| Format: QMS/FMT/001<br>Revision No: 0<br>Effective Date: 22 Jan 19 | **Division** | **Quality Control Laboratory** |
|---|---|---|

| Document type: **Standard Operating Procedures** | | Doc. Number : QCL / SOP /010<br>Revision Number : 1<br>Revision Date : 14 June 2021<br>Effective Date : 14 June 2021<br>Review Due Date : 14 June 2023 |
|---|---|---|
| RWANDA FDA<br>Rwanda Food and Drugs Authority | **Title:**<br>Externally provided product and services | |

RWANDA FDA QUALITY CONTROL LABORATORY CONTROLLED DOCUMENT Toll free 9707

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

## 1. TABLE OF CONTENT

## 2. PURPOSE

The purpose of this procedure is to describe the process of acquisition of suitable externally provided products and services from request to receipt.

## 3. SCOPE

This procedure covers all the processes involved during the purchase, receipt and storage of all Laboratory Externally Provided Products and Services.

## 4. POLICY

ISO/ IEC 17025:2017, Clause6.6 externally provided product and service

## 5. DEFINITION AND ABBREVIATION

In the context of this System Procedure, the following abbreviations and terms are defined as follows in addition to those defined in Quality control laboratory manual:

### 5.1 Externally Provided Products and Services

Externally provided products and services include: equipment, consumable materials, reference materials and services such as calibration, sampling, testing, facility and equipment maintenance, proficiency testing, assessment and auditing services that affect laboratory activities.

### 5.2 Laboratory consumables

These are materials used in Quality Control Laboratory other than the Laboratory equipment. Laboratory Consumables include but not limited to the chemical standards, chemical reagents, sampling boats, latex gloves, spatulas, glass ware and cleaning materials.

### 5.3 Services

These can include but not limited to external training, equipment maintenance and repair, Proficiency test providers and accreditation services.

## 6. RESPONSIBILITIES

6.1 Request for acquisition of new externally provided products can be initiated once a need is identified either by senior management or by any Quality Control Laboratory personnel according to the customer need.

6.2 In addition to budgetary planning, the Division Manager is responsible for reviewing, approving of purchase requests, submitting technical specification and keep all approved records for purchased goods.

6.3 Division Manager is responsible to ensures that the reception of purchased goods and evaluation are done as per this procedure.

6.4 The Designated Store Keeper is responsible for the reception and storage of the purchased products.

## 7. SOP-DISTRIBUTION

7.1 Division manager
7.2 Designate Quality management system officer
7.3 All laboratory officer
7.4 All laboratory technician

## 8. SAFETY PRECAUTIONS

Not applicable to this SOPs

## 9. PROCEDURE

9.1 Selection and purchase of Laboratory Externally provided products and services

9.1.1 When the budget is available and there is a need for purchasing any Laboratory products it uses; the Division Manager notifies Director of Unit to prepare technical specifications relevant to the needed products.

9.1.2 The Director of Unit and Laboratory officer prepares the technical specification within the communicated time frame and submits to the Division Manager

9.1.4 The Division Manager review and approve specification of externally provided products and submit them to the procurement office for purchase processing.

9.1.5 The selection of externally provided products providers and procurement process in Quality Control Laboratory is done in accordance with public procurement Law n° 62/2018 of 25/08/2018 Governing Public Procurement (this include but not limited to Announcement of the tender, launching of the tender, evaluation of the tender document of tender documents, approval and contract signing).

9.1.6 On reception, the Director of Units ensures that purchased products that affect the quality of tests are not used until they have been evaluated or otherwise verified as complying with technical specification as described in the tender document.

9.1.8 After evaluation, the accepted supplies and accompanied documents are kept by the Director of Unit and the designated store keeper whilst the rejected ones are returned to the supplier.

9.1.9 Rejected supplies due to deviation from the contract are treated as per public procurement law.

9.1.10 For the accepted supplies the Division Manager provides the supplier with the filled purchase acceptance certificate signed by both parties.

9.1.11 For the Equipment, after physical examination and approval the supplier proceeds with installation and commissioning to ensure the purchased equipment operates in the way it is expected and meets the technical specifications.

9.1.12 In recognition of the equipment commissioning, the Division Manager awards acceptance purchase Form QCL/ FOM/012 (see Appendix C) however the supplier is responsible for any fault or malfunction of the manufacturer source within the manufacturer specified guarantee period.

9.1.13 For the proper management of accepted chemicals and consumables in use, are internally requested using consumable requisition form QCL/ FOM/ 020 in appendix B, and the daily use managed with the use of Chemical management form QCL/ FOM/018 in appendix C is used

9.1.14 Suppliers of critical consumables are evaluated after every individual contract through Rwanda FDA procurement office and evaluation report is submitted to the Rwanda public procurement Authority to take action

9.2.Testing services subcontracted with other laboratories

9.2.1. Sample reception.

9.2.1.1. The customer submits a sample to the designated sample control officer with the information of the parameters to be tested as per **QCL/S0P/031**.

