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RWANDA FDA Rwanda Food and Drugs Authority	Title: **STANDARD OPERATING PROCEDURES (SOPs) FOR TRAINING INSPECTORATE STAFF.**	Revision Number	:0
		Revision Date:	:15 May 2021
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STANDARD OPERATING PROCEDURES (SOPs) FOR TRAINING INSPECTORATE STAFF

	Author	Checked by			Authorized by	
Title				Quality Management Systems	Director General	Page 1 of 5
Signature & Date						

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance	
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1.0 Purpose

1.1 This standard operating procedures(SOPs)provide instructions for initiating and organizing training in the Food and Drugs Inspection and Safety Monitoring Department.

1.2 Ensure that the training is conducted in consideration of the identified training needs of the Inspectors.

1.3 Ensure that the training gives positive results through the effective follow-up

2.0 Scope

2.1 This Standard Operating Procedure applies to all trainings organized for Inspectors in the Food and Drugs Inspection and Safety Monitoring Department.

4.0 Responsibility

4.1 Head of Food and Drugs Inspection & Safety Monitoring Department is responsible for ensuring that all trainings are initiated and organized in accordance with these procedures.

4.2 The Division managers, are responsible for the organization and coordination of the training.

4.3 Quality assurance analyst ensures the use of update version of the SOP, recalls obsolete documents and keeps document master list.

4.4 Inspectors participate in the organized training

5.0 Distribution

5.1 The Head of Food and Drugs Inspection and Safety Monitoring Department

5.2 Division Managers of Food and Drugs Inspection and Safety Monitoring Department

5.3 Quality assurance analyst

5.4 Inspectors

6.0 PROCEDURES

6.1 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

6.2 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

6.3 Preparation of training material

6.3.1 Trainers will prepare and submit the training material to the respective Division Manager within 5 days before the date of the training

6.3.2 The Division Manager will verify the content of the training material and submit to the Head of Department for approval

6.4 Training Activities

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

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

6.4.3 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

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

6.4.5 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.

6.5 Areas of training

6.5.1 Knowledge and understanding of RWANDA FDA's role, functions, regulations and guidelines.
6.5.2 Build capability to conduct investigations that aid convictions & maintain chain of evidence.
6.5.3 Technical skills and capacity to ensure that regulated products are of the required quality, safety and efficacy.
6.5.4 Skills in investigation and handling of defective products on the market.
6.5.5 Detailed understanding on GMP, GDP and GCP of all Products
6.5.6 Basic training in Good Manufacturing Practice inspection.
6.5.7 Training in supply chain inspection techniques and report writing.
6.5.8 Training in risk management with emphasis on risk-based approaches and integrating risk management into the Rwanda FDA regulatory operations.
6.5.9 Effective communications skills and Ethics.
6.5.10 Food and Pharmaceutical technology
6.5.11 Microbiology, process and ventilation engineering, analytical instrumentation, computer systems process validation, the statistical aspects of quality control.
6.5.12 Medicine and food products legislations at National and International levels
6.5.13 The general principles of Quality Management Systems
6.5.14 Training in proper food protection principles, personal hygiene and good sanitary practices
6.5.15 Judiciary procedures
6.5.16 Public health principles
6.5.17 Joint training Inspections
6.5.18 Basics of HACCP

18. Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
/ /	0	GMP and GLP Inspector	First issue

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