Format: QMS/FMT/001 Revision No: 0 Effective Date: 24 Aug	**Division**	**Quality Control Laboratory**
RWANDA FDA Rwanda Food and Drugs Authority	**Title: Quality Control Laboratory Safety Measures**	Document Number : QCL/SOP/016 Revision Number : 0 Revision Date : 14 August 2020 Effective Date : 24August 2020 Review Due Date : 24August 2022

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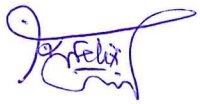
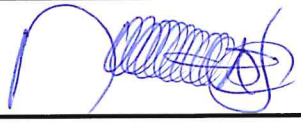
SIGNATURE			
DATE	24 August 2020	24/08/2020	24/08/2020

INSTRUCTIONS

1. Controlled issues of this SOP may **not** be copied
2. **All** amendments are written on the page provided
3. **Only** authorized, numbered, stamped copies of this SOP as described in the document control section above, are used
4. This SOP shall **not** be used outside the Rwanda FDA Quality Control Laboratory without the authority of the authorizing personnel.

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2. Purpose

This Standard Operating Procedure describes the procedure for maintaining safety in the laboratory.

3. Scope

This Standard Operating Procedure:

1.1 Applies to safety measures to be implemented and observed by all Rwanda FDA Quality Control Laboratories.

4. Policy

3.1 The Law N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning states in:
Article 8 (3) … *"establish the quality assurance and quality control...through designated quality control laboratories"*

3.2 ISO 9001:2015 Clause 7.5.3.1 states that "*Documented information required by the quality management system and by this International Standard shall be controlled*".

3.3 WHO Good Practices for Pharmaceutical Quality Control laboratories WHO Technical Report Series No. 957, 2010, Annex 1; sections 21 *"General and specific safety instructions made available to each staff member"*.

5. Definitions and Abbreviations

NA

6. Responsibility

6.1.The Quality Control Laboratory Division Manager is responsible for ensuring adherence to the safety policy and the contents of this SOP

6.2.Laboratory Officers and Analysts are responsible for following this procedure

7. Distribution

7.1.Division Manager, Quality Control Laboratory Division

7.2.A QMS shared folder on Rwanda FDA head office server on the following link: (\\rwandafdaserver\qms\sopxxxx)

7.3. Hard copies to staff that have no access to the Rwanda FDA server.

8. Safety Precautions

All precautions described in clauses 9.1, 9.2, 9.3, 9.1 and 9.5 shall be followed.

9. Procedure

9.1 General Health and Safety

Management shall put in place a Health and Safety Committee that shall

9.1.1 Work with management to formulate and implement appropriate safety policies and practices.
9.1.2 Monitor the procurement and use of hazardous chemicals and disposal of laboratory waste.
9.1.3 Have a working knowledge regarding regulated substances and laboratory chemical hygiene.
9.1.4 Train every new employee the first day of commencing work. In depth training shall be conducted in the relevant unit/division.
9.1.5 Improve the safety program and update the safety plan when necessary.
9.1.6 Review the safety plan at least annually.
9.1.7 Monitor laboratory activities to determine that proper job safety guidelines are used and those employees know and follow the chemical hygiene rules.
9.1.8 Determine the necessary protective equipment and clothing for specific laboratory tasks and ensure that this equipment/clothing is available and in good condition.
9.1.9 Conduct formal and informal inspections for chemical hygiene and housekeeping of the laboratory, associated facilities, and any emergency equipment.
9.1.10 Provide appropriate health and safety training for laboratory personnel or ensure that personnel receive training
9.1.11 Determine that facilities are adequate for chemicals and equipment used
9.1.12 Ensure that they have knowledge of the current legal requirements concerning regulated substances and chemical hygiene.

9.2 Personal Laboratory Safety

9.2.1 Eating, drinking, smoking in the laboratory is strictly prohibited.
9.2.2 Always use safety goggles for eye protection while handling corrosive and highly toxic materials.
9.2.3 Wear protective laboratory coats for all operations in the laboratory, and especially when handling corrosive, toxic or flammable materials.
9.2.4 Wear gloves when handling corrosive, and highly toxic materials
9.2.5 Know where safety equipment such as the eye wash stations, fire extinguishers are located and how to use them. Eye wash facilities should be within easy access.
9.2.6 Do not carry corrosive materials by the mouth of the bottle

9.2.7 Never pipette corrosive liquids by mouth. Use a pipetting bulb or other mechanical pipetting devices.
9.2.8 Do not attempt to identify chemicals by smell or taste. Never sniff reagents, especially corrosive ones.
9.2.9 Know how to clean up spillages of the chemicals you use in an appropriate and safe manner
9.2.10 Wash your hands after handling chemicals and before leaving the laboratory
9.2.11 Always wear protective shoes. Bare legs are not acceptable when handling, hot, cold, toxic or corrosive chemicals.
9.2.12 Keep appropriate safety equipment readily available and properly maintained to prevent or respond to such laboratory emergencies as personal contamination, fires, spills or splashes.
9.2.12 Always observe and obey the "two persons" rule. A second person should be aware that you are working in the laboratory.

9.3 Checklist for preliminary hazard analysis

9.3.1 Always check the safety precautions for the material you are using to understand the specific hazards involved.
9.3.2 Review the characteristics of all reagents, reactants in terms of flammability, toxicity and reactivity hazards. Where information is not available, treat the materials as hazardous.
9.3.3 Be aware of the type of hazard, (inhalation, ingestion, eye, skin contact) and what protective measures are required.
9.3.4 What is the recommended first aid in case of accidental exposure?
9.3.5 Can waste be safely handled and arrangements for disposal completed?

9.4 Safety Controls

9.4.1 Engineering controls are usually the best choice for regulating hazardous materials. Therefore, use wherever applicable:
9.4.1.1 fume hoods
9.4.1.4 local exhaust hoods

9.5 Chemical storage

9.5.1 Chemical storage should be under the supervision of a qualified person; store rooms must have adequate security

9.6 Conduct an annual inventory

9.6.1 To remove surplus hazardous chemicals
9.6.2 To remove chemicals that will not or have not been used in the past 1-3years
9.6.3 To correct incompatible storage
9.6.4 To identify which chemicals are present
9.6.5 To conduct a regular clean-up of containers and shelving

9.7 General rules

9.7.1 Shelving should be accessible with chemicals at eye level or lower; no high shelf storage.
9.7.2 Avoid floor chemical storage
9.7.3 Do not overcrowd shelves
9.7.4 Chain compressed gas cylinders
9.7.5 Keep solvent containers closed. Ensure chemical containers are intact. Ensure container lids are intact and closed. Regularly vent materials capable of building up pressure
9.7.6 For emergencies, have fire extinguishers of the approved type positioned near an escape route, control spillages and clean up any spillages.

9.8 Label properly

9.8.1 Label contents clearly
9.8.2 Labels must be intact and legible.
9.8.3 Do not overwrite labels.

9.9 Refrigerator storage

9.9.1 In the event that chemicals need to be stored in a refrigerator, follow the following rules:
9.9.1.1 The materials must be securely packaged, tightly sealed and properly labeled
9.9.1.2 Ensure that materials, especially those that are highly reactive or corrosive, are inspected and regularly and that lids are intact.

10. Appendices

Appendix A: Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
24 August 2020	0	Felix TUYISHIM	First issue

11. Reference

11.1 Rwanda FDA Quality Control Laboratory Policy Manual;

11.2 WHO Website (Information and the full text of the relevant WHO documents on Good Laboratory Practices can be found in the website) http://www.who.int/