9.2.1.2. The designated sample control officer proceeds by ascertaining if the sample and all parameters requested are covered in the QCL testing scope and or the samples can be tested in QCL.

9.2.1.3. In the case of limited resources, heavy work load or any other technical reason which may cause the sample or some parameters not to be tested by QCL at the time of sample delivery designated sample control officer informs the customer about the subcontracting optional.

9.2.1.4. If the customer agrees about the subcontracting option, the designated sample control officer responds by filling Subcontracting Acceptance Form, QCL/FOM/048, see Appendix E

### 9.3. Request for Subcontracting

9.3.1.1. First, the customer signs a contract with QCL by signing the filled test request form, QCL/FOM/001 at the sample reception desk.

9.3.1.2. The designated sample control officer directs the customer to the Director of Unit with filled Subcontracting Acceptance Form which will be received and filed by Director of Unit who in turn assists the customer to fill sample sub contraction form (QCL/FOM/051); In this case the sample sub contraction form will be the contract between the QCL and the subcontracted Laboratory.

9.3.1.3. The DM Places subcontracted work with a competent subcontractor complying with ISO 17025:2017 evidenced by being accredited, WHO prequalified or well performance in more than one consecutive proficiency tests in a particular parameters intended to be subcontracted. This helps Authority to recognize and accept reliance to resulting test results;

9.3.1.4. The Director of Unit together with division manager arrange for the transport of the sample to the subcontracting laboratory.

9.3.1.5. The Director of Unit maintains an updated list of approved subcontracting laboratories and evidence of their competence (QCL/FMT/016);

9.3.1.6. In case the customer does not trust the subcontracted laboratories, the Director of Unit asks the customer the laboratory to be subcontracted;

9.3.1.7. Director of Unit ensures the competence of proposed lab and in collaboration with DM manage modalities to be followed;

9.3.1.8. QCL remains responsible for the results obtained from the subcontractor except when the customer has specified which subcontractor is to be used.

9.3.1.9. Results of subcontractors are again checked and approved by DM by stamping or signing with "**checked**".

9.3.1.10. Test Report is submitted to office of Director General;

9.3.1.11. Copies of Certificates ( or test reports) provided by other laboratories are kept in file called "Test Reports from Other Labs" for purpose of records control.

9.2.2.12. Rwanda FDA recognize and relies on test results as provided by other laboratories during decision making.

## 10. APPENDICES

### 10.1. Appendix A: Consumable requisition form

| Document type: Form | | |
|---|---|---|
| RWANDA FDA<br>Rwanda Food and Drugs Authority | **Document title:** Consumable requisition form | Doc. No: QCL/FOM/020<br>Revision No: 1<br>Revision date: 14 June 2021<br>Effective date: 14 June 2021 |

Requested by……..
Date……
Lab ……...
Expected date of delivery……

| Serial number | Name of item | Specification | Quantity |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Specify any other description of item (if any)

1) .....
2) .....
....
3) .....
.....

Checked by immediate supervisor

Name.....
...
signature.....
Date.....

Approved by Division Manager

Name.....
....
signature.....
Date.....

### 10.2. Appendix B: Chemical management Form

| Document type: Form | | |
|---|---|---|
| RWANDA FDA<br>Rwanda Food and Drugs Authority | **Title: Chemical management form** | Doc. No: QCL/FOM/018<br>Revision No: 1<br>Revision date: 14 June 2021<br>Effective date: 14 June 2021 |

| Chemical Product name | | | | | | |
|---|---|---|---|---|---|---|
| date | Batch number | Quantity and size before opening | Date opened | Volume/weight Purpose measured | Fully emptying date | Username and signature |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

## 10.3. Appendix C: Purchase acceptance Form

| Document type: Form | | |
|---|---|---|
| RWANDA FDA<br>Rwanda Food and Drugs Authority | **Document title:**<br>Purchase acceptance form | Doc. No: QCL/FOM/012<br>Revision No: 1<br>Revision date: 14 June 2021<br>Effective date: 14 June 2021 |

This is to certify that the following consumable, reagents, culture media, herein included have been supplied (name and address of supplier)

.....
.....
.....
.....

And accepted by Quality control laboratory

| Serial number | Supply description | Quantity supplied | Quantity not supplied |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Observation, comment and Action

Supplier representative

| S/N | Names | Position | Signature& date |
|---|---|---|---|
| | | | |

Rwandafda representative

| S/N | Names | Position | Signature &date |
|---|---|---|---|
| | | | |

### 10.4. Appendix D: Samples to be tested by subcontracted labs

| FDA Sample ID No | Name And Batch No Of The Sample | Date Of The Sample Reception | Assigned Lab (Name) | Signature of laboratory director( transferring the sample) | Route of sample transfer (electronic-email or hard copies) | Comment |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |

## 10.5. Appendix E: Subcontracting Acceptance Form

| Document type: Form | | Doc. Number : QCL / FOM /048 |
|---|---|---|
| RWANDA FDA<br>Rwanda Food and Drugs Authority | **Title:** Subcontracting Acceptance Form | Revision Number : 1<br>Revision Date : 01 June 2021<br>Effective Date : 14 June 2021 |

I ....., on behalf of .....
.....

