Format: QMS/FMT/001 Revision N°: 0 Effective Date: 22 Jan 2019	Department	Food and Drugs		
Document Type: Standard Operating Procedure			Doc. Number	: QMS/SOP/068
	Title:		Revision Number	: 0
	PROCEDURE	FOR	Revision Date	: 15 May 2021
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RWANDA FDA Rwanda Food and Drugs Authority			Review Due Date	: 21May 2023

# 1.0 Purpose

To plan for the risk assesment based inspection of products regulated by Rwanda FDA

### 2.0 Scope

This procedure applies to all regulated products by Rwanda FDA

# 3.0 Responsibility

Division Manager of Food and drugs Inspection and compliance division

## 4.0 Accountability

Head of food and drugs inspection and safety monitoring department

#### 5.0 Distribution

- 5.1 Head food and drugs inspection and safety monitoring department
- 5.2 Division Manager of Food and drugs Inspection and compliance division
- 5.3 Quality Assurance Analyst
- 5.4 Inspectors: Analysts and Specialists

# 6.0 Procedure

# 6 Procedure for planning an inspection using risk assessment principles

6.1 Division Manager of Food and Drugs Inspection and compliance shall appoint the team and designate the team leader with the adequate competency as per the inspection to be undertaken The appointed team under the coordination of the Team Leader shall examine the product safety/quality risks factors from production environment, processes, products composition and the history of products to compliance with existing quality and safety management.

	Author	Auth	Approved by		
Title	Director food and drugs Inspection	QM Specialist	Division manager food and drugs inspection and safety monitoring	Head food and drugs inspection and safety monitoring department	Director General
Signature & Date					

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- 6.2 The appointed team shall select method of inspection and prioritise establishments to inspect as the results of the analysis of the risks factors of product safety/ quality.
- 6.3 The appointed team shall submit the risk categories of establishments depending on their products and prioritization of establishments for inspection to the division Manager of Food and drugs Inspection and compliance for review.
- 6.4 The reviewed risk assessment based inspection plan shall be submitted to The Head food and drugs inspection and safety monitoring department for approval.
- 6.5 After the approval of the plan, the inspectorate shall officially inform the manufacturer on the proposed date(s) of the inspection
- **6.6** The inspection plan shall be implemented as scheduled

#### 7.0 Records

- 8.1 All used forms, various meeting minutes, records of methodology used for the risk categorization of establishments, proof for periodic review of the inspection plan shall be maintained in appropriate files.
- 7.2 Records shall be kept for a period of five years and thereafter disposed by using appropriate means.

## **8.0 Document Revision History**

Date of	Revision	Document Number	Author(s)	Summary of	Reasons f	or
revision	number	$RM/\Delta$		Changes	revision	
				NA	New	
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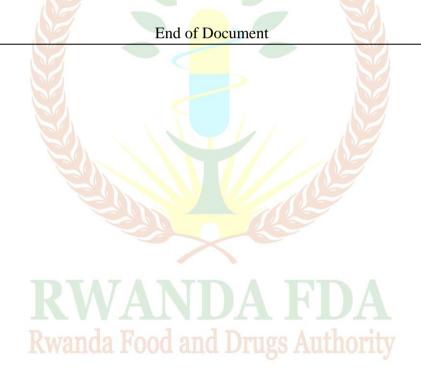
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Signature					
& Date					

Food and Drugs Format: QMS/FMT/001 Department Revision N°: 0 Effective Date: 22 Jan 2019 Document Type: Standard Operating Procedure Doc. Number : QMS/SOP/068 Revision Number: 0 Title: **Revision Date** : 15 May 2021 PROCEDURE FOR : 21 May 20201 Effective Date **INSPECTION PLANS** USING QRM PRINCIPLES

Review Due Date: 21May 2023

			Checked by		
Title	Senior Licensing Officers, Drug and Food	Head, Drug Inspectorate Services	Head, Drug Assessment & Registration	Head, Quality Management	Executive Secretary /Registrar
	Inspectorate				
Signature & Date					

RWANDA FDA Rwanda Food and Drugs Authority



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Signature					
& Date					