

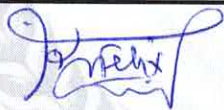
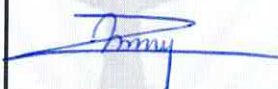
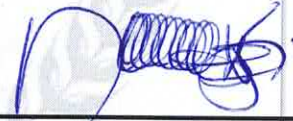


Format: QMS/FMT/001 Revision No: 0 Effective Date: 22 Jan 19		Division	Quality Control Laboratory
Document type: Standard Operating Procedures			Doc. Number : QCL / SOP /010
 RWANDA FDA Rwanda Food and Drugs Authority		Title: Externally provided product and services	Revision Number : 1 Revision Date : 14 June 2021 Effective Date : 14 June 2021 Review Due Date : 14 June 2023
			
	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.			

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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, Clause 6.6 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 ensure 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

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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/SOP/031**.

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- 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.

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10. APPENDICES

10.1. Appendix A: Consumable requisition form

Document type: Form		Doc. No: QCL/FOM/020 Revision No: 1 Revision date: 14 June 2021 Effective date: 14 June 2021	
	Document title: Consumable requisition form		
Requested by..... Date..... Lab Expected date of delivery.....			
Serial number	Name of item	Specification	Quantity

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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		Doc. No: QCL/FOM/018 Revision No: 1 Revision date: 14 June 2021 Effective date: 14 June 2021				
	Title: Chemical management form					
Chemical Product name						
date	Batch number	Quantity and size before opening	Date opened	Volume/weight Purpose measured	Fully emptying date	Username and signature

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

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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

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10.5. Appendix E: Subcontracting Acceptance Form

Document type: Form		Doc. Number : QCL / FOM /048
	Title: Subcontracting Acceptance Form	Revision Number : 1
		Revision Date : 01 June 2021
		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

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Reasons for subcontracting

.....


Any action(s) to limit subcontracting

.....

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10.6. Appendix F: Sample Sub Contraction Form

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

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. Name of the product: 2. Size of the submitted sample: 3. File reference number: 4. Labelling/identification: 5. Physical condition of the sample upon arrival: 6. Ref. standard specification: 7. Parameters to be tested: 8. Recommended storage temperature: 9. Details of sample: 10. Customs entry number: | <ol style="list-style-type: none"> 11. Customer release order number: 12. State of the source: 13. Subcontracted by: 14. Rwanda FDA Number: 15. Subcontractor: 16. Sender details: 17. Courier: 18. Remarks: |
|--|--|

Doc. No.: QCL/FOM/049	Revision Date: 14 August 2020	Review Due Date: 24 August 2022
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10.7. Appendix G: Format of the list of Approved Subcontractors (QCL/FMT/016)



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


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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
		Revision Date : 14 August 2020
		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

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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

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11. REFERENCES

- 11.1 ISO/ IEC 17025: Clause 6.6
- 11.2 Quality control laboratory Manual (QCL/MAN/001)
- 11.3 Rwanda FDA control document (QCL/SOP/001)



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