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RWANDA FDA Rwanda Food and Drugs Authority	**Title: Personnel**	

RWANDA FDA QUALITY CONTROL LABORATORY CONTROLLED DOCUMENT Toll free: 9707

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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 Procedure for Testing of equipment 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.

1. Table of contents

Contents

2. Purpase

This procedure describes how the laboratory management does determine and monitor the competence requirements, select, train, supervise and authorize the laboratory personnel in quality control laboratory to perform specific activity

3. Scope

This System procedure applies all quality control laboratory activities

4. Policy

4.1. ISO/IEC 17025:2017 Clause. 6.2

4.2. WHO Good Practices for Pharmaceutical Quality Control laboratories WHO Technical Report Series No 957, 2010, Annex 1; Sections 1.6

5. Definitions and abbreviations

DM: Division Manager
QCL: Quality control laboratory
Induction training:
Is an initial training given to a new staff in Quality Control Laboratory following the recruitment process.
Fresher's training
Means the training provided to the employee in Quality Control Laboratory who has been out of testing services for more than six months
Ongoing training
Is the training provided to the Quality Control Laboratory personnel after induction training in order to maintain the competence required?
Competence
Demonstrate ability to apply knowledge and skills to achieve intended results

6. Responsibility

6.1 Division manager, Designated Quality Management System Officer shall ensure that this SOP is followed.
6.2 All laboratory officer shall implement this S0P
6.3 DM is responsible to determine the competence requirements;
6.4 The Director of Unit is responsible in defining and specifying personnel training requirements in their respective units;
6.5 The Designated Quality Management System Officer is responsible to compile division training needs;
6.6 All Quality Control Laboratory staffs are responsible for the implementation of this procedure;
6.7 All Quality Control Laboratory staff are responsible to update their files following trainings attended, course, completion, workshop attended or any evidence of competence to Designated Quality Management System Officer office

7. Distribution

7.1 Division Manager of Quality Control Laboratory

7.2 Designated Quality Management System Officer
7.3 All laboratory officers
7.4 All laboratory technicians

8. Safety Precautions

NA

9. Procedure

9.1 Development of competence requirements

Competence requirements of each personnel who will carry out testing activities in the laboratory are initially determined based on Quality Control Laboratory staff job profile.

9.2 Personnel Recruitment

The selection and recruitment of the personnel in Quality Control Laboratory is done by Rwanda FDA human resource office and complies with the requirement as described in the presidential order n°144/01 of 13/04/2017 determining modalities for recruitment, appointment and nomination of public servants.

9.3 Personnel Identification and integration

9.3.1 Following recruitment, DM orients and presents the new to staff to the relevant Laboratories and to other Quality Control Laboratory staff whenever possible.

9.3.2 After recruitment, the direct supervisor orients the new recruited Personnel to fill the **Personnel Identification Form (QCL/FOM/024)** (see Appendix A)

9.3.3 The designated Quality Management System Officer keeps the records identifying the personnel and evidence of Qualification in a personnel file.

9.4 Personnel Training

9.4.1 Induction training

9.4.1.1. After orientation of the new staff, the Unit Director prepares the induction training program. The induction training themes where relevant includes but not limited to:

9.4.1.1.1 Structure, Mission and objectives of Rwanda FDA
9.4.1.1.2 Internal rules and regulations for Rwanda FDA;
9.4.1.1.3 Introduction to ISO/IEC 17025 Standard;
9.4.1.1.4 Quality Control Laboratory Manual-6.2
9.4.1.1.5 Quality Control Laboratory - documents (SOPs, Records related to his/her position
9.4.1.1.6 Safety Procedures
9.4.1.1.7 Laboratory environment control;
9.4.1.1.8 Laboratory equipment's; use, operation and functional checks;
9.4.1.1.9 Sample reception and transfer procedures
9.4.1.1.10 Interpretation of test results;
9.4.1.1.11 Reporting test results and Laboratory records keeping and control;
9.4.1.1.12 Sample and waste disposal procedure;

9.4.1.1.13 Basic statistics
9.4.1.1.14 Laboratory management skills
9.4.1.2. The Unit director communicates the training program to the proposed trainers and the personnel to be trained on different themes.
9.4.1.3. The staff undergoing training is supervised until training is completed and competency demonstrated.
9.4.1.4. After training, each trainer evaluates the new staff and submits the filled personnel competence evaluation form (see appendix B) to the DM for final compilation.
9.4.1.5. After evaluation, the new staff is authorized to perform the work according to the evaluation results.
9.4.1.6. The Induction training does not exceed three months after recruitment, however induction training period may be extended to six months depending on performance evaluation results and re – evaluation is done.

