Introduction to validation

Definition of Calibration

Definition

- **Calibration** is the process of comparing the measurements of an instrument or equipment with a known standard (reference standard) to determine its accuracy and, if necessary, adjusting it to eliminate errors.

  #### According to ISO:

  - Calibration is a set of operations performed under specified conditions that establishes the relationship between values indicated by a measuring instrument and the corresponding known values of a standard.

Purpose of Calibration

- To ensure accurate measurements.
- To maintain consistency in production.
- To minimize measurement errors.
- To comply with regulatory requirements.
- To improve product quality.

Examples

- Calibrating a weighing balance using standard certified weights.
- Calibrating a thermometer using a reference thermometer.
- Calibrating a pH meter using standard buffer solutions.

Definition of Qualification

Basic Idea

- Qualification is a documented process that demonstrates that facilities, equipment, utilities, and systems are properly designed, correctly installed, operate as intended, and consistently perform according to predetermined specifications.
- Qualification provides evidence that equipment and systems are suitable for their intended use in pharmaceutical manufacturing and other regulated industries.

Objectives

- To ensure that equipment and systems function correctly.
- To verify that installation and operation meet specified requirements.

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- To maintain product quality and patient safety.
- To comply with regulatory requirements and Good Manufacturing Practices (GMP).

Types of Qualification

1. Design Qualification (DQ)

- Design Qualification confirms that the proposed design of equipment or systems meets user requirements and regulatory standards.
- It verifies that the selected design is suitable for the intended purpose.

2. Installation Qualification (IQ)

- Installation Qualification confirms that equipment and systems are installed correctly according to approved specifications and manufacturer recommendations.
- It verifies that all components, materials, and documentation are available and accurate.

3. Operational Qualification (OQ)

- Operational Qualification confirms that equipment and systems operate according to predetermined operating ranges and specifications.
- It verifies that controls, alarms, and operating functions perform correctly.

4. Performance Qualification (PQ)

- Performance Qualification confirms that equipment and systems consistently perform effectively under routine operating conditions.
- It demonstrates that the process produces expected results repeatedly.

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Importance of Qualification

- Qualification ensures that equipment and systems are reliable.
- Qualification helps reduce the risk of process failures.
- Qualification supports compliance with regulatory expectations.
- Qualification contributes to consistent product quality.

Definition of Validation

Basic Idea

- Validation is a documented process that provides evidence that a specific process, method, system, or procedure consistently produces results that meet predetermined quality standards and specifications.
- Validation focuses on ensuring that the final product consistently meets its intended quality, safety, and effectiveness requirements.

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Objectives

- To ensure consistent product quality.
- To minimize variability in manufacturing processes.
- To identify and control potential risks.
- To comply with regulatory and GMP requirements.

Scope of Validation

1. Process Validation

- Process Validation confirms that manufacturing processes consistently produce products meeting quality requirements.

2. Cleaning Validation

- Cleaning Validation confirms that cleaning procedures effectively remove residues, contaminants, and microorganisms.

3. Analytical Method Validation

- Analytical Method Validation confirms that testing methods provide accurate, precise, and reliable results.

4. Computer System Validation

- Computer System Validation confirms that computerized systems function correctly and maintain data integrity.

5. Utility Validation

- Utility Validation confirms that systems such as water, compressed air, and heating, ventilation, and air conditioning systems perform consistently.

Types of Process Validation

1. Prospective Validation

- Prospective Validation is performed before routine commercial production begins.

2. Concurrent Validation

- Concurrent Validation is performed during actual production.

3. Retrospective Validation

- Retrospective Validation uses historical data to evaluate previously established processes.

4. Revalidation

- Revalidation is conducted after significant changes or at defined intervals to ensure continued process control.

Importance of Validation

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- Validation improves product quality and consistency.
- Validation reduces manufacturing risks and errors.
- Validation enhances patient safety.
- Validation supports regulatory compliance.

Frequency of Validation

- Validation is not performed only once.

It should be performed:

1. **Initial Validation**
   - ➢ Before commercial production starts.
2. **Revalidation**
   - ➢ When significant changes occur.
   - ➢ Examples:
     - Equipment modification
     - Process change
     - Formula change
     - Location change
3. **Periodic Validation**
   - ➢ Performed at regular intervals to maintain confidence.
4. **After Major Maintenance**
   - ➢ Whenever equipment undergoes major repairs.
5. **After Product Failure**
   - ➢ When repeated failures indicate possible process issues.

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Difference Between Calibration and Validation

Feature	Calibration	Validation
Definition	Comparison with a standard to check accuracy	Evidence that a process consistently produces desired results
Purpose	Accuracy of measuring instruments	Consistency of process/system

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Applies To	Measuring instruments	Processes, equipment, methods, systems
Adjustment	May involve adjustment	Does not involve adjustment itself
Frequency	Regular intervals	Initially and whenever significant changes occur
Example	Balance calibration	Tablet manufacturing process validation

Calibration of Weights and Measures

- Calibration ensures measuring devices provide accurate readings.

Weights

- Standard certified weights are used.

Examples:

- 1 mg
- 10 mg
- 100 mg
- 1 g
- 10 g
- 100 g
- 1 kg

Procedure

- Clean the balance.
- Level the balance.
- Warm up the instrument.
- Place certified weights.
- Record displayed values.
- Compare with standard values.
- Adjust if required.
- Document results.

Measuring Instruments

Includes:

- Measuring cylinders

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