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1.0 PURPOSE:

To lay down the procedure for the qualification of equipment and to provide a high degree of assurance that the equipment meets all the design and installation specifications, Operates under the requisite conditions and perform consistently.

2.0 SCOPE:

This procedure covers all the new equipment being procured and installed at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

- 3.1 User department head shall ensure that new equipment is qualified before usage in manufacturing process.
- 3.2 It is the responsibility of Engineering Department is responsible to prepare and execute the Qualification protocol of DQ, IQ & OQ.
- 3.3 It is the responsibility of concerned user to prepare the Performance Qualification Protocol and report and get it approval from QA.
- 3.4 It is the responsibility of Quality assurance to review and approve the Equipment Qualification protocols and reports.


4.0 DEFINITIONS:

Qualification: Action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation.

Design Qualification (DQ): documented verification that the proposed design of the facilities, equipment, or systems is suitable for the intended purpose.

Installation Qualification (IQ): documented verification that the equipment or systems, as installed or modified, comply with the approved design, the manufacturer's recommendations and/or user requirements.

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Operational Qualification (OQ): documented verification that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges.

Performance Qualification (PQ): documented verification that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications.

Site Acceptance Test (SAT): Inspection and/or dynamic testing of systems or major system components to support the qualification of an equipment system conducted and documented at the manufacturing site.

Factory Acceptance Test (FAT): is a process that evaluates the equipment during and after the assembly process by verifying that it is built and operating in accordance with design specifications.

5.0 PROCEDURE :

5.1 The Equipment shall be qualified / validated before intended use.

5.2 User department shall provide the User requirement specification to purchase / fabricate the equipment.

5.3 User Requirement Specification:


5.3.1 In case of specific condition, protocol shall be prepared by user department as per the defined format by incorporating all requirements.

5.3.2 The user requirements shall be specified by the user department in association with the engineering department in a current version of QA027-FM037.

The details of URS shall be classified into the following sections.

- Functional requirements required for the process.
- Utilities and supporting functional requirements.
- Specific process requirements where and when applicable.
- Safety requirements.

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e. Document requirements.

5.3.3 In case of proprietary equipment procurement URS is not required.

5.4 Design Qualification

5.4.1 Design qualification shall be carried out by pre approved protocol and report shall be prepared once the equipment fabrication is completed.

5.4.2 Purchase shall raise purchase order to design and fabricate the equipment as per Discovery labs URS.

5.4.3 The equipment manufacturer shall prepare the design specifications of the equipment as per URS.

5.4.4 The equipment manufacturer shall provide the design specification data, which prepared based on the URS and the same shall be reviewed and approved by Engineering personnel of Discovery labs in coordination with user department.

5.4.5 The equipment manufacturer shall fabricate the equipment as per approved design data and shall provide all necessary documents to support the fabrication.

5.4.6 Factory Acceptance Test (FAT) shall be carried out at manufacturer premises before dispatch of the equipment. The details shall be recorded.

5.4.7 On receipt of the equipment at site, Engineering personnel shall check the equipment and ancillary systems and documentation received is as per the PO using Site Acceptance test (SAT) check list (SAT shall be prepared to respective equipment same shall be qualify)


5.4.8 The design qualification report shall be prepared based on verification of fabrication data against design data, documents and equipment.

5.4.9 Equipment shall be provided with unique identification number for further use.

5.4.10 The report shall be reviewed and shall be approved by Quality assurance.


5.5 **Installation Qualification (IQ):**The installation qualification shall be carried as follows:

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- 5.5.1 Once the Design qualification is completed, the installation shall be carried out by using pre approved protocol.
- 5.5.2 The Installation qualification protocol shall be prepared by engineering personnel and shall be approved by Quality assurance.
- 5.5.3 Along with protocol, checklists shall be prepared for qualifying the respective equipment and ancillary systems by using comprehensive checks along with acceptance criteria, where all aspects of equipment are systematically examine for its completeness.
- 5.5.4 The checks shall include the verification of all the equipment components and ancillaries receipt and installation with the following, but not limited to:
- 5.5.4.1 Equipment name, model number, equipment identification number.
 - 5.5.4.2 List of services to be connected and acceptance criteria.
 - 5.5.4.3 Equipment installation location, signature of the person carried out installation.
 - 5.5.4.4 Confirmation of maintenance manual, if any.
 - 5.5.4.5 Spare parts list, if any.
 - 5.5.4.6 Details of lubricants used, if any.
 - 5.5.4.7 Verification of the services.
 - 5.5.4.8 Safety features.
 - 5.5.4.9 Drawings/ Manuals.
 - 5.5.4.10 Instruments to be connected.
- 5.5.5 The IQ study shall be carried by using the equipment qualification check points.

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5.5.6 Once the equipment is installed and verified all checks along with documents, report shall be prepared by concluding the qualification status of respective equipment and the report shall be approved by Quality assurance.

5.5.7 Once the report is verified and approved, operation qualification shall be carried out.

5.6 Operational Qualification (OQ):

5.6.1 In this phase of Qualification, it is intended to check whether the equipment is operating as per the equipment manual specifications and whether this is meeting the PO requirements.

5.6.2 Once the Installation qualification is completed, the operation qualification shall be carried out by using pre-approved protocol.

5.6.3 The qualification protocol shall be prepared by engineering personnel and shall be approved by Quality assurance.

5.6.4 Along with protocol, checklists shall be prepared for operation verification of respective equipment and ancillary systems by using comprehensive checks along with acceptance criteria, where all aspects of equipment are systematically examine for its function.

5.6.5 Calibration of master instrument / gauge shall be ensured before carrying out the calibration of ancillary systems.

