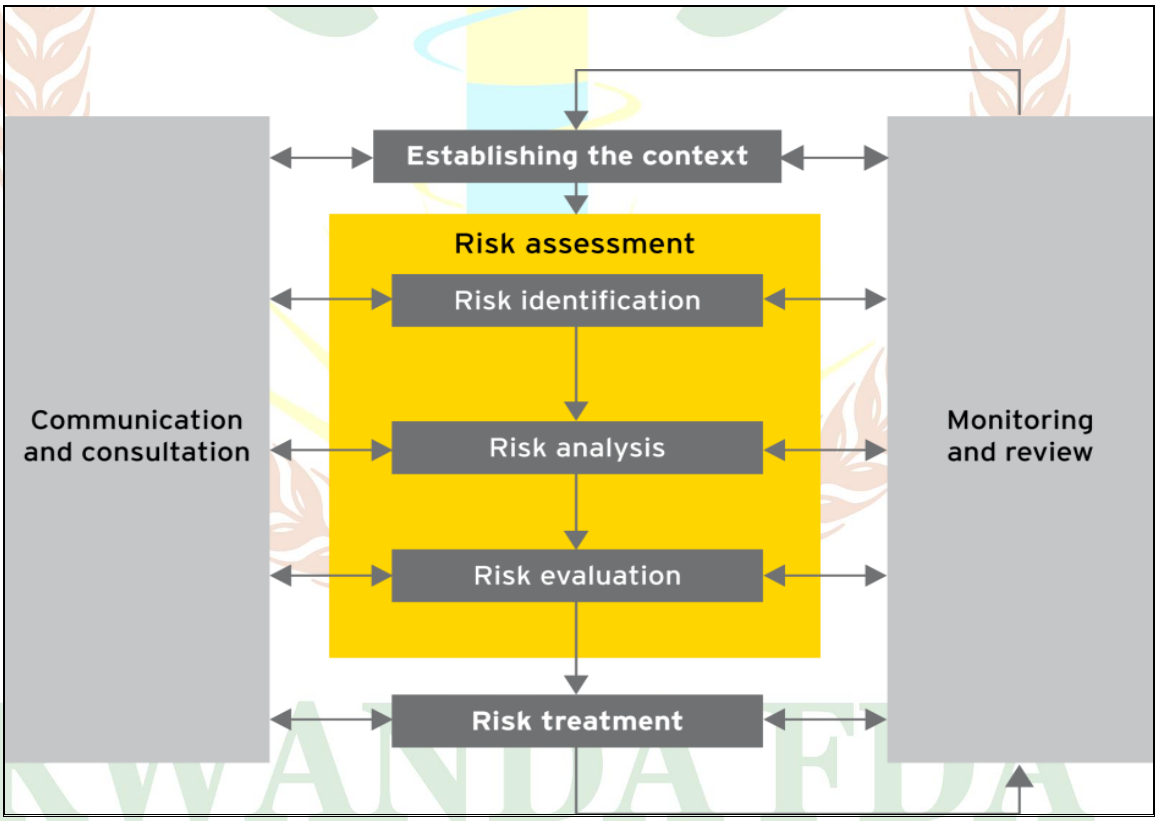

Figure 1: Risk management procedures (Source: ISO 31000:2009)

5.1.1 Establish the Context

The objective of establishing the context is to provide a comprehensive appreciation of all the factors that may have an influence on the ability of Rwanda FDA to achieve its

intended outcomes. The context shall be established by understanding its legal mandate, mission, vision, strategic direction, goals, plans, objectives, activities, programs and its inherent risks. The Rwanda FDA context as elaborated in chapter two of this document shall take into consideration both internal and external factors that may affect its ability to achieve the intended objectives.

5.1.2 Risk identification

This is a process of identifying and documenting a list of risks based on the events and circumstances that might enhance, prevent, degrade or delay the achievement of strategic objectives of the Authority. Rwanda FDA shall follow the following steps in the process:-

a. understand the context – use the key elements defined in establishing the context earlier to understand the nature of the Rwanda FDA's strategic objectives and potential problems;

b. gather data to identify risks against each objective. These will include historical data and discussions with staff with knowledge, skills and experience from the directorates and zone offices;

c. categorize risks according to strategic objectives; and

d. document each risk in a "Risk Identification and Analysis Sheet (QMS/FOM/010) for reference (**Template 1**).

5.1.2.1 Risk identification techniques and tools

The Authority will use any or combination of the following tools and techniques as it sees appropriate:-

a. team-based brainstorming (e.g. Control and Risk Self Assessment-CRSA);

b. checking the lists of registered risks and judgments based on experience and records; and

c. scenario analysis in risk identification process.

