| Format: QMS/FMT/001<br>Revision No: 0<br>Effective Date: 22 Jan 19 | **Division** | **Quality Control Laboratory** |
|---|---|---|
| **Document type: Standard Operating Procedure** | | Doc. Number : QCL / SOP /001 |
| RWANDA FDA<br>Rwanda Food and Drugs Authority | **Title: Document Control for Quality Control Laboratory** | Revision Number : 1<br>Revision Date : 01 June 2021<br>Effective Date : 14 June 2021<br>Review Due Date : 14 June 2024 |

RWANDA FDA QUALITY CONTROL LABORATORY CONTROLLED DOCUMENT Toll free : 9707

| | **Author** | **Authorized by** | **Approved by** |
|---|---|---|---|
| **TITLE** | Designated QMS Officer | Director of Medicines and cosmetics Testing Unit | Division Manager |
| **NAME** | TUYISHIME Felix | MUGWIZA Emmanuel | MUKUNZI Antoine |
| **SIGNATURE** | | | |
| **DATE** | 14 June 2021 | 14/06/2021 | 14/06/2021 |

**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.

## 1. Table of Content

## 2. Purpose

This Standard Operating Procedure (SOP) is to ensure that all quality system documents used in Quality Control Laboratory are properly developed, revised, approved, disseminated and retrieved. This SOP compliments the Rwanda FDA Standards Operating Procedure QMS/SOP/001 for document control.

## 3. Scope

This Standards Operating Procedure applies to the control of all documents pertaining to Quality Control Laboratory, Quality management system.

## 4. Policy

The ISO/IEC 17025:2017 Clause 8.3.1 states that ''the laboratory shall control the document (internal *and external) that relate to the fulfilment of this document''*.
WHO Good Practices for Pharmaceutical Quality Control laboratories WHO Technical Report Series No 957, 2010, Annex 1, section 3''Control of Document''

## 5. Definitions and Abbreviations

The definitions and abbreviations provided in the QMS/SOP/001 document of Rwanda FDA and QCL/MAN/001 shall be applied in addition to the following:

**DM:** Division Manager
**DU:** Director of Unit

## 6. Responsibility

**6.1** DM is responsible to ensure implementation of document control system and is the final reviewing and approving authority of the Standard Operating Procedure.

**6.2** Laboratory Officers are responsible for Verifying the technical accuracy of the different Laboratory Support Documents (LSD) in their Specific area.

**6.3** Designated QMS is responsible in implementation and maintenance of document control system, coordinates reviews and revisions of quality system documents, Maintains Documents Master List to ensure active and revised documents are to staff, and archives superseded or obsolete documents.

**6.4** All QCL staff are responsible for verifying that the official version of the document is used, review and determine need for new procedures or modification of procedures and Initialization of changes by completing a Document Change proposal form QCL/FOM/022

## 7. Distribution

This System Standards Operating Procedure **(QCL/SOP/001)** is issued on a control basis. Holders and their document rights are shown in **Appendix I.**

## 8. Safety Precautions

Not applicable to this SOP

## 9. Procedure

### 9.1. Development, review and Amendments of Quality Control Laboratory documents

9.1.1 A request for the creation or revision or amendment of a document is initiated by completing the Document change proposal Form **(QCL/FOM/022; see appendix II.)** and obtaining approval as indicated in the form.

9.1.2 The Quality Control Laboratory personnel initiating the document change, forwards the completed Document change proposal form to the **QCL** designated Quality Management System officer to implement the document change.

9.1.3 The Quality Control Laboratory designated Quality Management Systems officer coordinates with the staff in the Quality Control laboratory monthly meeting and come up with a new amended proposal that will be approved by Quality Control Division Manager and then the document amended accordingly

9.1.4 Hand written amendments are not permitted for the QCL – QMS documents.

9.1.5 For identification, the altered text in the document is highlighted by the **green** shading which is removed during the following document revision.

9.1.6 The new or amended documents are forwarded for Authorization and thereafter issued.

9.1.7 For planned reviews: the level 1 document, QCL/MAN/001 is reviewed after every **three** years, level 2 documents, SOPs reviewed after **two** years and level 3 documents, other laboratory documents (Laboratory Support Documents, Standards Testing Procedures, Work Instructions, Registers, Forms and Format) are reviewed after **one** year.

### 9.2. Authorization of Quality Control Laboratory documents

9.1.1. The Quality Manual (QCL/MAN/001) document(s) is authorized by DM and approved by Director General.

9.1.2. Standard Operating Procedures (SOPs) documents are authorized by Unit Director then approved by DM.

9.1.3. All other laboratory documents (Laboratory Support Documents, Standards Testing Procedures, Work Instructions, Registers, Forms and Format) are authorized by the laboratory officer and approved by Unit director.