9.4.2 Ongoing Competence evaluation

9.4.2.1 Quality Control Laboratory personnel is only authorized to independently perform specific activities such as testing different parameters in various matrices, operating different equipment, verifying and validating methods, interpreting results and reporting after competence evaluation.
9.4.2.2 Competence evaluations are conducted by the immediate supervisor to every staff involved in testing activities to ensure that the personnel have the competence to perform laboratory activities for which they are responsible and evaluate the significance of deviations through different checks. Competence evaluation form is filled.
9.4.2.3 When evaluated staff is not declared competent in certain evaluated parameters, the staff is re-trained and reevaluated until the competence is declared.
9.4.2.4 Based on outcomes of competence evaluation the immediate supervisor prepares and updates the skills matrix (see appendix C) for all Laboratory personnel performing testing services.
9.4.2.5 The filled competence evaluation forms and skills matrix are kept in Designated QMS office.
9.4.2.6 Basing on the performance evaluation, scope extension need, audit outcome, proficiency test results, training needs are identified.
9.4.2.7 The training needs are identified by the Unit Director in collaboration with individual staff and are submitted to Human resource of Rwanda FDA for approval.
9.4.2.8 Designated Quality Management System Officer compiles the division training needs identified and collaborate with DM to come up with the training program before the end of the fourth quarter of the year

9.4.3 Fresher's training

9.4.3.1 Under the supervision of the staff appointed personnel, the staff who has been out of testing services for more than six months undertakes fresher's training basing on the relevant themes.
9.4.3.2 The training theme covers all the activities that he/she is going to undertake.
9.4.3.3 The fresher's period does not exceed one month after which the evaluation to demonstrate competence is done by the supervisor.

9.4.4 Personnel competence performance evaluation criteria

9.4.4.1 Each laboratory has laboratory support document on personnel describing details on competence evaluation criteria, and any other documents that can be taken as evidences for the competence evaluation.
9.4.4.2 maintains all the personnel records pertaining competence evaluation

10. Appendices

Appendix A: Personnel Identification Form (QCL/FOM/024)

Document type: FORM		Doc. Number : QCL/ FOM /024 Revision Number : 1 Revision Date : 01 June 2021 Effective Date : 14 June 2021
RWANDA FDA Rwanda Food and Drugs Authority	**Title: Personnel Identification Form**	

1.Names			
Family Name:			
First Name:			
Middle Name:			
Malden Name, if any:			
2.Date of Birth : Month: Year:	**3.Place of Birth**	**4.Nationality**	**5.Sex**
6.Position:	**7.Section:**		
8. **Knowledge of Languages**			

Languages	**Read**		**Write**		**Speak**		**Understanding**	
	Easy	Not easy	Easy	Nor easy	Easy	Not easy	Easy	Nor easy

9.EDUCATION								
UNIVERISTY	**ATTENDED FROM TO**		**DEGREE AND ACADEMIC DISTINCTIONS OBTAINED**	**MAIN COUSE OF THE STUDY**				
NAME,PLACE,COUNTRY	**M/Y**	**M/Y**						
SCHOOL OR OTHER FORMAL TRAINING OR EDUCATION FROM AGE 14(Eg.High school, technical school or Apprenticeship)								
	ATTENDED FROM TO		**TYPE**	**CERTIFICATES OR DIPLOMAS OBTAINED**				
NAME,PLACE,COUNTRY	**M/Y**	**M/Y**						

Appendix B: Competence Evaluation Form

Document type: FORM		Doc. Number : QCL/FOM/027 Revision Number : 1 Revision Date : 01 June 2021 Effective Date :14 June 2021
RWANDA FDA Rwanda Food and Drugs Authority	**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:..... Signature:.....

Date ....

Position:

Comment (Optional):

Comment by the evaluated staff:

Signature: **Date:**

Appendix C: Equipment Skills Matrix Form

Document type: FORM		Doc. Number : :QCL/FOM/023 Revision Number : 1 Revision Date : 01 June 2021 Effective Date : 14 June 2021
RWANDA FDA Rwanda Food and Drugs Authority	**Title: Equipment Skills Matrix Form**	

Parameter / Equipment personnel name						

X represent: **Not competent**

Approved by DM

Name:
(Signature).....Date

Appendix D: Document revision history

Date of revision	Revision numbe	Author(s)	Changes made and/or reasons for revision
24 August 2020	0	Felix TUYISHIME	First issue
01 June 2021	1	Felix TUYISHIME	Cover page updated

11. References

11.1. ISO/IEC 17025:2017

11.2. WHO Good Practices for Pharmaceutical Quality Control laboratories WHO Technical Report Series No 957, 2010, Annex 1;

11.3. Quality Control Laboratory Quality Manual, clause 4.