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| RWANDA FDA<br>Rwanda Food and Drugs Authority | **Title: Qualification of Quality Control Laboratory equipment** | |

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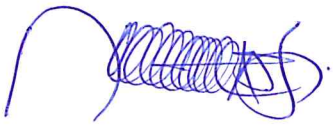
| **SIGNATURE** |  |  |  |
| **DATE** | 24 August 2020 | 24/08/2020 | 24/08/2020 |

**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







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## 2. PURPOSE

To lay down the procedure for qualification of equipment, machines and systems including installation, operational and performance qualification.

## 3. SCOPE

This procedure is applicable for all the equipment, machines and systems installation, Operation and Performance in Quality Control Laboratory.

## 4. POLICY

4.1. The ISO/IEC 17025:2017 Clause 6.4.4, *"The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service"*.

***4.2.*** WHO Good Practices for Pharmaceutical Quality Control laboratories, WHO Technical Report Series No 957, 2010 44th report, Annex 1 part 2: Clause 12.3 stating about *"Calibration, verifi cation of performance and qualification of equipment, instruments and other devices"*.

## 5. Definitions and Abbreviations

5.1. The definitions and abbreviations provided in the QMS/SOP/001 document of Rwanda FDA and QCL/MAN/001 shall be applied.

5.2. **WHO/GLP:** World Health Organization/ Good Laboratory Practice for pharmaceutical quality control laboratories.

5.3. **E.Q**: Equipment/Machine Qualification Protocol

5.4. **IQ**: Installation Qualification

5.5. **OQ**: Operational Qualification

5.6. **PQ**: Performance Qualification

## 6. RESPONSIBILITY

6.1. The Division Manager of Quality Control Laboratory is responsible to approve the SOP for equipment qualification;

6.2. The designated QMS Officer has to review this SOP;

6.3. The supplier of new equipment is required authentic evidence that DQ, IQ, OQ, and PQ have been done to demonstrate that the equipment can be used for its intended use,

6.4. It is the responsibility of laboratory analyst to ensure that DQ has been conducted for the supplied equipment of Quality Control Laboratory, prior to equipment installation and keep records from supplier,

6.5. It is the responsibility of laboratory analyst to ensure that IQ has been conducted for the supplied equipment of Quality Control Laboratory, prior to equipment use for its purpose,

6.6. It is the responsibility of laboratory analyst to keep records in equipment file as evidence that IQ has been conducted,

6.7. It is the responsibility of laboratory analyst to ensure that **OQ** has been conducted for the supplied equipment of **Quality Control Laboratory**, and to ensure that records of OQ are properly kept,

6.8. It is the responsibility of laboratory analyst to ensure that PQ has been conducted for the supplied equipment of Quality Control Laboratory and ensure that records of PQ are properly kept in equipment file,

6.9. Laboratory technicians are responsible to maintain documentation evidence for DQ, IQ, OQ, and PQ in the equipment file.

## 7. Distribution

6.1. This System Standards Operating Procedure (**QCL/SOP/028**) is issued on a control basis.
6.2. Division Manager, Quality Control Laboratory Division have access to tis SOP,
6.3. A QMS shared folder on Rwanda FDA head office server on the following link: (\\rwandafdaserver\qms\sopxxxx)
6.4. Hard copies to staff that have no access to the Rwanda FDA server.

## 8. Safety Precautions

8.1. Always wear gloves and a laboratory coat and/or apron while carrying out all preparations.
8.2. Always use the fume hood chambers when working with hazardous solvents
8.3. Always use the available face masks and splash guards when necessary
8.4. Wear heat resistant gloves when handling hot object or touching the hot surface of measuring equipment;
8.5. Wear also uv-resistant eye goggles when using UV light.

## 9. PROCEDURE

### 9.1. Equipment/System qualification

It should include following:
9.1.1. Design Qualification
9.1.2. Installation Qualification
9.1.3. Operational Qualification
9.1.4. Performance Qualification

### 9.2. Design Qualification (DQ)

9.2.1. DQ defines the functional and operational specifications of the instrument and details the conscious decisions in the selection of the supplier.
9.2.2. DQ should ensure that instruments/system have all the necessary functions and performance criteria that will enable them to be successfully implemented for the intended application and to meet business and regulatory requirements.