5.1.3 Risk analysis

This is a step by step procedure to determine the magnitude of each identified risk. The difference in the magnitude and impact determines the diversity of appropriate actions to counteract the effect of each impact on the achievement of Rwanda FDA objectives. The following steps will be followed during risk analysis:-

a. Identify and evaluate existing controls

This involves identification of controls in place in order to mitigate the risk. Such controls should be effective (designed appropriately for the intended purpose) and operational (control works as effectively as intended).

b. Determine risk likelihood and impact

i. Determination of the level of likelihood and impact of an event should be assessed in view of the effectiveness of the existing strategies and controls;
ii. The most relevant sources of information that the Authority will use during analyzing the consequences and likelihood will include: Past records, practical and relevant experience, relevant published literature and Results of public consultation; and
iii. Where no reliable or relevant past data available, subjective estimates may be made which reflect an individual's or group's degree of belief that a particular event or outcome will occur.

The magnitude of the likelihood and impact will be based on Authority's chosen rating scale of 5-Band rating scale as indicated below in **Table 2**.

Table 2: Risk Ratings in 5-Band Rating Scale

Number	Impact	Likelihood
5	Very High (VH) - Catastrophic	Very High (VH)- Almost certain
4	High (H) - Major	High (H) - Likely
3	Moderate (M) - Moderate	Moderate (M) - Possible
2	Low (L) - Minor	Low (L) - Unlikely
1	Very Low (VL) - Insignificant	Very Low (VL) - Rare

c. Rating the risk likelihood and impact.

The interpretation of rating of the likelihood and impact will be in accordance with the risk classified below in **Table 3 and 4 respectively**.

Table 3: Classification Guidance on Risk Likelihood

Rank	Score	Explanatory Note
Very High *(Almost Certain)*	**5**	• The adverse event will definitely occur, probably multiple times in a year.
High *(Likely)*	**4**	• The adverse event is expected to occur in most circumstances eg from 60% onwards chance of occurring in the next 12 months or 6 out of every 10 years. History of events in the institution or similar organizations.
Medium *(Possible)*	**3**	• The risk event should occur at sometime e.g. between 10%-59% chance of occurring in the next 12 months or between 2- 5 out of every 10 years. i.e. (50/50 chance of occurring within the next year).
Low *(Unlikely)*	**2**	• The risk event may occur only in exceptional circumstances e.g. below 10% chance of occurring in the next 12 months or once in 10 years
Very Low *(Rare)*	**1**	• Highly unlikely to occur in the next 5 years. No history of adverse event in the organization

Table 4: Classification Guidance on Risk Impact

Rank	Score	Explanatory Note
Very High *(Catastrophic)*	**5**	• Non-delivery of services/ impact that would result in failure to achieve three or more of our strategic aims, objectives or key performance targets • Significant financial loss (e.g. budget reduction by 20%) • Death and/or loss of reputation or image that may take more than five (5) years to recover or involves litigation

Rank	Score	Explanatory Note
		• Event that involves significant management time
High *(Major)*	**4**	• Non-delivery of services/ impact that would result in failure to achieve one to two of our strategic aims, objectives or key performance targets • High financial loss (e.g. budget reduction by 10%) • Multiple loss of life and/or loss of reputation or image that may take 2-5 years to recover or involves litigation • Event that involves relatively higher management time
Medium *(Moderate)*	**3**	• Partial delivery of services/ restricted ability to achieve one or more of our strategic aims, objectives or key performance targets • Moderate financial loss (e.g. budget reduction by 5%) • Moderate loss of life and/or loss of reputation or image that may take 1 year to recover
Low *(Minor)*	**2**	• Delivery of services with acceptable levels of problems/ some aspects of one or more of our strategic aims, objectives or key performance targets • Minor financial loss (e.g. budget reduction below 5%) • Event that involves little management time
Very Low *(Insignificant)*	**1**	• No impact • Insignificant financial Loss

Table 5: Plotted Risk Heat Map showing risk profile

Likelihood	**Almost Certain**	5	10	15	20	25
	Likely	4	8	12	16	20
	Moderate	3	6	9	12	15
	Unlikely	2	4	6	9	10
	Rare	1	2	3	4	5
		Low	Minor	Moderate	Major	Catastrophic
Legend:	**Impact**					

Risk Evaluation

This involves comparing the overall risk exposure against risk tolerance (Risk Appetite). Risk evaluation enables the Authority to determine and prioritize risks, which need treatment and shall involve the following steps:-

a. ranking the risks according to an agreed criteria;

b. consideration on how each risk ranks in relation to other risks; and

c. developing priority list of the risks.

The evaluation of risks will be based on risk intensification as indicated in Table 6 below.

Table 6: Risk intensification

Extreme (15-25)	• Very serious. Immediate action required and review actions and controls regularly (Active Management)
High (10-14)	• Serious concern; higher priority. Take immediate action and review at least three times a year
Medium (5-9)	• Develop procedures to manage risk including contingency plans (steady action required). Review actions and controls bi-annually
Low (1-4)	• No major concern (Accept/Tolerate). Current actions and controls are adequate. However, review them annually.

The analyzed risk is compared against the documented and approved tolerable risk criteria. If the protected risk is greater than the tolerable risk level the risk needs additional control measures or improvements in the effectiveness of the existing controls.

