Qualification of Pharmaceutical Production Equipment

Learning objectives

Students will be able to:

- Gain a comprehensive understanding of the significance of equipment qualification in pharmaceutical manufacturing.
- Distinguish between the processes of qualification and validation.
- Apply the knowledge of qualification stages.

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1. Introduction

Production equipment is the main link between raw materials and the final product. Equipment must be installed, operated, and maintained within design specifications

Raw Materials > Equipment > Final Product

Qualification of equipment is an essential part of good manufacturing practice (GMP) and is required by regulatory authorities such as the FDA and the EMA. By ensuring that equipment is properly qualified, pharmaceutical manufacturers can help to ensure the safety, efficacy, and quality of their products.

2. Qualification vs Validation

Qualification and validation are complementary processes.

- Qualification is essential for ensuring that the equipment, facility, utility or system is capable of performing as intended.
- Validation is essential for ensuring that the process does what it is supposed to do.

3. Qualification stages

In the pharmaceutical industry, and according to GMP's annex 15, the V-cycle method is pivotal for design and qualification steps, ensuring a systematic approach. This model follows a 4Q sequence:

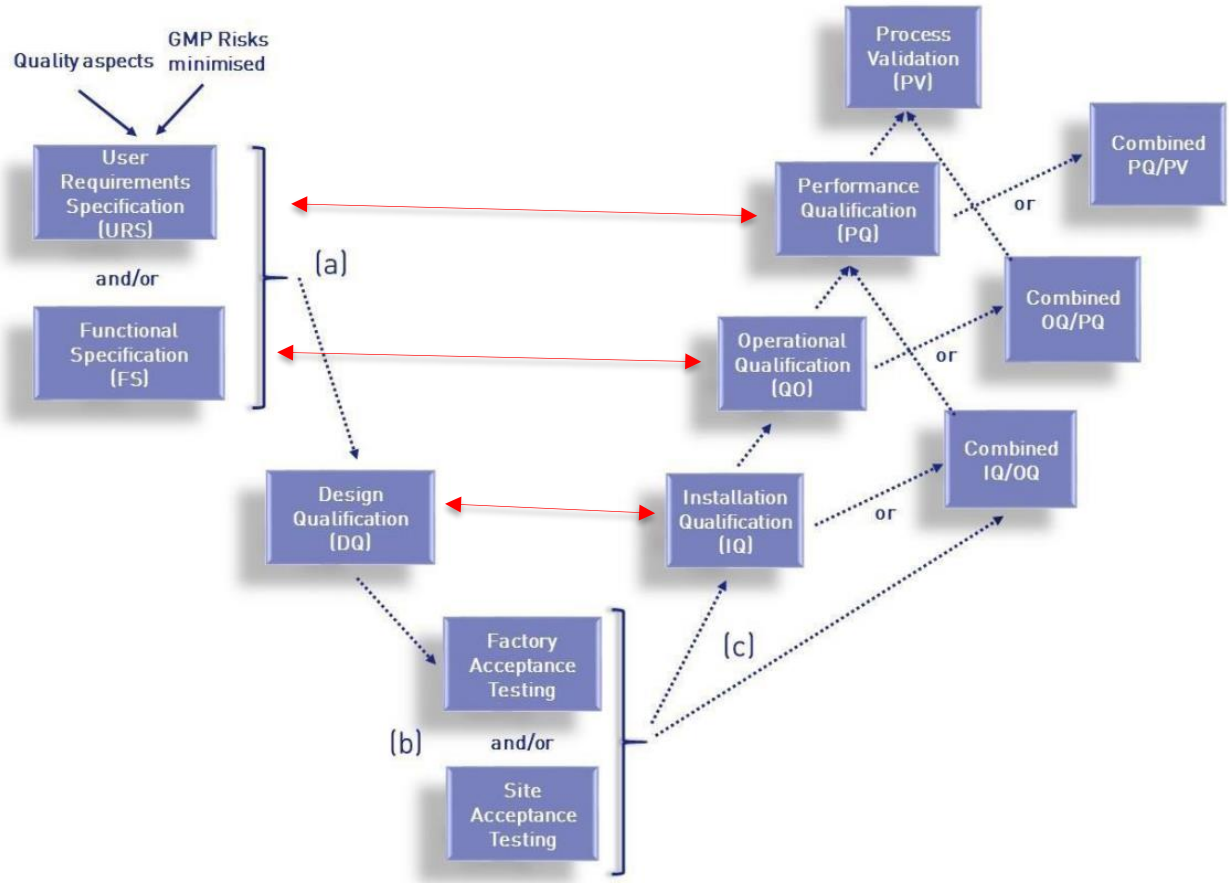
- Design Qualification (DQ),
- Installation Qualification (IQ),
- Operational Qualification (OQ),
- Performance Qualification (PQ),

Every sequence is composed of:

- protocols,
- tests,
- reports.

