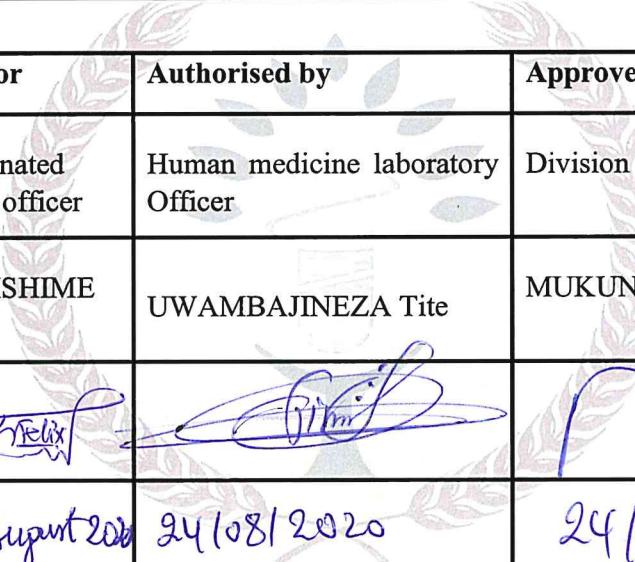
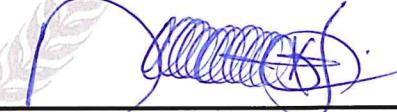


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| Document type: Standard Operating Procedures | | Doc. Number : QCL / SOP /030 Revision Number : 0 Revision Date : 14 August 2020 Effective Date : 24 August 2020 Review Due Date : 24 August 2022 | |
|  RWANDA FDA <small>Rwanda Food and Drugs Authority</small> | Title: Training of Quality Control Laboratory Staff | | |
|  | | | |
| | Author | Authorised by | Approved by |
| TITLE | Designated QMS officer | Human medicine laboratory Officer | Division Manager |
| NAME | TUYISHIME Felix | UWAMBAJINEZA Tite | MUKUNZI Antoine |
| SIGNATURE |  |  |  |
| DATE | 24 August 2020 | 24/08/2020 | 24/08/2020 |
| INSTRUCTIONS | | RWANDA FDA Rwanda Food and Drugs Authority | |
| 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 document control section above, are used 4. This SOP shall not be used outside the Rwanda FDA Quality Control Laboratory without the authority of the authorizing personnel. | | | |

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|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 1 of 13 |

Table of Contents

| | |
|--|----|
| 2. Purpose | 3 |
| 3. Scope..... | 3 |
| 4. Policy | 3 |
| 5. Definitions and Abbreviations | 3 |
| 6. Responsibility | 4 |
| 7. Distribution..... | 4 |
| 8. Safety Precautions | 4 |
| 9. Procedure | 4 |
| 9.1 General Principles..... | 4 |
| 9.2 New employee induction | 5 |
| 9.3 Employee training..... | 5 |
| 9.4 Evaluation of training and training plan | 5 |
| 9.5. Documentation..... | 6 |
| 10. Appendices | 7 |
| 11. Reference | 13 |

| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 2 of 13 |

V. J.

2. Purpose

This Standard Operating Procedure is to:

- 2.1 Outline the procedure for training Quality Control Laboratory staff at Rwanda FDA in order to ensure high, uniform and consistent competencies among staff performing laboratory analysis;
- 2.1 Provide a way of improving working skills.

3. Scope

This Standard Operating Procedure:

- 3.1 Applies to all staff employed by Rwanda FDA Quality Control Laboratory Division to carry out quality control testing of products regulated by Rwanda FDA.

4. Policy

4.1 The Law N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning states in:

Article 8 (3) ... “establish the quality assurance and quality control...through designated quality control laboratories”

4.2 ISO 9001:2015 Clause 7.5.3.1 states that “Documented information required by the quality management system and by this International Standard shall be controlled”.

4.3 WHO Good Practices for Pharmaceutical Quality Control laboratories WHO Technical Report Series No. 957, 2010, Annex 1; sections 6 “sufficient personnel with the necessary education, training”.

5. Definitions and Abbreviations

5.1 “the Law”

Law N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning

5.2 “Training”

A process of teaching or learning a skill through interaction to qualify personnel by appropriate education and experience for performing work functions.

| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 3 of 13 |

U. JF

5.3“Training programme”

A schedule of training/ staff development activities.