### 9.3. Cover page /control page

The cover page /control page is placed at the start of all quality control documents except for the forms and shall be presented as per follow:

| | | |
|---|---|---|
| Format: QMS/FMT/XXX<br>Revision No: 0<br>Effective Date: D MM YYY | **Division** | **Quality Control Laboratory** |
| Document type: | | Doc. Number :<br>Revision Number :<br>Revision Date :<br>Effective Date :<br>Review Due Date : |
| RWANDA FDA<br>Rwanda Food and Drugs Authority | Title: | |

| | **Author** | **Authorized by** | **Approved by** |
|---|---|---|---|
| **TITLE** | | | |
| **NAME** | | | |
| **SIGNATURE** | | | |
| **DATE** | | | |

**INSTRUCTIONS**

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

### 9.4.Header of forms

The header of each form will be as follow:

| Document type: **Form** | | Doc. Number :<br>Revision Number :<br>Revision Date :<br>Effective Date : |
|---|---|---|
| RWANDA FDA<br>Rwanda Food and Drugs Authority | Title: | |

### 9.5. Footer of quality control document

9.5.1. The quality control document shall have on every page the Rwanda FDA water mark, header of size 0.3 from top and footer of size 0.2 from bottom; the header and the footer presented as follow:

**9.5.2. Header of quality control document:**

RWANDA FDA

**Rwanda Food and Drugs Authority Laboratory Quality Manual**

9.5.3. Footer of quality control document:

| Doc. No.: …… | Revision Date: DD/ MM /YYYY | Review Due Date: DD/ MM/ YYYY |
|---|---|---|

9.5.4. For Forms, Flow charts, Figures; which occupy the whole page, the headers and or footer are replaced by the Rwanda FDA logo.

## 9.6. Font Specifications for Header, Footer and Body Text

9.6.1. Level 1, level 2 and level 3 QCL-QMS documents are in font type of times new roman. The font size is preferably 12 as per Rwanda FDA SOP for document control QMS/SOP/001, however in some cases (i.e. Figures, tables, flow charts, forms) font size may be reduced to 10.

9.6.2. Table of acceptable Font Specifications for Header, Footer and Body Text

| | |
|---|---|
| Font Type | Times New Roman |
| Font Size | 12<br>(Note1: Tables, figures, flow chart and forms may be in font size 10 depending on size of the contents.<br>Note 2:The front and rear covers of manuals, strategic plan and other high level documents may be in other font sizes) |
| Font Color | Black<br>(Note: manuals, strategic plan and other high level documents may have other font colors) |
| Font Style | Regular for body text, italics for citations, bold for headings |

## 9.7. Design of the document revision history

9.7.1. Level 1, level 2 and level 3 documents shall have at the end, the document revision history presented as follow:

| Date of revision | Revision number | Author(s) | Changes made and/or reasons for revision |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

9.7.2. The level 2 documents and level 3 documents have to be revised after 2 and 1 year respectively.

**9.8.Identification of internal documents**

9.8.1. Quality manual (level 1 document) and SOPs (level 2 document) and their related forms shall be identified as per Rwanda FDA SOP for document control QMS/SOP/001, and level 3 documents shall be identified by three letters yyy as below:

9.8.2. The source of originating division, laboratory shall be indicated by three letter code XXX as assigned below:

| Document Type | Code |
|---|---|
| Standards Testing Procedures | STP |
| Laboratory Support Document | LSD |
| Work Instruction | WOI |
| Form | FOM |
| Format | FMT |
| Registers | REG |
| Checklist | CKL |
| Chart | CHT |
| Protocol | PTC |
| Process flow outline | PRF |

| Name of source | Code |
|---|---|
| Quality Control Division | QCL |
| Medicines and cosmetics Testing Unit | MCU |
| Food Testing Unit | FTU |
| Pesticides& poisonous substance and Chemical Unit | PCU |
| Medical Devices and Instrumentation Testing Unit | MDU |

9.8.3. Level 3 documents number shall be indicated by QCL / XXX/ YYY/ ZZZ where QCL donates Division where the document belongs, XXX indicate the originating laboratory, and YYY indicates the document type and the ZZZ donate the document number, Example : The standard Testing procedure from Food Testing Unit, shall be identified by **QCL/ FTU/ STP /001**

## 9.9. Issuing Quality Control Laboratory documents

9.9.1. Quality Manual and SOPs documents are issued and Distributed in hard copies to the shown copy holders in appendix I and provide read only access of soft copies to all laboratory staff. Other laboratory documents are issued/distributed by Laboratory officer, soft and hard copies are sent to the designated QMSO for confirmation.

9.9.2. Level 3 documents are registered and stamped by designated Quality Management System Officer for control purpose before put into use.

9.9.3. The designated Quality Management System Officer updates the concerned Quality Control Laboratory personnel; the relevance and implementation of the new or amended document.

