Validation of Utility Systems

Pharmaceutical Water System and Pure Steam

Basic Idea

- Pharmaceutical water systems are designed to produce, store, and distribute water of a specified quality for pharmaceutical manufacturing and cleaning operations.
- Pure steam is steam produced from purified water or water for injection and is used for sterilization processes and equipment contact applications.
- Since water and steam directly affect product quality, their systems require comprehensive validation.

Types of Pharmaceutical Water



1. **Purified Water (PW)**
   - Purified water is used for cleaning equipment, preparation of non-sterile products, and laboratory applications.
2. **Water for Injection (WFI)**
   - Water for Injection is used in the manufacture of sterile pharmaceutical products and for final equipment rinsing.
3. **Pure Steam**
   - Pure steam is used for sterilization of equipment, containers, and pipelines.

Objectives

- To ensure consistent production of water and steam meeting predefined quality specifications.
- To prevent microbial contamination and endotoxin formation.
- To maintain system reliability and product safety.
- To comply with regulatory requirements.

Major Components of the System

- Feed water supply system.

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- Water treatment units.
- Storage tanks.
- Distribution pipelines.
- Pumps and valves.
- Heat exchangers.
- Pure steam generators.

Validation Stages

A. Design Qualification (DQ)

- The system design is reviewed to ensure compliance with user requirements.
- Materials of construction, flow patterns, and sanitary design features are evaluated.
- Dead legs, pipe slopes, and drainability are assessed.

B. Installation Qualification (IQ)

- Equipment identification details are verified.
- Piping, tanks, and components are checked against approved drawings.
- Utility connections and instrumentation are verified.
- Calibration certificates and technical documents are reviewed.

C. Operational Qualification (OQ)

- Operating parameters such as flow rate, pressure, temperature, and conductivity are tested.
- Alarm functions and control systems are verified.
- Sanitization procedures are evaluated.
- System operating ranges are confirmed.

D. Performance Qualification (PQ)

- Water and steam samples are collected according to a predefined sampling plan.
- Chemical, microbiological, and physical quality attributes are evaluated.
- Routine operation is monitored over an extended period to demonstrate consistent performance.

Critical Quality Attributes

- Conductivity.
- Total organic carbon (TOC).
- Microbial count.
- Endotoxin level.

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- Temperature.
- Flow rate.
- Pressure.
- Steam dryness.
- Non-condensable gases.

Routine Monitoring

- Regular sampling is performed at predefined locations.
- Microbiological and chemical testing is conducted according to approved procedures.
- Sanitization effectiveness is verified periodically.
- Trends are evaluated to identify system changes.

Documentation

- User Requirement Specification.
- System drawings and piping diagrams.
- Qualification protocols and reports.
- Calibration records.
- Sampling records.
- Trend analysis reports.

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Importance

- Ensures the quality and safety of pharmaceutical products.
- Reduces the risk of contamination.
- Maintains compliance with regulatory guidelines.
- Supports reliable manufacturing operations.

Heating, Ventilation, and Air Conditioning (HVAC) System

- A Heating, Ventilation, and Air Conditioning (HVAC) system controls environmental conditions within pharmaceutical manufacturing and laboratory areas.
- The HVAC system maintains temperature, humidity, air cleanliness, and pressure differentials required for product quality and personnel safety.
- Validation ensures that the HVAC system consistently maintains the specified environmental conditions.

Objectives

- To maintain controlled environmental conditions.

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- To prevent cross-contamination.
- To minimize microbial and particulate contamination.
- To comply with GMP requirements.

Major Components of the System

- Air handling units (AHUs).
- Heating and cooling systems.
- Ductwork.
- Filters, including High-Efficiency Particulate Air (HEPA) filters.
- Air diffusers and return grilles.
- Sensors and control systems.

Validation Stages

A. Design Qualification (DQ)

- Room classifications and environmental requirements are defined.
- Airflow patterns and pressure cascades are evaluated.
- Filter specifications and system capacities are reviewed.
- Risk assessments are conducted.

B. Installation Qualification (IQ)

- Equipment installation is verified against approved specifications.
- Ductwork, filters, and instrumentation are inspected.
- Utility connections are checked.
- Calibration certificates are reviewed.

C. Operational Qualification (OQ)

- Temperature and humidity controls are tested.
- Airflow rates and pressure differentials are verified.
- Alarm functions and control systems are evaluated.
- Air change rates are confirmed.

D. Performance Qualification (PQ)

- Environmental conditions are monitored during routine operations.
- Airborne particulate counts are measured.
- Microbiological monitoring is performed.
- Airflow visualization studies may be conducted.

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Important Validation Parameters

- Temperature.
- Relative humidity.
- Air changes per hour.
- Differential pressure.
- Air velocity.
- Airflow pattern.
- HEPA filter integrity.
- Particle count.
- Microbial count.

Common Qualification Tests

- Airflow visualization studies.
- Recovery tests.
- Differential pressure testing.
- Particle count testing.
- Temperature mapping.
- HEPA filter leak testing.

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Documentation

- User Requirement Specification.
- Airflow diagrams.
- Qualification protocols and reports.
- Calibration records.
- Environmental monitoring records.
- Maintenance records.

Importance

- Validated HVAC systems protect products from contamination.
- Controlled environmental conditions ensure consistent product quality and regulatory compliance.

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