6. Responsibility

The Quality Control Laboratory Division Manager is responsible for:

- 6.1.Identifying training needs for individual employees;
- 6.2.Preparing and executing the annual departmental training plan;
- 6.3.Organising departmental training through internal and external trainers/facilitators;
- 6.4.Evaluation of training, and to arrange re-training, if required;
- 6.5.Laboratory Officers and Analysts are responsible for undergoing the prescribed requisite training;
- 6.6.The Designated Quality Management System shall maintain accurate training records for each laboratory officer, laboratory Technician or analyst.

7. 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.

8. Safety Precautions

Not applicable to this procedure.

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9. Procedure

9.1 General Principles

- 9.1.1 All Laboratory Officers and Analysts shall be trained to carry out analytical tests, accurately and safely according to laid down procedures as required.
- 9.1.2 The minimum qualification for analysts who work in the Quality Control laboratories shall be a:
 - 9.1.2.1 Bachelor of Pharmacy
 - 9.1.2.2 Bachelor of Science Degree in Chemistry or Life Sciences
 - 9.1.2.3 Bachelor of Technology Degree
- 9.1.3 The minimum qualification for analysts in the Medical Devices unit shall be a Higher National Diploma with a minimum of three (3) years of relevant experience.
- 9.1.4 These qualifications shall be stated in the employee's job description

| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date:14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 4 of 13 |

U.11

9.2 New employee induction

- 9.2.1 Each new employee will work under the close supervision of an experienced analyst.
- 9.2.2 New employees will receive orientation to the laboratory and will be properly trained to perform each assigned task. The induction period is not less than six (6) months. A competence assessment will be carried out on the new employee at the end of the induction period when appropriate.
- 9.2.3 This induction follows a specific training programme in which the trainee will be signed off by the trainer after successful completion of each training stage. The trainee will acknowledge completion of each stage by signing in agreement to the area of training completed.
- 9.2.4 The new employee will not be allowed to perform any testing of official samples without supervision, until the Division Manager has deemed the employee competent as defined by unit competence assessment procedures.
- 9.2.5 The training will include test procedures, product specifications, proper operation and maintenance of equipment and calibration, data calculation and documentation.

9.3 Employee training

- 9.3.1 Once every two years, all analysts will receive refresher training on any of the following as deemed necessary; according to respective unit/division annual training plan:
- 9.3.1.1 Health & Safety issues
 - 9.3.1.2 Good Laboratory Practices (GLP)
 - 9.3.1.3 Laboratory policies and procedures
 - 9.3.1.4 Standard test methods
 - 9.3.1.5 Instrumental techniques
 - 9.3.1.6 ISO Awareness and GMP issues biennially.

Note; Evidence of training shall be in the form of an Attendance Register and Certificate of Attendance/Staff Training Record Form.

- 9.3.2 Whenever methods/procedures are revised or test equipment is modified or replaced all analysts will be appraised of the changes and retrained in the new or changed methods.
- 9.3.3 The Division Manager will determine the training needs of personnel through;
- 9.3.3.1 Completion of Assessment of Training Needs Form by employees.
 - 9.3.3.2 Competence Assessment Form
 - 9.3.3.3 Intra-laboratory proficiency testing general supervision; When deficiencies are noticed re-training of the analyst will be recommended by the Division Manager

9.4 Evaluation of training and training plan

| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 5 of 13 |

U.T

9.4.1 At the end of each training programme, the Division Manager will evaluate the training completed by the analyst for effectiveness.

9.4.2 For external training carried outside Rwanda FDA by other capacity building partners or sponsored by Rwanda FDA, the trained individual(s) will be required to train other members of the team after attending the training as a way of building capacity, adding value to the organisation and assessing the effectiveness of the training obtained

9.4.3 All annual training plans for units and divisions will be evaluated for implementation and effectiveness against set staff development and training objectives at the end of each year. Gaps will be identified for future planning and this covers both internal and external training.

9.5. Documentation

9.5.1 The Division Manager will continuously assess the effectiveness of the training undertaken.

9.5.2 All training given will be documented on the Training Record Form. The original copy of the form will be placed in the employee's personal file kept in the Administration, one copy is given to the analyst and the other copy to the Division Manager.

