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Processing-Area Qualification and Validation

Practical 12 - Facility-record practical

Aim

To evaluate processing-area qualification and its connection to process validation.

Principle

Facility qualification addresses the intended environmental and utility conditions. Process validation assesses the manufacturing process; a qualified room alone does not validate a product process.

Materials and Requirements

- Fictional facility plan and area classification rationale
- HVAC qualification and environmental records
- Personnel/material flow and cleaning procedures
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Define intended operations, contamination risks, cleanroom requirements where applicable and adjacent areas.
3. Review air handling, filters, airflow direction, pressure differences and recovery or other relevant qualified tests.
4. Map personnel, material, waste and equipment movements; assess cleaning, monitoring locations and environmental trends.
5. Connect facility evidence to the process-control strategy and identify gaps, deviations and requalification needs.
6. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Area / function	Required condition	Qualification evidence	Gap / action
Dispensing	Define	Review	Assess
Processing	Define	Review	Assess
Transfer route	Define	Review	Assess

Calculations

- Pressure difference = pressure in the defined room - pressure in the stated reference room

Worked Example

Illustrative room pressure +15 Pa and adjacent reference +5 Pa give a +10 Pa difference relative to that space. The required direction and acceptable range must come from the facility contamination-control strategy.

Result and Interpretation

• Provide a flow diagram and requirement-to-evidence matrix with an authorised-use recommendation.

Precautions

• Do not infer cleanroom class from pressure alone.
• Distinguish at-rest and operational conditions.
• Use qualified personnel for facility challenges.

Viva Questions and Answers

What does positive pressure imply?

A pressure relationship; airflow and contamination control still need evaluation.

Why map flows?

Crossing routes can create contamination or mix-up risks.

Does room qualification validate a process?

The process requires its own lifecycle evidence.

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