RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department
Document Type: **Standard Operating Procedure**		Doc. Number : DIS/SOP/….
RWANDA FDA Rwanda Food and Drugs Authority	Title: **Rwanda FDA internal Data Collection Procedure**	Revision Number : Revision Date: : Effective Date : Review Due Date :

1.0 Purpose

The document is designed to serve as; source of getting information, a reference and guide for effective internal data collection at Rwanda FDA.

The main objective of this document is:

- Establish and maintain official data collection procedure.
- To provide detailed instructions to be followed while collecting internal data.
- To enhance the effective production of monthly operational status of the Authority.
- To conduct the analysis on institutional performance
- Provide a single reference source for department-wide data collection, procedures, and focal person.

2.0 Scope

This Standard Operating Procedure: Shall apply to all internal data collection to be conducted to Rwanda FDA based on regulated products and services offered by the Authority.

3.0 Definitions and Abbreviations

3.1 Definitions

Abstract: a detailed summary of the study. It should include a broad overview of the research, research question, the significance of the study, methodology of the research and findings

Background: a brief outline of the most important studies that have been conducted so far presented in a chronological order which are in line with your research/study.

Conclusion: The part that describes the findings and recommendation.

Methodology: technique used to identify, select, process, and analyse information about a topic. This section of study allows the reader to critically evaluate a study's overall validity and reliability.

Quantitative research: a study that involves collecting and analysing numerical data

Qualitative research: collecting and analysing non-numerical data to understand concepts, opinions, or experiences.

Data: Set of information

Data Set: a collection of relational data records for computer processing.

Data collection: Gathering information for generalised analysis and description.
Statistical analysis: a scientific process of collecting and analysing data to identify patterns and trends or behaviour.
Descriptive statistics: regards summarizing and organizing characteristics of a data set
Inferential statistics: making predictions or generalizations based on your data. Testing the hypothesis or use sample data to estimate the population parameter.
Result: findings from the analysis based upon the information gathered
Survey Questioning: Ask questions of a group of people in-person, over-the-phone or online.
Systematic/Observation Data: way of collecting data by observing/contacting people on desk review.
Secondary research method: Collecting data that has been gathered for other purposes (historical records) or the use of existing data to further knowledge about regulated products and service offered.

7.0 .0 Abbreviations and Acronyms

DG: Director General
DM: Division Manager
HoD: Head of Department
RWANDA FDA: Rwanda Food and Drugs Authority
SOP: Standard Operating Procedure

5.0 Responsibility

The Rwanda FDA Director General/CBM is responsible to oversee the implementation of this SoP.
Heads of all departments, Division Managers are accountable for the implantation of this SOP by nominating the focal personal who will be providing the data to Rwanda FDA Research and Statistics office.
Planning, Monitoring & evaluation and Research Unit is responsible to:

- Recommend and facilitate any ongoing internal data collection
- Ensure that all procedures including data confidentiality, validity are conducted in accordance to this SOP Implementation of this SOP through monitoring all data collection activities within this SOP.
- Developing all internal data collection tools that may facilitate data collection procedure.

- Developing format for data recording and Dataset reflecting the all Rwanda FDA needs and target.
- Informing all Rwanda FDA staffs about the ongoing internal data collection
- Maintaining statistical record generated from all data collected.
- Ensuring confidentiality

6.0 Distribution

4.1 Director General
4.2 Deputy Director General
4.3 Heads of Departments
4.4 Chief of Finance Office
4.5 Division Managers
4.6 Planning Unit

7.0 Reference

- Rwanda FDA Strategic Plan
- Law Establishing Rwanda FDA (http://www.rwandafda.gov.rw/web/fileadmin/law_rwanda_fda.pdf)

8.0 Safety Precautions

The data gathered should be kept under confidentiality
It is forbidden to use the institutional data for personal interest without Rwanda FDA approval.
The data collected are in accordance with Rwanda FDA mandate supersede

10.0 PROCEDURES

10.1. Operational Data collection and submission procedure

Activity	Focal Person	Timeline/ Period	To be submitted to	Supervision

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Data for Import /Export licensing	HoD For FDISM	5th of the following month	Research & Statistics office	Planning Directorate
Data for inspected premises (Pharm)	HoD For FDISM	5th of the following month	Research & Statistics office	Planning Directorate
Data for inspected premises (Food)	HoD For FDISM	5th of the following month	Research & Statistics office	Planning Directorate
Data for licensed premises (Pharm)	HoD of FDISM	5th of the following month	Research & Statistics office	Planning Directorate
Data for licensed premises (Food)		5th of the following month	Research & Statistics office	Planning Directorate
Data for Products Registration (Pharm)	HoDof FDAR	5th of the following month	Research & Statistics office	Planning Directorate
Data for Products Registration (Food)	HoD od FDAR	5th of the following month	Research & Statistics office	Planning Directorate
Data for recalled	HoD of FDISM	5th of the following month	Research & Statistics office	Planning Directorate

products (Food & Pharm)				
Data for ADR report	HoD of FDISM	5th of the following month	Research & Statistics office	Planning Directorate
Data for circular released	HoD of FDISM	5th of the following month	Research & Statistics office	Planning Directorate
Financial data	DF	First week of the month	Research & Statistics office	Planning Directorate
HR Data	HR Office	First week of the month	HR Office, Research & statistics Office	Planning Directorate & HR Directorate
Food and Pharmaceutical products testing	DM QCL	First week of the month	HR Office, Research & statistics Office	Planning Directorate & HR Directorate
QMS Data	QAA	First week of the month	HR Office, Research & statistics Office	Planning Directorate & HR Directorate
Pricing and Industrial Data	Pricing and Market Analyst	First week of the month	HR Office, Research & statistics Office	Planning Directorate & HR Directorate

10.2. Rwanda FDA Desk Review Data collection

1. Rwanda FDA Planning Unit discuss with different departments the idea and reason of the ongoing data collection.
2. Rwanda FDA Planning Unit develop questionnaire (2 WEEKS)

3. Rwanda FDA Planning Unit present the developed questionnaire to the Rwanda FDA Management for validation and testing. (5 working days)
4. Rwanda FDA Planning Directorate create awareness for the ongoing date collection activity if involves all staff data collection. (5Working days before piloting)
5. Rwanda FDA HoDs, Division Managers, Directors Nominate staff to support in data collection. (4 working days before piloting)
6. Rwanda FDA Planning Unit call for coordination meeting to train the nominated staff about how data are going to be collected and discuss questionnaires. (3 working days before piloting)
7. Desk review and data collection (2 weeks)
8. Compiling collected data (3 working days)
9. Data cleaning and analysis (10 working days)
10. Developing Report (5 working days)
11. Rwanda FDA Planning Unit present finding and recommendation to Rwanda FDA Management and/or stakeholders (1 working day)