9.5.3 All forms will be signed by the trainee and trainer or supervisor.

| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 6 of 13 |



10.Appendices

10.1. Appendix A:

ASSESSMENT OF TRAINING NEEDS RECORD FORM(QCL/FOM/026)

Express yourself as clearly and freely as possible. Your answers will help to determine the areas for a structured training programme. Shortfalls or deficiencies in skills, knowledge, work processes, procedures, methods and attitudes are identified and this assessment considers if the problems can be solved by training.

The deadline for submitting the completed forms is _____

Name of Officer: _____

Designation: _____

Unit/Division: _____

Division: _____

JOB ANALYSIS

Referring to your job description, do you feel that the listed tasks you are expected to perform are adequate? If not please state, the extra tasks you are doing.

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PERSON ANALYSIS *Rwanda Food and Drugs Authority*

Which tests or techniques have you been assessed and gauged competent to do without supervision?

| Test / Technique | Competent | | Date Assessed | Comment |
|------------------|-----------|----|---------------|---------|
| | Yes | No | | |
| | | | | |
| | | | | |

Which techniques do you require further training and/or supervision?

| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 7 of 13 |

U.T

Training Quality Control Laboratory Staff

In the unit or section, you are working now, can you identify the skills or knowledge needed to effectively ensure that the quality of the job is enhanced?

What other skills do your workmates have which could be imparted to you?

What other skills can you impart to the other workmates?

Can you identify and list any training needs that would help you in meeting the goals of the unit.

What 3 key activities should the unit work to improve over the next 2 years?

Any other comment(s):

RWANDA FDA
Rwanda Food and Drugs Authority

Officer: _____
Name _____ Signature _____ Date _____

To be completed by Assessor

Comment(s):

| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 8 of 13 |

V.J.P



Training Quality Control Laboratory Staff

Recommendation(s):

Assessed
by: _____ Name _____ Designation _____ Signature _____ Date _____

10.2. Appendix B: COMPETENCE EVALUATION FORM(QCL/FOM/027)

| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 9 of 13 |

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|--|--|---|
|  <p>RWANDA FDA Rwanda Food and Drugs Authority</p> | Division: Quality Control Laboratory | Doc. N°: QCL/FOM/027 Revision N°: 0 Effective Date: 24 Aug. 2020 Ref: Doc: QCL/SOP/001 |
| | Doc Title: Competence Evaluation Form | |

Name and position of personnel under evaluation:.....

Laboratory/Area:

| Induction Evaluation | Ongoing Evaluation | Annual Evaluation | Refresher's Evaluation | |
|--|--|---------------------------------|------------------------|---------|
| LEVER OF COMPETENCE | COMPETENCE EVALUATION CRITERIA | | | |
| 1. Competent& can perform independently& is able to assess other staff; 2. Competent & can perform independently; 3. Some experience, may require practice or assistance; 4. Little or no experience. | A. Direct observation B. Monitoring the recording C. Review of intermediate test results, QC records, proficiency test results; D. Assessment of test performance through testing IQC and EQC samples; E. Frequency of carrying out particular parameter; F. Interview; Others(Specify) | | | |
| DATE | CRITERIA USED | TRAINING THEME/EVALUATION THEME | COMPETENCE LEVEL | COMMENT |
| | | | | |
| | | | | |
| | | | | |

Evaluation Done By:

Date

Signature:

.....

Position:

Comment (Optional):

Comment by the evaluated staff:....

Signature: ...

Date:.....

| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 10 of 13 |

U. J.

10.3. Appendix C: STAFF TRAINING RECORD FORM (QCL/FOM/028)

| Name of Officer | | Designation | Employee Number | |
|-----------------|-------------------|----------------------------------|----------------------|------------------------------------|
| Dates(s) | Title of Training | Remarks by Trainer or Supervisor | Signature of Trainee | Signature of Trainer or Supervisor |
| | | | | |
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|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 11 of 13 |



10.4. Appendix D: Document Revision History

| Date of revision | Revision number | Author(s) | Changes made and/or reasons for revision |
|------------------|-----------------|-----------------|--|
| 24 August 2020 | 0 | Felix TUYISHIME | First Issue |
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|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 12 of 13 |

Uif

11. Reference

11.1 Rwanda FDA Quality Control Laboratory Policy Manual

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/>



| | | |
|-----------------------|--------------------------------|---------------------------------|
| Doc. No.: QCL/SOP/030 | Revision Date: 14 August 2020 | Review Due Date: 24 August 2022 |
| Revision No.: 0 | Effective Date: 24 August 2020 | Page 13 of 13 |