5.6.6 The checks shall include the verification of all the operating parameters and its acceptance criteria:

5.6.7 The operational qualification documentation shall include, but not limited to:


5.6.7.1 Calibration procedure including limits

5.6.7.2 Reference to the manual/ national/ compendia standards

5.6.7.3 Operational parameters

5.6.7.4 Acceptance criteria as per manual and design specifications.

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5.6.7.5 Operational runs across the entire operating range, and signature (s) of the person who operated the equipment.

5.6.7.6 Operational results

5.6.7.7 Conclusions

5.6.7.8 training records (if applicable)

5.6.8 If the equipment operates within the specified operational parameters and tolerances the equipment shall be operationally qualified.

5.6.9 The results/ outcome of the qualification study shall be recorded in the equipment qualification checklists and the same shall be approved by Quality assurance.

5.6.10 After carrying out the installation and operational qualifications, the equipment shall be handed over to user.

5.7 Performance Qualification (PQ):

5.7.1 In this phase of Qualification, it is intended to check whether the equipment is performing as per the user requirement specifications.

5.7.2 Once the Operational qualification is completed, the performance qualification shall be carried out by using pre approved protocol.

5.7.3 The qualification protocol shall be prepared by user and shall be approved by Quality assurance.


5.7.4 User shall prepare a protocol with the below requirements:

5.7.5 The activities to be carried out with respect to PQ shall be defined.

5.7.5.1 The number of tests/ challenges and trial runs to be carried out for the purpose of qualification/ validation shall be repeated sufficient number of times to assure reliability and reproducibility.

5.7.5.2 The equipment material of construction suitability against the reactions / chemical proposed to use in the respective equipment.

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5.7.5.3 Description of test/ challenge

5.7.5.4 Number of test/ challenges conducted, number of trials performed.

5.7.5.5 Results of the tests/ challenges, signature of the person(s) performed trials

5.7.5.6 Conclusions.

5.7.6 The results shall be tabulated after the trials are carried out and then compared against the pre-set parameters.

5.7.7 If the results obtained are in accordance with acceptance criteria, it shall be concluded that the equipment is performing satisfactorily and hence qualified for regular use.

5.7.8 If any test/ Challenge shows that the equipment does not perform as per the specification, an investigation shall be carried out as per deviation SOP and appropriate actions shall be taken.

5.7.9 Report on performance qualification shall be prepared and shall be approved by Quality assurance.

5.8 QA shall conclude from the Installation & Operational and Performance Qualifications whether the equipment is qualified to carry out its specific functions.

5.9 **Re- Qualification:**

The existing qualified equipment shall be re-qualified as per the above procedure by following the re-qualification checklists when they are transferred/shifted to other area or whenever major changes takes place.

5.10 The Re-Qualification frequency time line 5 years \pm 3 months.


5.11 The Qualification protocols shall have following data, but not limited to:

5.11.1 Purpose

5.11.2 Scope

5.11.3 Responsibilities

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5.11.4 Definition

5.11.5 Procedure

5.11.6 Acceptance criteria

5.11.7 Deviations

5.11.8 Summary and conclusions

5.11.9 Attachment

5.12 The qualification protocol and report numbering system as follows:

XXZ/NNNN/YYSSS

Where :

XX Indicates type of protocol i.e. **DQ** for Design qualification; **IQ** for Installation Qualification; **OQ** for operational Qualification; **PQ** for Performance qualification.

Z indicates type of document i.e. **P** for Protocol; **R** for Report

NNNN indicates Equipment number / Tag number (for DQ)

YY indicates the last two digits of year

SSS indicates sequential number i.e. 001, 002, 003 which starts from each calendar year

Example:

Protocol number --IQP/RV040/19001

Report number – IQR/RV040/19001

5.13 The numbering system for URS as follows:

URS/NNXX/YYSSS

Where

URS indicates User requirement specifications


NN indicates equipment name / code i.e. for reactor RV

XX indicates Material of construction SS for stainless steel; GL for glass lined

YY last two digits of the year

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SSS sequential number

Example: URS/RVSS/19001


- 5.14 Engineering department personnel shall ensure that the equipment is included in the master equipment list and in calibration and/or preventive maintenance schedules (where applicable) and QA shall record the changes in the change request form.
- 5.15 If the equipment is used for process validation of any process, the same validation data shall be considered as equipment performance.
- 5.16 In case of procurement of proprietary equipment like Quality control testing instrument, design qualification is not required to be carried out. The Installation and Operational Qualifications shall be carried out based on equipment manual.
- 5.17 In case of equipment / instrument qualification (IQ & OQ) is to be done by the vendor, the certification for qualification of the equipment shall be taken from the vendor.
- 5.18 Performance qualification shall be carried out as per instrument specific as defined in the manual and / or in-house procedures.
- 5.19 The utility equipment shall be qualified based on vendor documents and its preventive maintenance / calibration shall be performed on frequent basis.
- 5.20 If any additional testing is required as part of qualification, third party assistance shall be taken and the same shall be recorded in the respective qualification / calibration document.

6.0 FORMATS/ANNEXURE(S):

- 6.1 User Requirements Specifications : QA027-FM037
- 6.2 Protocol template : QA027-FM038
- 6.3 Report template : QA027-FM039

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7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	24.01.2011	New SOP is introduced	--
01	01.01.2014	Formats are changed	--
02	26.04.2017	1. SOP format changed make to inline with SOP-QA-001-05. 2. Altogether procedure has been rephrased for better clarity.	CCF/GEN/17013
03	30.05.2019	1. The Qualification procedure detailed with inclusion of pre-approval requirement of protocols and acceptance criteria for qualification parameters. 2. Formats are merged as single template, Protocol numbering and URS numbering system redefined. 3. Procedure elaborated with more clarity	CCF/GEN/19005
04		5.10 The Re-Qualification frequency time line 5 years \pm 3 months.	

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