### 9.3. Design Qualification should include these steps:

9.3.1. Selection of the technique and/or type of equipment,
9.3.2. Description of the intended environment,
9.3.3. The description of how the instrument will be used in the selected environment and within a process. If the instrument will be used for several applications, describe a few typical scenarios.
9.3.4. Preliminary selection of the supplier.
9.3.5. Final selection of the equipment and qualification of the supplier and equipment.

9.3.6. Discussion and documentation of warranty, Familiarization, Training, Consulting and other vendor services.

9.3.7. Development and documentation of final functional and operational specifications.

9.3.8. Review and approval of user requirement and functional specifications by users of the system and by the Validation Team.

**9.4.Installation Qualification (IQ)**

9.4.1. Installation qualification establishes the documented evidence that the equipment is received as designed and specified that it is properly installed and configured in the selected environment and for the intended application.

9.4.2. Installation qualification should include the following steps:

9.4.3. Check if the environmental and safety conditions, e.g., power condition requirements, meet the criteria as specified for the instrument.

9.4.4. Compare equipment, as received, with the purchase order (including software, accessories, and spare parts).

9.4.5. Check the documentation for completeness (operating manuals, maintenance instructions, standard operating procedures for testing, safety and validation certificate).

9.4.6. Check equipment for any damage,

9.4.7. Install hardware (computer, equipment, fittings and tubing for fluid connections, power cables, data flow and instrument control cables),

9.4.8. Switch on the instruments and ensure that all modules power up and perform an electronic self- test,

9.4.9. Install software on the computer following the manufacturer's recommendation,

9.4.10. Verify correct software installation, e.g., verify that are all files loaded. Utilities to do this should be included in the software itself,

9.4.11. Make a backup copy of the software,

9.4.12. Configure peripherals, e.g. printers and equipment modules,

9.4.13. Identify and make a list with a description of all hardware, including drawings where appropriate,

9.4.14. Make a list of all software installed on the computer with description,

9.4.15. List equipment manuals and SOPs,

9.4.16. Develop Operation and calibration procedures,

9.4.17. Make entries into the equipment logbook,

9.4.18. Prepare an installation report.

**9.5.Operational Qualification (OQ)**

9.5.1. Operational qualification (OQ) is the process of demonstrating that an instrument will function according to its operational specification in the selected environment.

9.5.2. The instrument should be tested against critical performance specifications as specified in the Design Specifications;

9.5.3. Follow the following steps while carrying out operational qualification:
9.5.3.1. Obtain functional and performance specifications (preferably use information from DQ);
9.5.3.2. Identify Critical functions that should be tested in the user environment,
9.5.3.3. Link the test cases to the user requirement and functional specifications as defined in DQ.
9.5.3.4. Develop SOPs for testing,
9.5.3.5. Test procedure should include what to test how testing should be conducted and the expected results with acceptance criteria,
9.5.3.6. Don't use the manufacturer's performance specification limits if the performance is expected to deteriorate over time. Take performance specification as required by the application,
9.5.3.7. Define the frequency of OQ as recommended by the vendor,
9.5.3.8. Define re-qualification criteria and procedures after equipment up-dates, moves and repairs.

**9.6. Performance Qualification (PQ)**

9.6.1. Performance qualification (PQ) is the process of demonstrating that an instrument consistently performs according to the specification appropriate for its routine use.
9.6.2. This gives confidence in the performance of the equipment;
9.6.3. Define test procedures and the performance criteria for the complete system selecting critical parameters.
9.6.3.1. For example, for Chromatographic System the performance parameters are:
9.6.3.1.1. The precision of the amount
9.6.3.1.2. The precision of retention time
9.6.3.1.3. Resolution between two peaks
9.6.3.1.4. Peak width at half height
9.6.3.1.5. Peak tailing
9.6.3.1.6. Limit of detection and
9.6.3.1.7. limit of quantitation Wavelength accuracy
9.6.4. Define the test intervals.



10. **Appendix**

**10.1. Document Revision History**

| Date of revision | Revision number | Author(s) | Changes made and/or reasons for revision |
|---|---|---|---|
| 24 August 2020 | 0 | Felix T. | First Issue |
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11. **REFERENCE**:

**WHO/GLP** For Pharmaceutical Quality Control Laboratories,