

Validation of Equipment

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Validation is a process by which a high degree of assurance is generated and documented that a facility, process, piece of equipment or assay is appropriate for its intended use.



Basic Protocol for Equipment Validation

- Establish an Evaluation Team
- Assign Responsibilities
- Establish User Requirements
- Select and order
- Confirm delivery and verify installation
- Establish “in situ” that the equipment has the capability of operating within specifications.

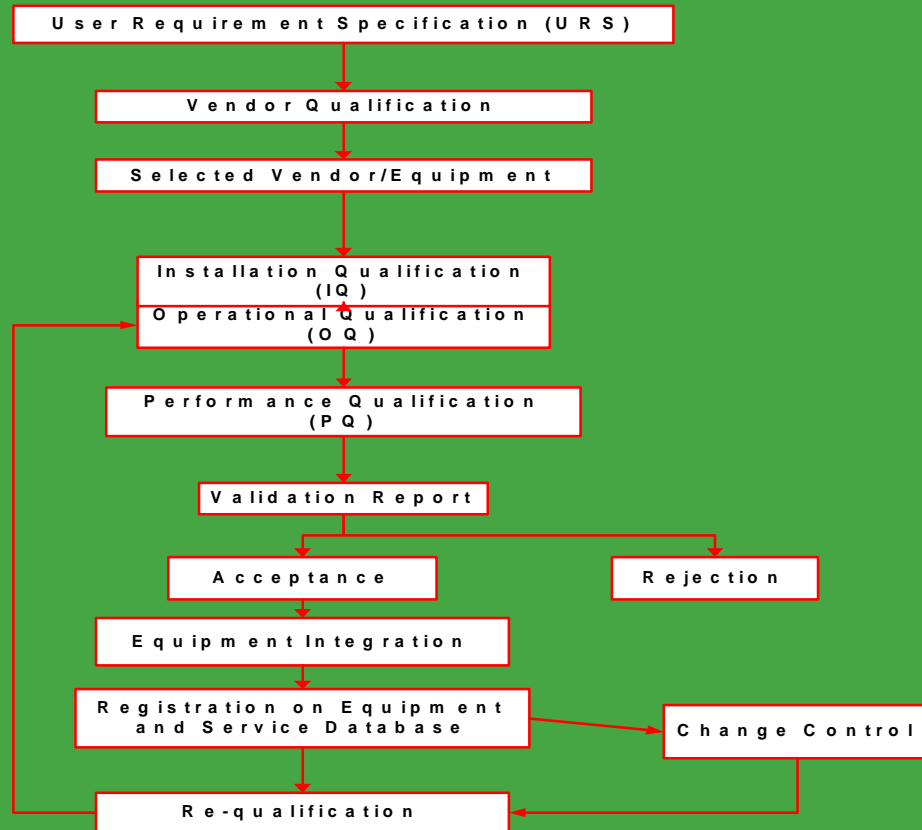


Basic Protocol for Equipment Validation

- Perform protocols to ensure that the equipment consistently meets predetermined specifications.
- Accept or Reject
- Monitor the equipment during routine operations
- Re-qualify as required.



Equipment Validation Sequence



User Requirement Specification (URS)

A document stating the specific user requirements for a selected piece of equipment including training requirements, safety, repair, maintenance etc.



User Requirement Specification (URS)

- Functional and Operational Requirements
- Documentation Requirements
- IT Requirements
- Environmental Requirements
- Training Requirements
- Health and Safety Requirements
- Quality Requirements
- Validation Requirements
- Provision of Aftercare
- Cost



Vendor Selection

Develop a vendor qualification questionnaire

- Has the vendor a certified quality system?
- Does the vendor provide assistance in equipment installation, qualification, maintenance and repair?
- Is there a customer feedback system for problems or change requests?
- Is there a change control system to notify users?
- How long have they been suppliers of the relevant equipment?
- Request a list of current users



Equipment and Supplier Selection

- Review completed URS and Vendor Questionnaire
- Scoring system
- Select the supplier and equipment

Prior to installation:

- Verify correct environmental conditions by arranging a site visit with engineer
- Installation and operational qualification protocols



Installation Qualification (IQ)

Installation Qualification establishes that the equipment is supplied as specified and installed in the selected environment and that this environment is suitable for the operation and use of the instrument.



Installation Qualification (IQ)

- Prepare an Equipment Installation Checklist
- Check the equipment for damage
- Verify specified documentation is supplied (operating manuals, maintenance instructions, FAT results, procedures for testing, safety certificates,)
- Verify receipt of ancillary equipment (UPS, barcode scanner, PC)
- Verify correct installation by the engineer (check tubing connections, power cables etc)

Record model and serial no, software version



Installation Qualification (IQ)

- Switch on the instrument and ensure it powers up
- Engineer performs self test
- Install relevant software
- Configure printers etc
- Record signatures of personnel involved in IQ
- Record Deviations
- Indicate Acceptance/rejection



Operational Qualification (OQ)

Testing the equipment '*in situ*' to ensure that the equipment will function according to its operational specification



Operational Qualification (OQ)

- Procedures are performed (by engineers or sub-contractors) as per manufacturers detailed method
- Calibration of test parameters with calibrated reference instruments (time, temperature, volume verification, wavelength)
- Record the details of the test instruments and verify calibration status
- Perform functional tests
- Verify user specific requirements (barcode reader verification for specific barcode, use of specific tubes, interface to specified LIS)
- Record signatures of personnel involved in OQ
- Record Deviations
- Indicate acceptance/rejection



Performance Qualification (PQ)

Performance Qualification is the process of demonstrating that the instrument consistently performs according to a specification appropriate for its routine use

- Validation of the appropriate test method including additional interfaces
- Comparative or parallel studies



Validation Report

- Protocols(external/internal)
- User Requirement Specification, Vendor Qualification
- IQ checklist and associated documents
- OQ and PQ results associated documents
- Non conformance records
- Conclusions
- Report signed off
- Statement confirming acceptance/rejection
- Payment



Equipment Acceptance

Registration on Equipment Database

- In-house identifier/asset no
- Name of equipment
- Model & serial no.
- Suppliers name, address, no. for service/repair calls
- Date of Purchase
- Date placed in service
- Current location
- Cost

Registration on Maintenance Database

- Type of contract
- Date PM/Calibration
- Engineer's Reports



Re-qualification

Re-qualification is repetition of the validation sequence or a specific portion of it(OQ)

- Maintenance
- Significant Change
- Major Non-conformance



Equipment Validation Sequence

