EVENT: PROGRAM OF RWANDA FDA NEW STAFF MEMBER ORIENTATION
(One-day Induction training)

1. Introduction

This program is designed for newly recruited employees to facilitate their integration into Rwanda FDA and allow them to quickly familiarize with the organization's operations.

2. Induction schedule

Date	Time	Activities	Responsible
07/06/2021	09h00 - 09h30	Arrival and self-introduction	MC - Planning
	09h30 - 09h40	Welcome remarks	Director General
	09h40-10h00	Rwanda FDA overview	Director of Planning
	10h00 - 10h20	Presentation from DG's Office	Regulatory Affairs
	10h20 - 10h40	Overview of Rwanda FDA quality management system	QMS Specialist
	10h40 - 11h00	Progress on attaining ML3, AMA and Other Ongoing Initiatives	HoD- Drug & Food Assessment and Registration
	11h00 - 11h30	Presentation by Department of Drug & Food Assessment and Registration	Head of Department of Drug & Food Assessment and Registration
	11h30 -12h00	Presentation by Food and Drugs Inspection and Safety Monitoring Department	Head of Department of Food and Drugs Inspection and Safety Monitoring
	12h00 -12h30	Questions	All
	12h30- 14h00	Lunch	
	14h00-14h30	Presentation for Quality Control Division	Division Manager Quality Control
	15h00-15h40	Presentation on HR management and staff benefits	Director of HR and administration
	15h40 -16h30	Questions& Answers	All
	16h30-16h40	Closing remarks and way forward	Director General

3. List of the staff who were oriented:

The list of staff members that were inducted is attached to this report

4. Induction program proceedings

The induction program started at 9:30 am, all Rwanda FDA newly appointed staff were invited to attend this induction. All participants introduced themselves for easer communication and knowing each other.
Thereafter, the Director General of the Rwanda FDA started with opening remarks where he congratulates the Rwanda FDA new staff member on their newly appointment and informed them that with their high and rare skills, the institution and the Country in general has high expectations from them.
After the opening remarks from Director General, the flow was given to support services and technical departments to give a general overview of the institutions', mandate, vision and mission. The presentations were presented as follows:

4.1. Rwanda FDA overview

Rwanda FDA overview presentation was delivered by Mr Gervais BAZIGA, the Director of planning and M&E, the aim of this presentation was to give a clear picture of Rwanda FDA
-*Organization structure* of 194 staff categorized in seven levels: Director General, Deputy Director General, CFO and HoDs; Division managers &Analysts, Directors & Specialists, Officers and support staff dispatched in Director General and CFO offices, core departments and Quality control lab.

-Rwanda FDA mandate, vision, mission, and core value: Rwanda FDA mandate is to protect public health by regulating Food and Drugs with a vision of becoming a world class regulatory Authority. Participants were informed of the five Rwanda FDA core values namely; professionalism, integrity, accountability, team work and innovation.

-Rwanda FDA key functions are dispatched in 2 core departments (food and drugs Inspection and safety monitoring and food and drugs assessment and registrations) and Quality control laboratory division, Additional to that, there are DG and DDG offices for coordination and CFO offices for support services

4.2.Presentation by Department of Drug & Food Assessment and Registration (DFAR)

Drug and Food Assessment and Registration is one of the core department in Rwanda FDA as it plays a big role. The department deals with assessment of product application.

HoD Mr. Joseph KABATENDE made a presentation outlining the core business of this department, its achievements, challenges and Innovative initiatives. DFAR department is one of the technical Departments of Rwanda FDA with a main function of assessing application dossiers (food, drugs, Medical devices, cosmetics, chemicals and other public health related products) and recommends for the issuance of market authorizations/ product registration. Dossier assessment is a deep and scientific exercise that needs expertise, time and concentration and registered products are published on a register which is updated when any products are recommended of market authorization. Participants were informed that, DFAR department has 46 staff which have multidisciplinary expertise and dispatched in four (4) divisions.

4.3.Progress on attaining ML3, AMA and Other Ongoing Initiatives

Mr Joseph KABATENDE continued in explaining key ongoing initiatives where Rwanda FDA is playing a role and among them:

- **WHO Maturity Level 3 certification**: He informed the new staff that Rwanda FDA is working towards achieving maturity level three (ML3). This is a very important undertaking for the Authority to be able oversee vaccine manufacturing and attract investment in Health sector. The assessment will be conducted on key regulatory functions area.
- He also introduced to the participants the African Medicine Agency (AMA): A specialized continental agency and Rwanda intends to bid for the hosting of the au specialized organ. The Agency is established
    - To improve their capacities to regulate medical products;
    - To ensure the coordination and strengthening of continental initiatives to harmonize medical products regulation, provide guidance, and improving access of medical products on the continent.