For which I am employed as .....
.....

Hereby authorize Rwanda FDA/QCL to sub-contract my sample(s);

Sample description:

Rwanda FDA number:

We accept responsibility for all the costs involved; including:

- The test charges;
- Time results take to reach RSB and
- Freight charges

Signature ..... Date .....

**Rwanda FDA/QCL use only**

Reasons for subcontracting .....
.....
.....
Any action(s) to limit subcontracting .....
.....
.....

| | | |
|---|---|---|
| Doc. No.: QCL/SOP/010 | Revision Date: 01 June 2021 | Review Due Date: 14 June 2023 |
| Revision No.: 1 | Effective Date: 14 June 2021 | Page **1** of **...** |

## 10.6. Appendix F: Sample Sub Contraction Form

| Document type: Form | | Doc. Number : | QCL / FOM /051 |
|---|---|---|---|
| RWANDA FDA<br>Rwanda Food and Drugs Authority | **Title:** Sample Sub-contraction Form | Revision Number<br>Revision Date<br>Effective Date | : 1<br>: 14 June 2021<br>: 14 June 2021 |

1. Name of the product: .....
2. Size of the submitted sample: .....
3. File reference number: .....
4. Labelling/identification:
   Description: .....
   .....
   .....
   Lot No: .....
   Man. Date: .....
   Expiry date: .....
5. Physical condition of the sample upon arrival:
   **State**: Frozen, chilled, Room temperature
   **Packaging**: Sealed, Unsealed, Damaged, Undamaged
   **General appearance**: Good, Poor
6. Ref. standard specification:
   .....
7. Parameters to be tested:
   .....
   .....
   .....
   .....
   .....
   .....
   .....
8. Recommended storage temperature:
   .....
9. Details of sample:
   Place/Country of origin:
   .....
   Exact point source: .....
10. Customs entry number: .....
11. Customer release order number:
    .....
12. State of the source:
    Frozen, chilled, room temperature
13. Subcontracted by:
    .....
    Sent by: .....
    Signature: .....
    Date &time of submission: .....
14. Rwanda FDA Number: .....
15. Subcontractor
    Name: .....
    Address: .....
16. Sender details
    Name: .....
    Company: .....
    Designation: .....
    Address: .....
17. Courier: .....
    .....
    Address: .....
    Date and time of sample receipt:
    .....
    Courier track No:
    .....
    Signature: .....
18. Remarks:

| | | |
|---|---|---|
| Doc. No.: QCL/FOM/049 | Revision Date:14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 1 of 1 |

## 10.7. Appendix G: Format of the list of Approved Subcontractors (QCL/FMT/016)

RWANDA FDA
Rwanda Food and Drugs Authority

**Format of the list of Approved Subcontractors (QCL/FMT/016)**

| S/N | Name of the Laboratory | Address | Matrix and parameter to be subcontracted | Proof of competence | |
|---|---|---|---|---|---|
| | | | | **Accredited** | **Satisfactory results in more than one consecutive proficiency tests** |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |



| | | | | | |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |



| | | |
|---|---|---|
| Doc. No.: QCL/FMT/014 | Revision Date: 01 June 2021 | Review Due Date: N.A |
| Revision No.: 1 | Effective Date: 01 June 2021 | Page **1** of **1** |

## Appendix H: Service/Purchase evaluation form

| Document type: Form | | Doc. Number : QCL / FOM /050 |
|---|---|---|
| RWANDA FDA Rwanda Food and Drugs Authority | Title: Service/Purchase evaluation Form | Revision Number : 0<br>Revision Date : 14 August 2020<br>Effective Date : 24 August 2020 |

| Type of service/ supplies | Service/ supplies Description | Date service/ supplies provided | Quality of service/ supplies provided (Good/Bad) | Remarks | Name and Signature of evaluator and date evaluated |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

## 10.4. Appendix I: Document history review

| Date of revision | Revision number | Author(s) | Changes made and/ or Reasons for revision |
|---|---|---|---|
| 14 August 2020 | 0 | Felix TUYISHIME | First issued |
| 24 May 2021 | 0 | Felix TUYISHIME | Clause 9.2 added |
| 01 June 2021 | 1 | Felix TUYISHIME | Clause 9.1.5 rephrased |
| 01 June 2021 | 1 | Felix TUYISHIME | Clause 9.1.1, 9.1.2& clause 9.1.3: Laboratory officer replaced by Director of Unit |
| | | | |
| | | | |

## 11. REFERENCES

11.1 ISO/ IEC 17025: Clause6.6
11.2 Quality control laboratory Manual (QCL/MAN/001)
11.3 Rwanda FDA control document (QCL/SOP/001)