Format: QMS/FMT/001 Revision No: 0 Effective Date: 13 Jan 2020	Department/Division	Food and Drugs Inspection and Safety Monitoring Department	
Document Type: **Standard Operating Procedure**		Doc. Number	: DIS/SOP/146
RWANDA FDA Rwanda Food and Drugs Authority	Title: **TRAINING PLAN FOR INSPECTORATE STAFF**	Revision Number Revision Date Effective Date Review Due Date	: 0 : 09 Jul 2021 : 16 Jul 2021 : 16 Jul 2024

	Author	Checked by		Approved by
Title	Drugs Inspections Compliance Analyst	Quality Assurance Analyst	DM/FDIC	HoD/FDISM
Names	Clarisse AYINKAMIYE	Dr. Vedaste HABYALIMANA	Dr. MURINDAHABI M. Marilyn	Alex GISAGARA
Date	16/07/2021	16/07/2021	16/07/2021	16/07/2021
Signature				

1.0 Purpose

This Standard Operating Procedure is to ensure that:

1.1 Instructions for initiating, organizing and deploying training in the Department of Food and Drugs Inspection and Safety Monitoring are provided

1.2 Effective training was performed by identifying both of main objectives and specific objectives of the training

1.3 The training gives positive results through the effective follow-up

1.4 There is and established and defined internal training program to ensure the competency of inspectorate staff. Training and training verification are key factors for successful inspection operations.

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to all trainings organized by the Department of Food and Drugs Inspection and Safety Monitoring.

2.2 Applies to on-the-job training and new-hire training. The training is verified and recorded. The training procedure is applicable to new employees and for the introduction of new procedures and methods.

3.0 Policy

3.1 Law No. 003/2018 of 09/02/2018 establishing Rwanda FDA, determining its mission, organization, and functioning states in:
Article 11" Rwanda FDA operates on the basis of performance contract";

4.0 Definitions and Abbreviations

4.1 **"SOP"** Standard Operating Procedures

4.2 **"Training"** developing in oneself or others, any skills and knowledge that relate to specific useful competencies within the National Regulatory Agency

4.3 "***Pre-test****"* is a test given to training participants before the instruction is presented or received. "

4.4 "**Post-test"** is a test given to training participants after the instruction is presented or completed. Using pre-testing and post-testing can show the percentage of knowledge gained

4.5 **"Competency"** refers to the knowledge, skills, behaviors or attributes required to achieve the desired performance

4.6 "**Responsibility**" indicates the designations or titles of the Rwanda FDA staff or member and briefly describe their specific responsibilities in performing the procedure in a document and in ensuring that the document is implemented and performed correctly and consistently.

5.0 Responsibility

5.1 Head of department is responsible for:

a) Ensuring that all trainings are initiated, organized and deployed with accordance to this SOPs
b) Ensuring the effectiveness of training through well-organized objectives of training.
c) Monitoring and evaluation of the follow-up of the training

5.2 The Division manager is responsible for:

d) Sorting objectives of training
e) Reviewing the concept note of any training provided under his/her portifolio
f) Identification of participants

g) Reviewing invitation letters of the participants in a training

5.3 Specialists and/or Analysts are responsible for:

a) Preparation of the concept note for trainings
b) Preparation of the invitation letters for the participants

6.0 Distribution

6.1 The Head of food and drugs inspection and safety monitoring department
6.2 Division Manager of food and drugs inspection and compliance
6.3 Staffs: Analysts and Specialists

7.0 Safety Preparations

Not applicable to this SOP

8.1 Quality manual

8.0 Procedures

8.1 Preparation of concept note of the training

The Division Managers prepare the concept note of the training providing the general introduction, the Rationale of the training for inspectors, the methodology to be used, the trainers, the budget of the training and the expected results

8.2 Preparation of Invitations addressing to the participants

Division Managers prepare and submit Invitations to the participants within 10 days before the date of the training

8.3 Preparation of training material

8.3.1 Trainers will prepare and submit the training material to the respective Division Manager within 5 days before the date of the training
8.3.2 The Division Manager will verify the content of the training material and submit to the Head of Department for approval

8.4 Training Activities

8.4.1 Each staff must accumulate at least 10 days of continuing education in food and medical products safety every year.