9.9.4. The official copy holders of the new or amended document signs in the Quality Control Laboratory – Document control register (QCL/REG/001 see Appendix III).

9.9.5. If the new or amended document is at level 3, the official holders signs in the QCL-SOP Register (QCL/REG/001; see Appendix III). The register is generated by designated Quality Management Systems officer and distributed in different laboratories for use.

9.9.6. Quality Control Laboratory designated Quality Management Systems officer distributes the updated version as per (Appendix I) and **OBSOLETE** version is withdrawn from all points of issue /use, stamped OBSOLETE DOCUMENT and kept till due time for disposal whilst the original should be kept for possible tracking of documents valid back in time.

9.9.7. Quality Control Laboratory designated Quality Management Systems officer thereafter withdraws level -1 and level-2 obsolete documents and mark them by stamping ("**OBSOLETE DOCUMENT**") and followed by their withdrawal. The document holder's signs for the withdrawal in the respective Register (QCL/REG/002, see Appendix IV)

## 9.10. Monitoring of QCL Documentation

9.10.1. Quality Control Laboratory designated Quality Management Systems officer monitors, prepare and update master list for level 1 and level 2 documents (see master list format Appendix V)

9.10.2. Director monitor, prepare and update the master list of level 3 documents found in relevant laboratory see master list format (see master list format Appendix V)

9.10.3. The document of external sources used in laboratories are controlled by a specifically designated stamp clearly identified with the term "**DOE**", they are also listed in the master list of document in relevant laboratories.

**9.10.4.** Each copy of the authorized Master document under circulation for use shall be stamped "**CONTROLLED COPY**" in blue color;

9.2.1 Any controlled internal document that will not be further revised and its use terminated, shall be stamped "**OBSOLETE DOCUMENT**" in blue ink on the front of the first page and the back of the last page.

9.10.5. Whenever changes/amendments are made in the QCL-QMS documents, the QCL- Quality Management Systems officer / any other responsible personnel depending on the level of the document changed or amended ensures that electronic documents are updated.

### 9.11. Communication of Changes/ Amendments

9.11.1. If changes/amendments/alterations are made in the QCL-QMS documents level 1 and level 2, the Quality Control Laboratory designated Quality Management Systems officer notifies all the QCL personnel through an outlook message and keep records thereof.

9.11.2. If changes/amendments/alterations are made in the QCL-QMS documents level 3 the Director notifies all the concerned staff in that particular Laboratory.

9.11.3. Quality Control Laboratory designated Quality Management System Officer distributes the updated version as per (Appendix I) and **OBSOLETE** version is withdrawn from all points of issue /use, stamped OBSOLETE DOCUMENT and kept till due time for disposal whilst the original should be kept for possible tracking of documents valid back in time

9.11.4. Quality Control Laboratory designated Quality Management System Officer is responsible in the disposal of all QCL documents found in level 1 and level 2 while all documents in level 3 are disposed of by relevant Director in their respective unit;

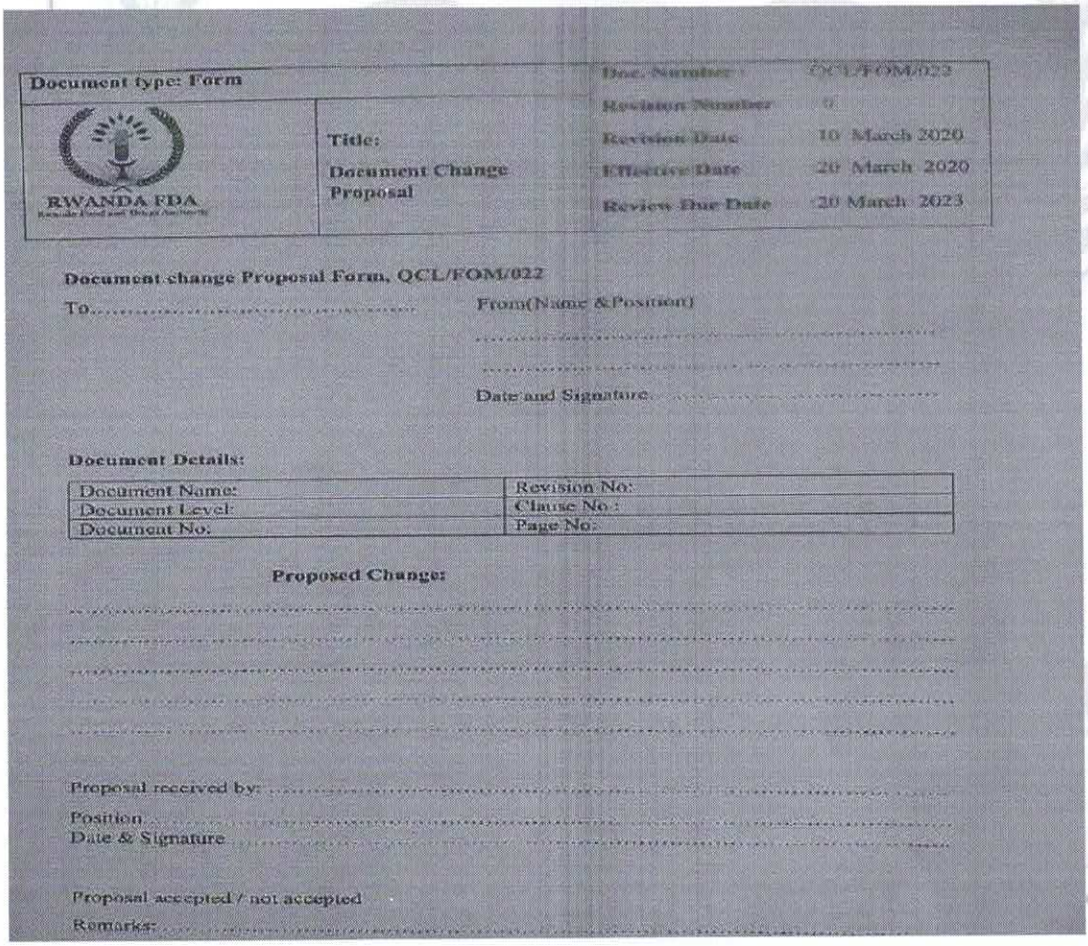
9.11.5. Disposal of documents is done through incineration or shredding and all disposed documents are recorded in the document disposal register (see appendix IV)