4.4.Presentation by Food and Drugs Inspection and Safety Monitoring Department (FDISM)

Mr Alex GISAGARA, HoD, introduced FDISM as a department with 74 staff dispatched in three (3) Divisions .This department is in charge of inspection and compliance; Import & Export control, Pharmacovigilance & Food Safety Monitoring. In FDISM there is an ongoing initiative, The Pharmaceutical Inspection Co-operation Scheme (PICS), with aims of harmonizing inspection procedures worldwide by developing common standards in the field of Good Manufacturing Practices by providing training opportunities to inspectors and also facilitating co-operation and networking between competent authorities, regional and international organizations, thus increasing mutual confidence.

4.5.Presentation for Quality Control Laboratory Division

DM Mr Antoine explained that Quality Control Laboratory Division has a mandate of analyzing different categories food and food products, medicines, medical devices and Public health products, samples are submitted from pre market, post shipment and Post Market Surveillance. Test results generated are important in ensuring that products comply with the set standards and enables the Authority to make evidence-based regulatory decisions.
Additional to that he explained how a well-functioning QC lab must have a quality management system, quality manual and quality policy detailed in SoPs on testing processes for accurate test results in compliance with international standards.

4.6.Overview of Rwanda FDA quality management system (QMS)

This presentation was led by Mr. Ndayambaje Theogene and he explained in deep why regulatory body need QMS.
Quality Management System is a formalized system that documents processes, procedures, and responsibilities for achieving quality policy and objectives. It helps to coordinate and direct an institutions' activities to meet customer and regulatory and requirements and improve its effectiveness and efficiency on a continual basis.
"Quality is not accidental but the result of systematic commitment" he quoted.
The QMS of Rwanda FDA is based on ISO 9001:2051 an approach that encourages analysis of customer requirements, define the processes that contribute to the achievement of a product which is acceptable to the customer, and keep those processes controlled(Refer: *Rwanda FDA Quality Manual) with the following key elements:*

- **Document Control**: Ensure that only current, numbered, documents are used.
- **Quality Audits**
- **Corrective and Preventive Action (CAPA) Management:** Actions to identify, resolve and prevent product defect and compliance issues.

He concluded saying that a good QMS must be:

- *Conformance to specification* (meeting standards)
- *Fitness for purpose* (meeting people's needs)

4.7.Presentation from DG's Office

The presentation of DG's office was done by Mme AKEZA Sandra, Advisor to Director General; she outlined the functions of Director General's office as an overseer office of Rwanda FDA:

- in charge of regular monitoring and coordination of Rwanda FDA Activities
- in charge of coordination and final decision making within Rwanda FDA
- ensures the implementation and monitoring of the strategic plan and annual plans
- in charge of promoting and protecting partnerships and memberships

4.8.Presentation on HR management and staff benefits

Lastly, Mme Adrienne ITEGERE, Director of Human Resources and Administration informed the Rwanda FDA new staff members on their roles and responsibilities within Rwanda FDA, their allowances and benefits as public servants and other key information needed by a new staff to be familiar within the Institution.

5. Conclusion

The Rwanda FDA new staff members were very interested by the presentations and were keen to know and be familiar with Rwanda FDA processes and procedures. They asked many questions to presenters and the discussion was interesting and fruitful. It was agreed that the induction program will continue at departmental level. The one-day induction program was ended at 6:30PM and concluded by closing remarks of Mme BERWA Francoise, Chief Finance Officer, on behalf of DG. She reiterated the welcoming message and promised any support needed by new Rwanda FDA staff member while performing their daily duties and emphasized on the country high expectations on them.

6. Appendix

All presentations and attendance list

Prepared by:

ITEGERE Adrienne
Director of Administration and HR

Approved by:

Dr. Charles KARANGWA
Ag. Director General

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Rwanda FDA Attendance List

Activity Title: Induction day Program **Venue:** Nyamata La Palisse **Date :** 07/06/2021

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	2.	Sandra Akeza Haile-Brugger	Advisor to DG	Rwanda FDA	0784839232	sakeza@rwandafda.gov.rw	Haile
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	10	Dr. BAHIZI Marcel	R.x.A. Market x Pricing Analyst	"	0788851263	bahimarcel@yahoo.fr	[illegible]

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4 14	Richard HABIMANA	Vaccines & Biosimilar Registration analyst	Rwanda FDA	0782551370	hrichard86@yahoo	
5 15	Rosine Manishimwe	DM - Veterinary medecine Devices	Rwanda FDA	0787303119	rosinem3@yahoo.fr	
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29	Dr. ALPHONSE NDAYAMBAJE	~~ndayambaje.alphan@gmail.com~~ Clinical Trial Analyst	FDA	0784345542	ndayambaje.alphan@gmail.com	[signature]

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