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RWANDA FDA Rwanda Food and Drugs Authority **Title: Purchase and receipt of consignments of materials**	Revision Number : 0 Revision Date : 14 August 2020 Effective Date : 24 August 2020 Review Due Date : 24 August 2022

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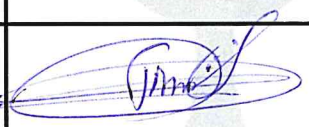
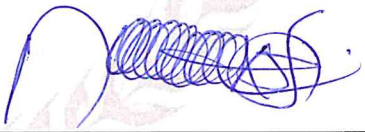
SIGNATURE			
DATE	24 August 2020	24/08/2020	24/08/2020

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 SOP as described in the Procedure of Purchase and receipt of consignment of materials, are used
4. This SOP shall **not** be used outside the Rwanda FDA Quality Control Laboratory without the authority of the authorizing personnel.

1. Contents

2.0 Purpose

This Standard Operating Procedure:

2.1 Outlines the procedure for the procurement and receipt of materials and reagents by Rwanda FDA Quality Control Laboratories.

2.2 Ensures the quality of the materials and reagents procured and that they are sourced from approved vendors.

3.0 Scope

This Standard Operating Procedure:

3.1 Applies to all materials and reagents that affect the quality of activities performed at Rwanda FDA Quality Control Laboratory Division.

4.0 Policy

4.1 ISO 17026:2017 Clause 6.6.3 states that "The laboratory shall communicate its requirements to external providers for: the products and services to be provided; the acceptance criteria; competence, including any required qualification of personnel; and activities that the laboratory, or its customer, intends to perform at the external provider's."

4.2 WHO Good Practices for Pharmaceutical Quality Control laboratories WHO Technical Report Series No. 957, 2010, Annex 1; section 10.2 "reagents should be purchased from reputable, approved suppliers"

5.0 Definitions and abbreviations

"Contract"

Agreed terms between the vendor and the Authority transmitted by any means

"Vendor"

An entity from which the Division procures materials and reagents that could affect laboratory activities

6.0 Responsibility

6.1 The Quality Control Laboratory Division Manager is responsible for:

a) Reviewing and approving purchase requests
b) Ensuring that criteria for evaluation of procured materials and reagents are clearly defined
c) Ensuring the performance of vendors is evaluated and monitored

6.2 The Designated Quality Management Systems officer is responsible for:

a) Ensuring the laboratory's approved vendor list is maintained
b) Ensuring records of evaluation and monitoring activities of vendors are maintained

6.3 Laboratory Officers and Analysts are responsible for:

a) initiating requests.
b) Ensuring specifications and requirements are provided.
c) Receipt of materials and reagents and verifying the vendors are on the approved vendor list.

7.0 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.

7.4 Electronic documents are accessed on the testing server by all QCL staff.

8.0 Safety Precautions

Not applicable to this SOP

9.0 Procedure

a. Vendor selection

i. Vendors are evaluated and selected based on the ability to meet contract conditions and quality system criteria. Approved vendor details shall be captured on the approved vendor list.

ii. Vendor approval shall be reviewed and updated periodically according to a schedule and responsibility determined by the laboratory in accordance with the global vendor qualification procedure.

iii. Materials and reagents shall be purchased from approved vendors with an acceptable rating.

iv. The performance level of routinely used vendors shall be monitored over time to ensure an acceptable level of quality is maintained. Evaluation and monitoring criteria can include but not be limited to, accuracy of orders received, product quality issues, recalls and other unsatisfactory events. Minimum evaluation criteria include, but is not limited to:

Does continued procurement from vendor meet the Authority's requirements?

1. Does the vendor meet product specification and delivery schedule?
2. Does vendor have consistently good service and product performance?
3. How is vendor's customer service and response to addressing problems?
4. If vendor accredited? (where applicable)

v. Documentation of this evaluation shall be maintained by the Division.

b. Receipt and inspection of materials and reagents

i. The Division shall ensure that purchased materials and reagents that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the test and/or calibrations concerned.

ii. When materials and reagents are delivered and received, they shall be signed for by the designated individual with date of receipt and initials annotated on the receiving records and container.

iii. Materials and reagents received are inventoried and verified against the original purchase order for accuracy and completeness.

iv. If a discrepancy is found that could affect the quality and integrity of test results, the material or reagent is either discarded or returned to the vendor

v. Records of unsatisfactory materials and reagents and their disposition shall be maintained by the Division. These records shall establish trends in vendor performance and ensure that the supply of good quality material and reagents continues.

vi. Materials and reagents shall be allocated/distributed for use.

c. Purchasing and receipt records

i. The Division shall retain records for the following:

1. Purchasing records
2. Vendor evaluation, selection, monitoring, re-evaluation;
3. Verification that received materials and reagents meet the Division's requirements; and
4. Actions taken as a result of vendor evaluation, monitoring or re-evaluation
5. Consumption records.

10.0 Appendices

10.1 Appendix A: Document revision history

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
24 Aug 2020	0	TUYISHIME Felix	First Issue

11.0 References

11.1 Rwanda FDA Regulations and Guidelines on Good Laboratory Practices and testing of samples.

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/