## 10. APPENDICE

### 10.1.Appendix I: Distribution / Controlled copy holder

| Job Titles | Document rights |
|---|---|
| Designated QMS Officer | Holder of copy - 1, printing, reading, review |
| DM | Holder of copy – 2 |
| Directors | Holder of copy – 3 |
| Laboratory Officer, Laboratory Technician | Holder of copy – 4 |

### 10.2.Appendix II: Document change Proposal Form, QCL/FOM/022



Document type: Form

RWANDA FDA

Title: Document Change Proposal

Doc. Number: QCL/FOM/022
Revision Number: 0
Revision Date: 10 March 2020
Effective Date: 20 March 2020
Review Due Date: 20 March 2023

Document change Proposal Form, QCL/FOM/022

To..... From(Name &Position)

.....

.....

Date and Signature.....

Document Details:

| | |
|---|---|
| Document Name: | Revision No: |
| Document Level: | Clause No.: |
| Document No: | Page No: |

Proposed Change:

.....

.....

.....

.....

.....

Proposal received by: .....

Position .....

Date & Signature .....

Proposal accepted / not accepted

Remarks: .....

### 10.3.Appendix III: Document Control Register QCL/REG/001

| S/N | Doc Title | Doc No | Doc Revision No | Doc Holders name | Holders signature | Effective date | Comment |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

### 10.4.Appendix IV: Document disposal register QCL/REG/002

| S/N | Document name | Reason for disposal | Date of Disposal | Method of Disposal | Disposed by | Comment |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |

### 10.5.Appendix V: Format of Master list QCL-QMS documents QCL/FMT/001

| S/N | Document Title | Doc No | Revision status | Date of Review | No.of copies | Distribution | |
|---|---|---|---|---|---|---|---|
| | | | | | | Copy N0 | Holder's Name |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

### 10.6.Appendix VI: Document Revision History

| Date of revision | Revision number | Author(s) | Changes made and/or reasons for revision |
|---|---|---|---|
| 20 March 2020 | 0 | TUYISHIME Felix | First Issue |
| 01 June 2021 | 0 | TUYISHIME Felix | Clause 9.8; MCP changed to MCU, FTL changed to FTU , MDI changed to MDU and MIC removed |
| 01 June 2021 | 0 | TUYISHIME Felix | Clause 9.8.3: FTL changed to FTU |
| 01 June 2021 | 0 | TUYISHIME Felix | Clause 9.9.4 and Clause 9.5.5: QCL/REG/021 Changed to QCL/REG/001 |
| 01 June 2021 | 0 | TUYISHIME Felix | Clause 9.9.7: QCL/REG/021 changed to QCL/REG/002 |
| 01 June 2021 | 0 | TUYISHIME Felix | Clause 9.10.2, 9.11.2 and 9.11.4 Laboratory Officer changed to Director |
| 12 July 2021 | 1 | TUYISHIME Felix | Clause |

## 11. Reference

11.1.ISO/IEC17025:2017, Clause 8.3. Control of management system documents,
11.2. Quality Control Laboratory Quality Manual, QMS/MAN/001, Clause 8.2. Control of management system documents,
11.3. Rwanda FDA document control, QMS/SOP/001