It enforces a structured process of "write what we should do, do what we wrote, and write what we did." Qualification activities must span from defining user requirements to the final use of equipment, facilities, utilities, or systems, promoting comprehensive traceability and stringent quality control.

The main stages are as follows:



2.1. User Requirements Specification (URS)

URS is the set of owner, user and engineering requirements necessary and sufficient to create a feasible design meeting the intended purpose of the system.

- Quality elements integrated.
- Mitigation of GMP risks.
- URS is the reference throughout validation.

2.2. Design Qualification (DQ)

DQ assesses the design of the equipment to ensure that it meets the requirements of the manufacturing process and the product specifications.

- Demonstrates design compliance with GMP.
- Verification of URS requirements during DQ.

2.3. Factory Acceptance Testing (FAT) / Site Acceptance Testing (SAT)

Equipment evaluation at the vendor.

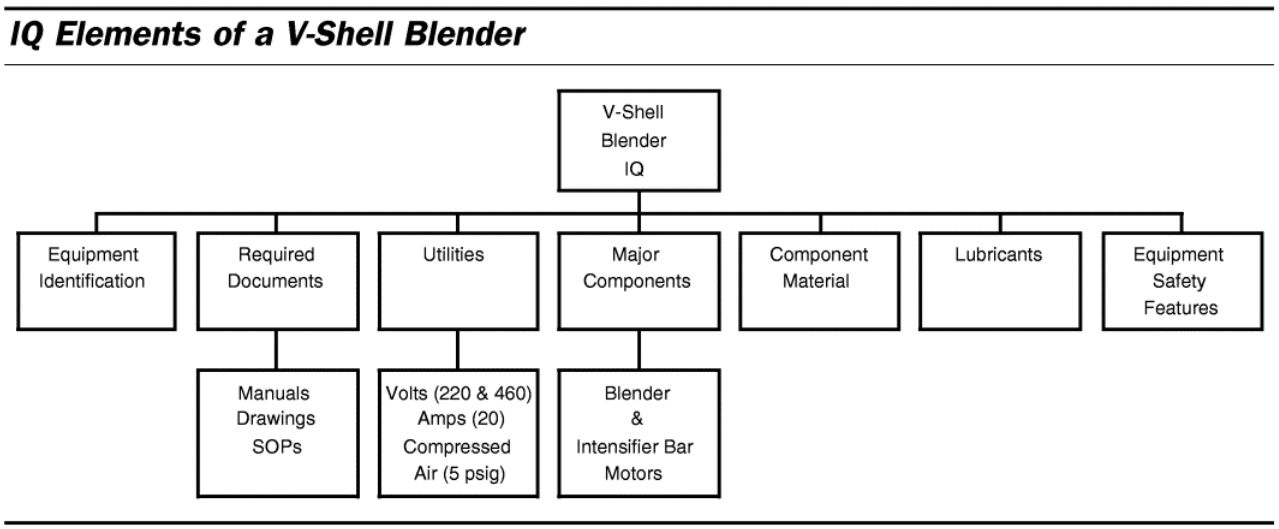
- Confirmation of URS/functional specification compliance.
- Possible documentation review and tests at FAT.
- FAT supplemented by SAT at the manufacturing site.

2.4. Installation Qualification (IQ)

IQ verifies that the equipment has been installed correctly and in accordance with the manufacturer's instructions.

- Performed on equipment, facilities, utilities, or systems.
- Includes verification of correct installation, calibration, and materials.

Example of the elements needed in a protocol of IQ for a V-shell blender are summarised here:

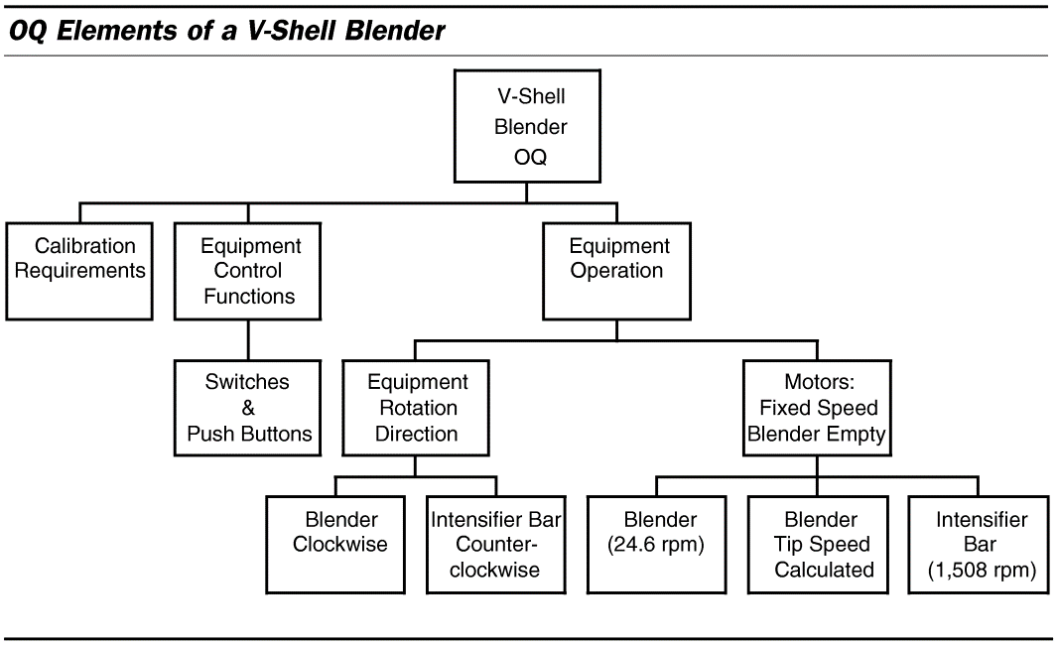


2.5. Operational Qualification (OQ)

OQ demonstrates that the equipment operates consistently within its specified parameters under normal operating conditions.

- Typically follows IQ but may be performed concurrently.
- Tests to ensure system operates as designed.
- Confirmation of operating limits and "worst-case" conditions.

Example of the elements needed in a protocol of OQ for a V-shell blender are summarised here:



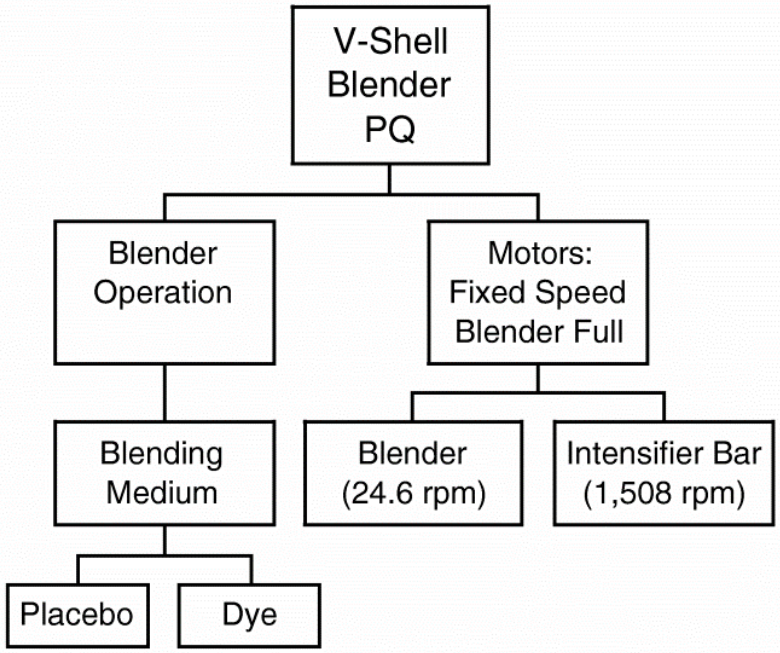
2.6. Performance Qualification (PQ)

PQ demonstrates that the equipment performs consistently and reliably over a period of time under the worst-case operating conditions.

- Usually follows IQ and OQ but may be conducted concurrently with OQ.
- Tests with production materials.
- Coverage of the operating range, unless documented evidence available.

Example of the elements needed in a protocol of PQ for a V-shell blender are summarised here:

PQ Elements of a V-Shell Blender



4. Re-Qualification

Equipment, facilities, utilities and systems should be evaluated at an appropriate frequency to confirm that they remain in a state of control.

- Justified frequency and criteria for re-qualification.
- Assessment of potential gradual changes over time.

5. Conclusion

In summary, the lesson on equipment qualification in pharmaceuticals highlights the vital steps to ensure safe and effective product manufacturing. Understanding the qualification stages, the difference between qualification and validation, and the role of user requirements is crucial for maintaining quality and meeting industry standards.

References

- Pharmaceutical equipment validation: the ultimate qualification guidebook by Phil Cloud. Informa healthcare. 1998.
- GMP. Annex 15: Qualification and Validation
- https://www.nalys-group.com/en/blog/technical-library/v-cycle-in-the-pharmaceutical-environment