6.C.5 SOP – "Qualification of facilities and equipment"

Each company should define their own specific qualification sequence in an SOP. One of many possible options is shown on the following pages.

Company name	Logo
Operating procedure	SOP no.
Title **Qualification of facilities and equipment**	Valid from
	Page x of y
	Facilities
	Replaces SOP no.
Binding for • Purchasing • Production • Quality control • Quality assurance	
For information to	
compiled by	
checked by	
approved	
Change index New compilation	

1 Introduction

Background/objectives
The qualification should verify that facilities and equipment used for manufacturing and testing are suitable for their intended purposes and that the required quality of the medicinal products manufactured can be guaranteed. Qualification is, thus, a basic factor for drug product quality and safety.

The SOP describes the general qualification procedure.

Other relevant rules and regulations
EU GMP Guideline 3.3.4 – equipment must be suitable.
Annex 15 to EU GMP Guideline
PIC/S PI 006 – qualification, validation and cleaning validation recommendations
Commission Directive 91/356/EEC of 13 June 1991 to define basic principles and guidelines of good manufacturing practice for medicinal products for human use, Chapter II Basic principles and guidelines of good manufacturing practice, Article 8.3 3.

United States 21CFR Parts 210 and 211 (Code of Federal Regulations) and Guideline on General Principles of Process Validation.

Definition

Note: While the specific definitions vary between the United States and the EU, the general intent is related closely, and therefore any variations between the countries or regions are considered insignificant unless otherwise noted for the purposes of this chapter.

Qualification
Documented evidence that facilities and equipment operate faultlessly and also produce the expected results is established. Qualification is a multi-stage process consisting of the following parts:

Design Qualification (DQ)
Documented evidence that the requirements for facilities and equipment assessed in the planning phase by the future operator (*user requirements)* are fully taken into account in the supplier's specification (technical specification).

User requirements
A summary of all contract giver requirements in relation to the scope of supply and services.

Technical specifications
A description of the implementation of all user requirements (specifications).

Installation Qualification (IQ)
Documented evidence that facilities and equipment satisfy the requirements of the design qualification in terms of identity, installation, conformity with the guidelines and documentation.

Operational Qualification (OQ)
Documented evidence that the equipment/facility is functioning correctly within the specified parameters. The operational qualification is carried out without the product.

Performance Qualification (PQ)
Documented evidence of the correct interaction of all facility and equipment components with the relevant process. This qualification phase is considered separately and is carried out by the user.

Scope and responsibilities

Person responsible for qualification
This person ensures the qualification of equipment within his area of responsibility. He appoints a qualification task coordinator and a qualification team, and also confirms that each qualification step has been concluded.

Qualification coordinator
This person coordinates the tasks of the qualification team and also compiles qualification protocols and reports.

Qualification team
The team members are staff who have specialist qualifications with regard to the technical functions; or, where computerized systems are the subject of the qualification, have specialist qualifications with regard to the relevant IT function. External companies may also be part of the team.

Quality assurance
Qualification protocols and reports are checked to verify their compliance with the rules of the quality assurance system and subsequently approved.

2 Implementation

Procurement of the equipment to be qualified is carried out by qualified suppliers.

A prospective qualification must be carried out for all new facilities and equipment. Existing equipment that is already in operation must be qualified retrospectively.

Each qualification is based on a risk analysis during which the critical parameters of the facility and the environmental conditions are observed.

The qualification scope may be confined to the operational qualification in the case of basic production and analysis equipment (e.g. pH meter or balance) and a risk analysis may be omitted.

The contents of the user requirements and technical specification may be used as the basis for the design qualification.

The technical specifications describe the purpose of the equipment and the requirements in relation to technical data and conditions

- Construction and workmanship,
- accessories and spare parts,
- physical and chemical parameters,
- operation and cleaning,
- safety at work,
- customer service,
- starting materials and products,
- sampling

as well as scheduling and regulatory requirements.

Changes to the requirements are monitored by a uniform change control system during the process. A requalification is required as a result of quality-relevant changes.

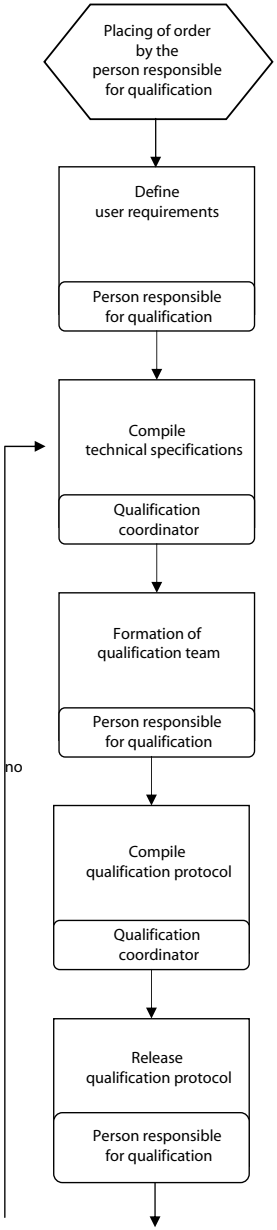
The required specification describes the conversion of the equipment requirements, as defined in the user requirements, into checkable technical specifications.

The qualification is carried out and documented in the aforementioned sequence. Each qualification step is followed by a formal confirmation that the necessary qualification work has been properly completed.

Training and instruction of the operating personnel is carried out in a timely manner and is documented.

Once the qualification has been successfully completed and the equipment and facilities approved by the persons responsible for qualification, the handover is made to the user, who in turn provides confirmation.