The Authority shall establish the decision of whether a risk is acceptable or not acceptable. A risk may be considered acceptable if:-

a. the risk is sufficiently low that treatment is not considered cost effective;

b. treatment is not available, e.g. a project terminated by a change of government; and

c. sufficient opportunity exists that outweighs the perceived level of threat.

Acceptable risks should be monitored and periodically reviewed to ensure they remain acceptable.

5.1.5 Risk Treatment

The objective of this step is to develop cost effective options for mitigating the risks. The Authority shall consider the following risk treatment actions in addressing unacceptable risks:

a. Avoid the risk by choosing a different strategy or terminating the activity that produces the risk;

b. Prevent the risk by implementing or improving the internal control system;

c. Transfer the risk to another party more competent to manage it by contracting out services, establishing strategic partnerships and buying insurance;

d. Accept the risk where cost and strategy considerations rule out alternative strategies; and

e. Exploit the risk factors by implementing strategies to take advantage of the opportunities presented by such risk factors.

In instances where the management of risk is not within the control of the Authority, the response strategies should consider measures such as forward planning.

The Authority shall consider the following factors when executing the risk treatment:

a. The possibility of reducing the likelihood of the risk to occur through detective, preventive maintenance, quality assurance and management, change in business systems and processes; and
b. The possibility of reducing the impact of risk through contingency planning, minimizing exposure to sources of risk or separation/relocation of an activity and resources.

5.1.6 Preparation of Risk Register

The output of risk identification and risk assessment process described above is the duly completed Risk Identification and Analysis Sheet (QMS/FOM/008) and the risk register (QMS/FOM/009) as indicated in **Templates 1 and 2** respectively.

The Authority shall prepare the risk register by recording the results of risk assessment related to the Organisation by taking inputs from the risk identification and analysis sheet (QMS/FOM/008).

5.1.7 Developing and Implementing Risk Treatment Action Plan

The Authority shall prepare and implement risk treatment to minimize or eliminate the potential impact of risks on the achievement of Rwanda FDA's objectives. Each risk owners is required to make decision and implement an appropriate course of action to address a particular risk, which is beyond tolerance level.

Once appropriate actions to address risks have been determined, risk owner shall assign an individual the responsibility of implementing the action and monitoring effectiveness in mitigating the residual risk. However, risk owners shall only delegate responsibility (but not accountability) to their subordinates. The risk treatment action plan as indicated in **Template 3** (QMS/FOM/010) shall be linked with daily implementation of strategies/operational activities to maximize the potential for curbing risks identified.

5.1.8 Risk monitoring and review

Continuous monitoring and review shall be performed on the risk management process. Periodic reviews as well as ad-hoc reviews shall be conducted in order to determine if risks still exist, new risks have arisen or likelihood and impact of the risk have changed and to reassess risk priorities within the internal and external context of the Authority.

Continual monitoring and evaluation and special reviews will consequently enhance the relevance and usefulness of the Rwanda FDA risk framework. In Rwanda FDA the following parties will do monitoring and evaluation:-

a. Risk Management Coordinator; Internally appointed, preferably from Quality Office

b. Department Heads (Risk owners);

c. Internal Audit unit;

d. Quality Management unit; and

e. Planning section (M&E). Currently does not exist within Rwanda FDA

Tools for Risk monitoring and control

The Authority shall use the following tools in monitoring, evaluating and controlling risk and the risk management process:-

a. quarterly implementation reports;

b. risk reassessment report - to identify new risks and to restart the risk management processes for making them managed;

c. risk and quality audits report- to examine and document the effectiveness of risk responses; and

d. meetings to analyze triggering situations.

5.1.9 Risk communication and consultation

The Risk management process calls for continuous communication and consultation with internal and external stakeholders as appropriate at each stage and on the overall process. Communication, consultation and regular feedback must take place during all steps in the risk management process.

5.1.10 Risk management reporting

Risk reporting is of paramount importance within risk management process and need to happen at various intervals during the year. The reporting shall follow the current Rwanda FDA reporting guidelines. Risk management quarterly implementation report shall be reported using the Form No. QMS/FOM/011 as indicated in **Template 4**.

6.0 Revision History

Date of revision	Revision number	Document Number	Author(s)	Summary of Changes	Reasons for revision

ANNEX 1: RWANDA FDA ORGANISATION STRUCTURE

[*to be inserted*]

ANNEX 2: TOOLKIT

Template 1: Format for Risk Identification and Analysis Sheet

[*To be formatted and inserted*] – refer to Electronic Folder of Risk Management Forms

Template 2: Format for Risk Register

[*To be formatted and inserted*] - refer to Electronic Folder of Risk Management Forms

Template 3: Format for Risk Treatment Action Plan

[*To be formatted and inserted*] - refer to Electronic Folder of Risk Management Forms

Template 4: Format for Risk Management Quarterly Implementation Report

[*To be formatted and inserted*] refer to Electronic Folder of Risk Management Forms

REFERENCES

1.International Organization for Standardization (ISO) for implementing Risk Management System (ISO 31000:2009).