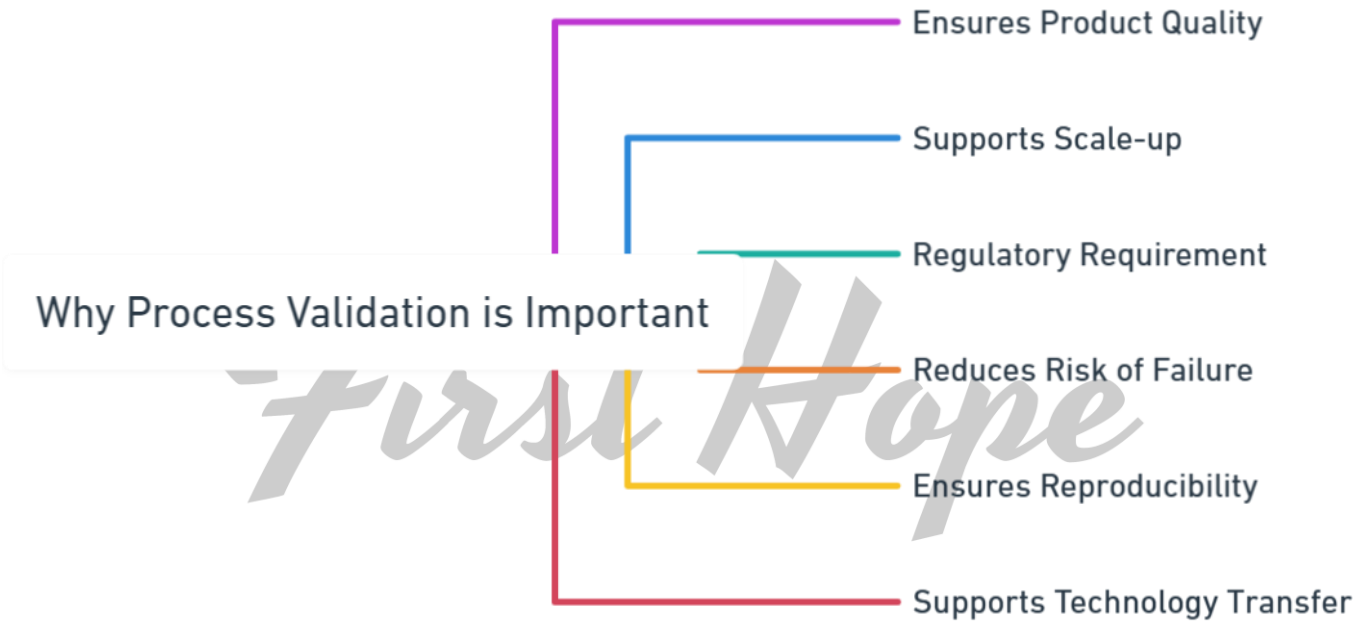
Equipment Qualification

Equipment Qualification – Importance (in Scale-Up & Technology Transfer)

Equipment Qualification: Importance

- Pharmaceutical manufacturing (especially in scale-up and technology transfer) requires that every equipment performs **consistently, safely, and as expected**.
- Equipment qualification ensures that the equipment used in production will produce **quality products every time**, even when moving from lab scale to commercial scale.

Why it is Important:



A. Ensures product quality

- Equipment directly affects drug properties (mixing, drying, sterilization).
- Any malfunction can change drug strength, stability, or safety.

B. Supports scale-up

- When increasing batch size, equipment behavior may change.
- Qualification ensures the same performance at larger scale.

C. Regulatory requirement

- Agencies like FDA, WHO require documented proof that equipment works properly.

D. Reduces risk of failure

- Prevents batch rejection, contamination, and costly recalls.

E. Ensures reproducibility

- Same process → same product → same quality.

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F. Supports technology transfer

- When process is transferred (R&D → production site), qualified equipment ensures smooth transfer.

Installation Qualification (IQ)

- IQ is the first stage of equipment qualification.
- It confirms that the equipment is installed correctly according to design and manufacturer specifications.

Key idea:

- "Was the equipment installed properly?"

Main activities:

A. Verification of equipment specifications

- Check model number, capacity, material of construction (e.g., SS 316).
- Ensure it matches the design requirements.

B. Checking installation

- Proper placement of equipment.
- Correct alignment and leveling.

C. Utility connections

- Electrical supply
- Water supply
- Steam, compressed air, vacuum
- All connections must be correct and safe.

D. Calibration of instruments

- Temperature sensors
- Pressure gauges
- Load cells
- Ensures accurate readings.

E. Documentation

- Equipment manuals
- Drawings (P&ID)
- Certificates (material, calibration)

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F. Identification

- Equipment ID number
- Labeling for traceability

Operational Qualification (OQ)

- OQ ensures that the equipment operates as intended under defined operating conditions.

Key idea:

- "Does the equipment work correctly?"

Main activities:

A. Testing operating ranges

- Minimum and maximum limits (e.g., temperature, speed, pressure).
- Example: Mixer speed from 50–200 RPM.

B. Functional testing

- All buttons, alarms, sensors, controls.
- Emergency stop function.

C. Challenge tests

- Run equipment under worst-case conditions.
- Example: Maximum load, highest temperature.

D. Process parameter verification

- Time, temperature, pressure, mixing speed, airflow.

E. Alarm and safety checks

- Overheating alarm
- Pressure release systems

F. Reproducibility

- Repeated runs to ensure consistent performance.

Performance Qualification (PQ)

- PQ confirms that the equipment consistently performs well during actual production conditions.

Key idea:

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- "Does the equipment produce good product consistently?"

Main activities:

A. Running actual batches

- Use real materials (not just water or placebo).
- Follow standard manufacturing procedure.

B. Multiple batch testing

- Usually 3 consecutive successful batches.
- Ensures consistency.

C. Product quality testing

- **Check final product parameters:**
  - Uniformity
  - Dissolution
  - Moisture content
  - Weight variation

D. Process consistency

- Same output in every batch.
- No unexpected variations.

E. Documentation

- Batch records
- Test results
- Deviations (if any)

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Autoclave – Qualification (IQ, OQ, PQ) in Scale-Up & Technology Transfer

- An autoclave is used for **moist heat sterilization** using steam under pressure.
- It is critical in pharmaceutical manufacturing for sterilizing equipment, media, and components.

Installation Qualification (IQ)

1. Equipment verification

- Check chamber material (usually SS 316)
- Verify chamber size and capacity (important during scale-up)

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2. **Utility connections**
   - Steam supply (quality and pressure)
   - Water supply
   - Drain system
   - Electrical connections
3. **Instrumentation check**
   - Temperature sensors
   - Pressure gauges
   - Timer
4. **Documentation**
   - P&ID diagrams
   - Manufacturer certificates
   - Calibration reports
5. **Safety features**
   - Pressure relief valve
   - Door interlock system

Operational Qualification (OQ)

A. **Empty chamber heat distribution test**
   - Use multiple temperature probes
   - Ensure uniform temperature (e.g., 121°C everywhere)

B. **Vacuum leak test**
   - Ensures no air leakage (important for steam penetration)

C. **Bowie-Dick test**
   - Checks air removal and steam penetration efficiency

D. **Cycle parameter testing**
   - Time, temperature, pressure verification

E. **Alarm testing**
   - High temperature alarm
   - Pressure failure alarm

Performance Qualification (PQ)

1. **Loaded chamber validation**

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