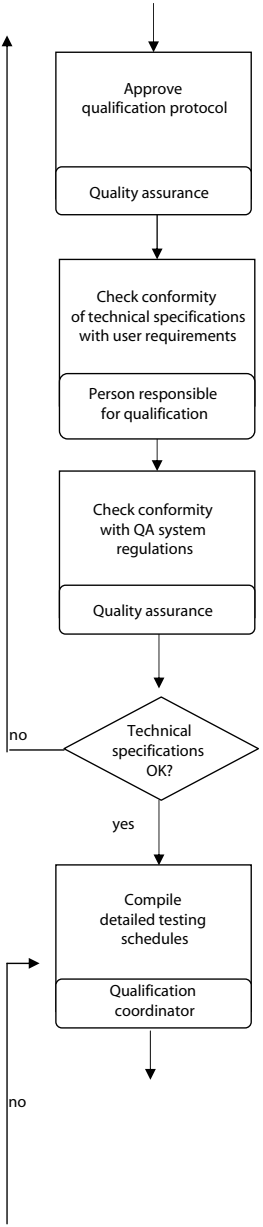
Flow chart
(See figure 6.C-8.)



The qualification protocol contains:

- Names of the persons responsible
- Responsibilities
- The objective of the qualification including scheduling
- Description of the equipment to be qualified and the qualification activities
- List of the necessary directions

Figure 6.C-8 Flow chart

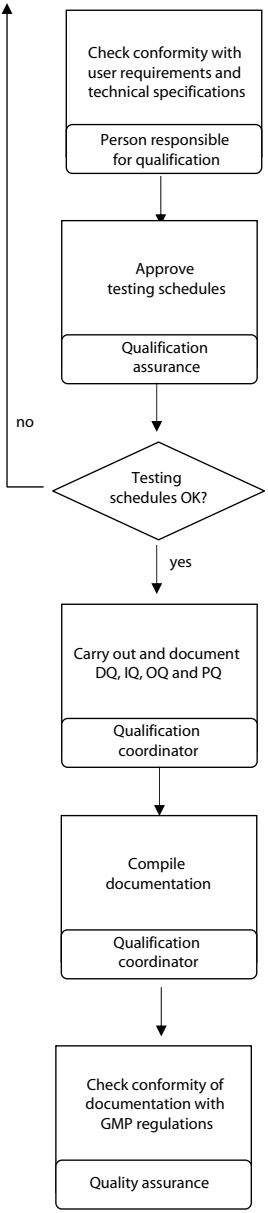


The testing schedules are based on the user requirements and the technical specification.

Evidence of compliance with the user requirements and the technical specification is provided by the test and calibration protocols.

The test and calibration documents are prepared.

Figure 6.C-8 Flow chart (cont.)



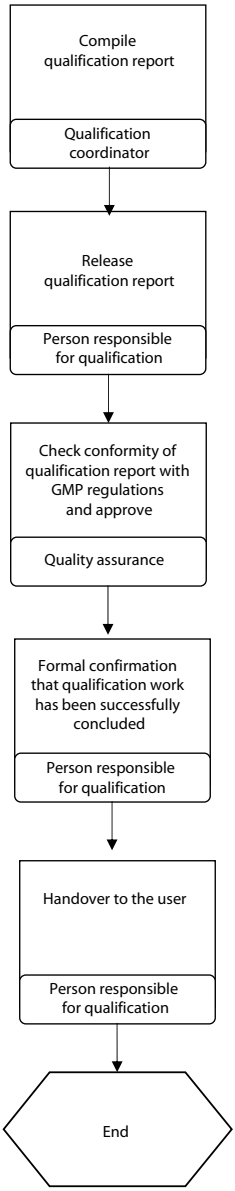
Necessary documentation:

- Risk analysis
- User requirements
- Technical specifications
- Qualification plan
- P&I diagrams, design drawings and bills of materials
- Description of the components
- Spare parts list
- Training documentation
- SOPs, directions for cleaning, operating instructions
- Maintenance and calibration instructions
- Checks required by law
- Qualification report
- Handover protocol

Necessary documentation for equipment that is already in operation:

- User requirements
- Qualification plan
- Description of the technical equipment
- Training documentation
- SOPs, directions for cleaning, operating instructions
- Maintenance and calibration instructions
- Log book
- Checks required by law
- Qualification report

Figure 6.C-8 Flow chart (cont.)



Minimum requirement for documentation of basic equipment used for production and tests:

- Risk analysis
- Description of the supply scope
- Training documentation
- SOPs, directions for cleaning, operating instructions
- Qualification report
- Maintenance and calibration instructions/protocols

The qualification report should at least contain the following:

- Names of the persons responsible
- Designation of the equipment
- Overall evaluation of the tests carried out
- List of measures still to be carried out including designation of responsibilities and scheduling

Figure 6.C-8 Flow chart (cont.)

Revision

Once the qualification status has been achieved, it is subsequently checked and evaluated every three to five years independent of the implementation of necessary requalification measures: the resulting measures and results are documented. United States regulators expect a documented quality assurance system and program to exist, which establishes the circumstances under which a revalidation or qualification should be performed. There is no specific predetermined period specified.

Documentation and storage

Once the qualification report has been approved, the qualification status of the equipment is labeled by inserting a qualification mark and comment in the log book.

The documentation should be retained for at least five years after the facility or equipment has been shut down or for at least the period established by local laws or regulations.

Summary

The qualification documentation consists of qualification protocols with acceptance criteria that have been defined and approved in advance, and qualification reports with the results and a final evaluation.

The qualification master plan is a management instrument used to monitor all qualification activities at a company: it lists the tasks to be carried out together with the responsibilities and schedules.

The general sequence is laid down in a qualification SOP.