8.4.2 Pre-test to assess the level of knowledge of inspectors have to be done before starting the training

8.4.3 The staff qualifies for 10 days of continuing education by participating in any of the activities that are related specifically to manufactured food/ medical products safety or manufactured food/ medical products inspectional work. Those activities are:

- Annual trainings organized by the Food and Drugs Inspection and Safety Monitoring Department
- Training approved by a qualified field inspection trainer
- Food/pharmaceutical safety related conferences and workshops
- Food/pharmaceutical related training provided by government or non-governmental institutions
- Attendance at national or regional seminars / technical conferences;
- Professional symposiums / college courses;
- Distance learning opportunities

8.4.4 Post-test to assess if the inspectors receive the required knowledge have to be done before closure of training

8.4.5 Documentation must accompany each activity submitted for continuing training credit. Examples of acceptable documentation may include:

- Certificates of completion indicating the course date(s) and number of hours attended or Continuing Education credits granted;
- Transcripts from a college or university;
- A letter from the administrator of the continuing education program attended;
- An agenda and attendance roster.
- Documentation approved by the qualified field inspection trainer.

8.4.6 Areas of training

8.4.6.1 Knowledge and understanding of RWANDA FDA's role, functions, regulations and guidelines.

8.4.6.2 Build capability to conduct investigations that aid convictions & maintain chain of evidence.

8.4.6.3 Technical skills and capacity to ensure that regulated products are of the required quality, safety and efficacy.

8.4.6.4 Skills in investigation and handling of defective products on the market.

8.4.6.5 Detailed understanding on GMP, GDP and GCP of all Products

8.4.6.6 Basic training in Good Manufacturing Practice inspection.

8.4.6.7 Training in supply chain inspection techniques and report writing.

8.4.6.8 Training in risk management with emphasis on risk-based approaches and integrating risk management into the Rwanda FDA regulatory operations.
8.4.6.9 Effective communications skills and Ethics.
8.4.6.10 Food and Pharmaceutical technology
8.4.6.11 Microbiology, process and ventilation engineering, analytical instrumentation, computer systems process validation, the statistical aspects of quality control.
8.4.6.12 Medicine and food products legislations at National and International levels
8.4.6.13 The general principles of Quality Management Systems
8.4.6.14 Training in proper food protection principles, personal hygiene and good sanitary practices
8.4.6.15 Judiciary procedures
8.4.6.16 Public health principles
8.4.6.17 Joint training Inspections

8.5 Monitoring and evaluation of the expected result of the training

8.5.1 There should be indicators showing how results from the training have been put into action on the side of participants
8.5.2 Ensures implementation of training procedure
8.5.3 Identifies training needs resulting from new or revised procedures and processes.
8.5.4 Maintains Staff training records.
8.5.5 Ensures training records are complete.
8.5.6 Ensures proper supervision of trainees until training completed.
8.5.7 Ensures training is conducted and recorded for quality management system policies and procedures.

8.6 The department of food and drugs inspection and safety monitoring specific goals

8.6.1 To ensure that all training is part of an integrated overall Rwanda FDA training program, designed to meet specific needs for competent Staff to do specific jobs and to enhance the opportunities of Staff to have satisfying careers.
8.6.2 To equip Staff with the necessary background knowledge both technical and administrative so that they can perform their jobs competently and with understanding.
8.6.3 To provide a work climate in which Staff are motivated to improve their performance and increase their potential for future responsibility.
8.6.4 To provide a wide variety of opportunities for participation in self-development and management-sponsored activities
8.6.5 To assure that Staff participate on an equitable basis in training programs consistent with their individual needs and capabilities.

8.7 Staff responsibilities

8.7.1 Completes required training within specified timeframe.

8.7.2 Reads and complies with standards, regulations, policies, procedures, and work instructions.

8.7.3 Becomes and stays knowledgeable in procedures and methods performed**.**

8.8 **Training and competency requirements**

8.8.1 Training requirements are outlined and documented on the basis of the position description of duties and responsibilities.

8.8.2 Training and competency is determined by the employee's educational qualifications and experience.

8.8.3 Employees may request training related to their duties.

8.8.4 Training and competency records shall be maintained.

8.8.5 The effectiveness of training is evaluated by but not limited to a Written Evaluation

8.8.6 Effective communications skills and Ethics.

8.8.7 Food and Pharmaceutical technology

8.8.8 Microbiology, process and ventilation engineering, analytical instrumentation, computer systems process validation, the statistical aspects of quality control.

8.8.9 Medicine and food products legislations at National and International levels

8.8.10 The general principles of Quality Management Systems

8.8.11 Judiciary procedures

9 Reference

9.3 Training Needs Assessment and Development Plan – 2019

9.4 Draft of procedures of qualification of inspector

10 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16 Jul 2021	0	Rwanda FDA Staff	First Issue

End of Document