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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 SOP for document control
4. This SOP shall **not** be used outside the Rwanda FDA Quality Control Laboratory without the authority of the authorizing personnel.

Involvement and contribution of Quality Control Laboratory in other regulatory functions

1. Content

Involvement and contribution of Quality Control Laboratory in other regulatory functions

2. Purpose

2.1. This procedure defines the responsibilities and roles of the QCL for its involvement and contribution to other regulatory functions.

3. Scope

This System procedure applies to all Rwanda FDA regulatory functions that need technical and scientific inputs of technical staffs of Quality Control Laboratory.

4. Policy

The Article 08 of the Law No. 003/2018 of 09/02/2018 paragraph 6 mandates the authority to establish quality assurance and quality control of regulated products

5.0 Terms and Abbreviations

In the context of this System Procedure, the terms defined in Level 1 shall apply in addition to the following:

5.1. : **PV-SM Division**: Pharmacovigilance and safety monitoring division;

5.2. GMP/GLP: Good Manufacturing Practice/Good Laboratory Practice.

6.0 Responsibility

6.1. All Quality Control Laboratory personnel are responsible for the implementation of this system procedure.

6.2. The Laboratory Officers and director of unit are responsible for provision of technical and scientific input to other regulatory function when required.

6.3. The Division Manager is responsible for designation of the staff of QCL who is responsible for provision technical and scientific input to other regulatory function.

7.0 Distribution

7.1. Division Manager of Quality Control Laboratory

7.2. Designated Quality Management System Officer

7.3. All Laboratory officers, specialists and laboratory technician.

8.0 Safety Precautions

Not applicable for this SOP.

9.0 Procedure

9.1. Roles and responsibilities of QCL for its involvement and contribution to other regulatory functions

9.1.1. The QCL interact with the different Divisions/Units of Rwanda FDA and provides technical and scientific inputs for the following key regulatory services:

9.1.1.1.Post-marketing surveillance (PMS) and Pharmacovigilance

a) DM of QCL as member of PMS committee contribute in setting priorities for PMS activities, planning PMS activities and provide recommendations on actions to be taken on noncompliant Pharmaceutical products
b) QCL conduct quality control tests on the PMS samples obtained using validated and/or approved methods;
c) To provide evidence based test results to inform regulatory action against identified substandard products.
d) QCL provides scientific evidence for products for which there has been a complaint or for products that are under investigation due to an adverse event raised by a patient or a health professional
e) QCL Staff may contribute in analysis and interpretation of vigilance data especially in analysis of the results from QCL after post marketing surveillance.

9.1.1.2.Registration of products

a) QCL support the assessment and review of marketing authorization applications during peer review meeting, special assessment and evaluation of medicine before being registered especially module 3 on product quality
b) QCL provides testing services to assess functionality of analytical methods in local conditions when data reviewers have some doubts
c) Testing shall be done in case required by a Division of registration to collaborate manufacturer's test results as a part of the evaluation for marketing authorization or for a variation to a marketing authorization

9.1.1.3.Inspection

a) QCL Staff provide technical support by participating in regulatory inspections of manufacturing plants or small scale productions Units of pharmaceutical products to ensure GMP/GLP.
b) QCL provide quality control of imported medicine samples if substandard or falsified medical product are suspected.
c) In the context of the support of the lot release by department of inspection and safety monitoring, testing shall be done for lot release and the concerned department will submit the sample to QCL for quality control purpose of such lot before it is released and QCL results will be the evidence based regulatory decision to such lot.
d) QCL help in interpretation of certificate of analysis submitted by importers

9.1.1.4. Authorization of Clinical trial

a) QCL participates in elaboration of clinical protocol
b) QCL Staff shall provide technical support in the review of clinical trial data in collaboration PV-SM division
c) QCL support inspection of clinical trial sites
d) QCL provide quality control of clinical trial samples

9.2.Nomination of QCL Staff to Participate to Other Regulatory Functions

9.2.1. DM of the division that need involvement of QCL staff for any regulatory function send the request to HoD clarifying the need of contribution from QCL;
9.2.2. HoD approves the need of contribution of QCL staff; then submit the request to DM of Quality Control Laboratory Division
9.2.3. After receiving request, the Division manager of QCL forward this request to Director of Unit who will designate the staff to participate in concerned activity (ies)
9.2.4. Before participation, the designated staff from QCL shall be required to read Quality manual, SOPs, STPs, guidelines, regulations, national and international standards and any other documents that are relevant to the concerned activity(ies) that he/she will provide technical and scientific input;
9.2.5. QCL Staff shall keep records of attendance in the support of other regulatory functions and he/she will provide them to designated quality management system officer's file.
9.2.6. The participating staff will elaborate a report and submit it to the Division Manager of Quality control laboratory.
9.2.7. If the need support is testing (quality control), procedure on Review of requests, tenders and contracts is followed

10.0 Appendices

10.1 Appendix C: Document revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
01June 2021	0	TUYISHIME Felix	First issue

11. References

11.1. LAW Nº 003/2018 OF 09/02/2018 ESTABLISHING RWANDA FOOD AND DRUGS Authority And Determining Its Mission, Organisation And Functioning Rwanda FDA Quality Manual

11.2.Laboratory quality Manual, QCL/MAN/001

11.3.Standard Operating Procedure for document control, QCL/SOP/001