1 Purpose

The purpose of this Guideline is to provide guidance on qualification of laboratory equipment within R&D.

2 Scope and Applicability

This Guideline is applicable to analytical equipment, and its operating software, used for GMP activities in R&D laboratories focusing on Commercial Off The Shelf Instruments (COTS).

3 Definitions

3.1 Analytical Equipment Qualification

Analytical equipment qualification is the collection of documented evidence, which demonstrates that specific equipment performs suitably for its intended purpose.

3.2 Commercial off The Shelf Systems (COTS)

Tried and tested equipment with a broad spectrum of commercial users supplied by a manufacturer / vendor to an already available design / specification.

3.3 Complexity

For the purposes of this document complexity refers to the technical complexity of the system, mechanically or in the software used as part of the system. The more complex, the more tests may need to be run to determine that the functionality works as intended.

3.4 Operational Qualification (OQ)

A process, which ensures that, the equipment as installed, operates according to the specification.

3.5 Performance Qualification (PQ)

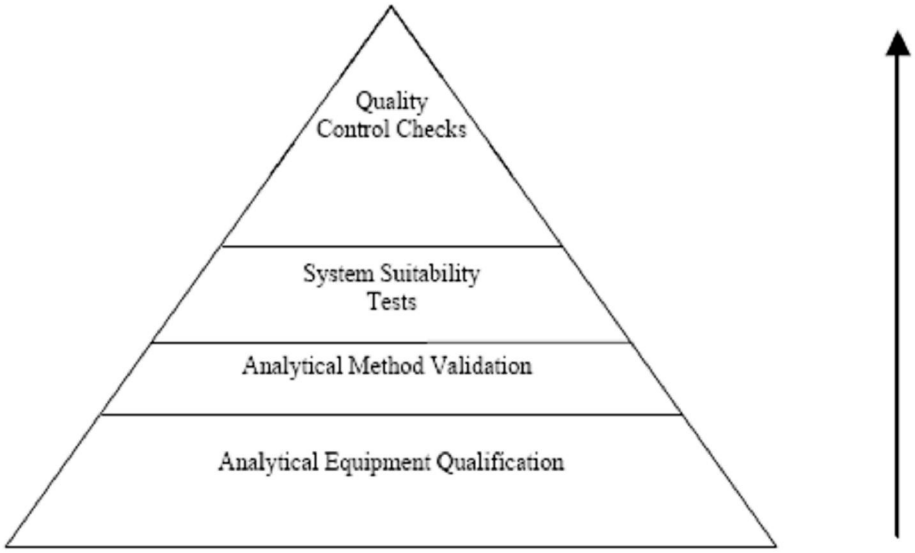
A process, which ensures/verifies the equipmentôs continued suitability for its intended use.

3.6 Quality Control Checks

In addition to calibration or standardizations, some analyses also require the inclusion of quality control check samples to prove an in-process or ongoing assurance of the analytical procedureôs suitable performance.

3.7 System Suitability Test

There are four critical components involved in the generation of reliable and consistent analytical data. The diagram below shows these components as layered activities within a quality triangle. Each layer adds to the overall quality of the data.



Analytical equipment qualification forms the foundation / base of these layered activities. This document considers the various activities, which demonstrate analytical equipment qualification.

5.2 Analytical Equipment Qualification

Analytical equipment qualification is the collection of documented evidence, which demonstrates that specific equipment performs suitably for its intended purpose.

Qualification is a logical step-wise process, which generally consists of the following stages:

- User Requirement Specifications and/or Design Qualification
- Installation Qualification
- Operational Qualification
- Performance Qualification

The amount of documentation and level of detail may vary depending upon the criticality to GMP and complexity of the new or modified equipment.

5.3 Overall Quality of Generated Data

The overall quality of generated data following analytical equipment qualification is controlled by:

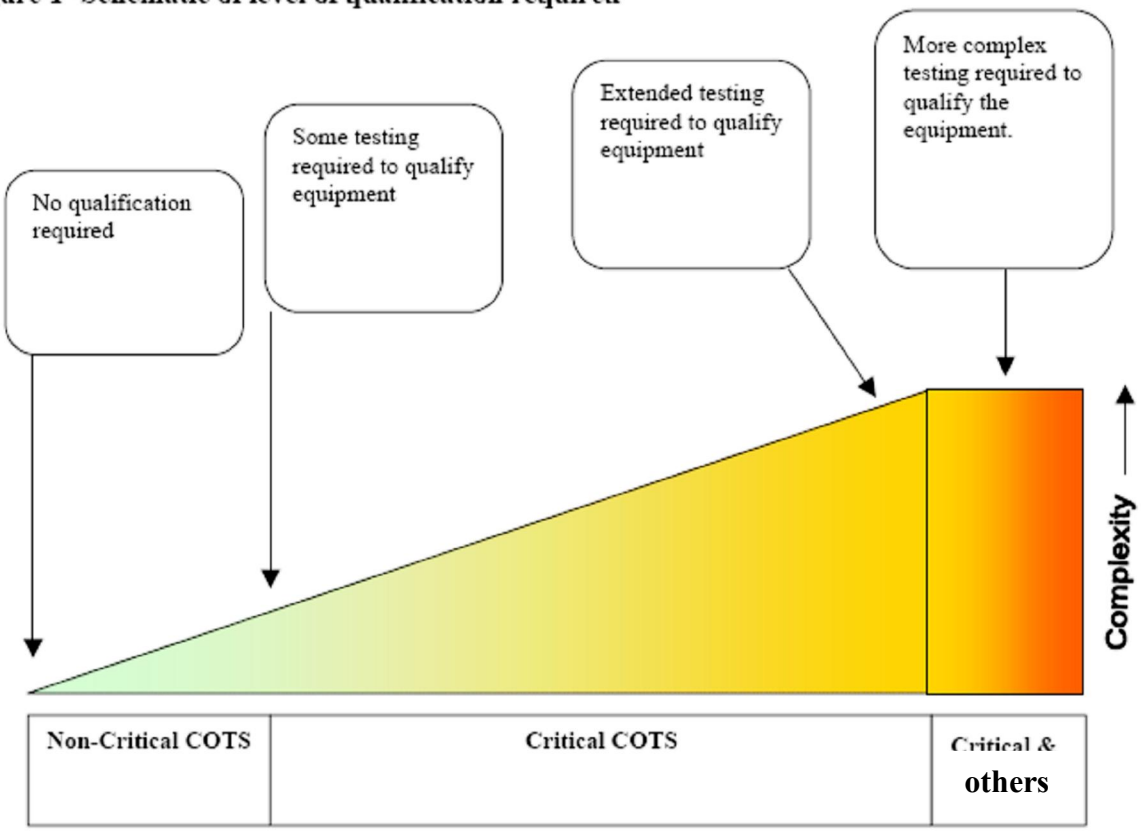
- Analytical Method Validation
- System Suitability Tests
- Quality Control Checks

As such they will always require the highest level of qualification for both the hardware and software. And a greater reliance on internal documentation to define the criteria and limits required.

5.4.2 Level of Qualification

The level of qualification for each type of equipment can be summarized as shown in Figure 1

Figure 1- Schematic of level of qualification required



No Qualification Documents	Company documents but relying on contractor qualification documents, if appropriate	Company documents

5.5 Qualification Phases

Qualification is a logical step-wise process; which may be risk assessed but which generally consists of the stages below. The outcome of all these stages must be summarized and reported(as a single document/report).

- The work required to perform the qualification and the acceptance criteria must be outlined in measurable terms in a protocol/plan.
- A qualification protocol/plan for each type of equipment must be

The extent of OQ testing any particular analytical equipment undergoes depends on the intended application and the type of equipment. Therefore, no specific OQ tests are cited here. As a guide to the type of tests to be considered during OQ the following are examples of tests, which may be undertaken for an HPLC system:

- Pump Flow
- Gradient Linearity
- Detector wavelength accuracy, linearity, drift and noise
- Injector repeatability

The successful completion of the operational qualification will normally be sufficient to confirm the correct operation of any installed operating software as indicated in GAMP 4.

As already stated in Section 5.5 a single operational qualification plan may be used for multiple purchases of the same type of equipment. The amount of qualification tests for subsequent purchase of the same type of equipment may be reduced. The option to carry out reduced testing must be included in the original plan. However, if modifications are required to an already approved plan, then a reduced document outlining the changes must be produced and approved by R&D QA as stated in section.

5.5.4 Performance Qualification (PQ)

Performance qualification provides documented verification that the analytical equipment function as intended and produce results repeatedly and reliably.

For commercial off the shelf equipment PQ may be satisfied by calibration, system suitability tests and the routine maintenance of the analytical equipment (GAMP categories from A to E)

For more complex equipment (GAMP Category F) more detailed PQ testing (e.g. a PQ program recommended by the system vendor) may be appropriate. In these circumstances it may be appropriate for scheduled preventative maintenance of the system to comprise full or partial execution of the PQ program.

The initial PQ should be included in the report outlined in section 5.5, and a record of all subsequent PQ/preventative maintenance should be collated.

5.6 Replacement of Modules

Within a modular system, individual modules may be changed from time to time. (i.e. a detector in a HPLC). In these cases only the module, which has been replaced, requires additional OQ. If the system is already covered by an OQ plan then that part of the plan should be used. If the replacement module has already been qualified then a system suitability test may be sufficient and it is not required that a new plan is written. For more complicated systems (COTS) it may be appropriate for scheduled preventative maintenance of the system to comprise full or partial execution of the PQ program.

