Summary - Systems Validation

This document provides guidance in the validation of systems (facilities, utilities, and equipment, including process control systems, and information systems), that support regulatory compliance – practices, validated processes and/or systems used in the production or storage and distribution of Active Pharmaceutical Ingredients (API),

For direct impact systems, user requirements specifications (URS) should document what the system must do to meet internal specification, product and regulatory requirements.

For new direct impact systems, specifications should document the critical aspects of the system design, system functionality, hardware and software components and system configuration.

Specifications for custom systems or configurable systems should be approved by a Subject Matter Expert (SME).

For Legacy Systems that require validation, any documentation that describes the system on a functional and design level (e.g., vendor manuals, drawings, configuration documents) can serve as specifications for critical components and functions.

Component level impact assessments, when performed, should be documented and approved by the responsible validation committee.

The assessment results and corresponding action plan should be documented. The action plan should identify activities required to minimize the impact of any missing or poorly documented validation deliverables required for legacy systems. The validation committee should approve the assessment results and action plan.

For new direct impact systems, a design review should be conducted, to ensure the system meets regulatory requirements and is suitable for its intended purpose. The review should be documented (e.g., DQ or Design Review, validation report) and should be approved by the responsible validation committee.

Installation Qualification (IQ) should verify and provide documented evidence that any required commissioning activities are complete and those critical components have been installed and configured according to specifications.

Operational Qualification (OQ) should verify and provide documented evidence that critical components perform according to specifications, throughout defined operating ranges and meet predetermined acceptance criteria.

Performance Qualification (PQ) should verify and provide documented evidence that the system performs according to requirements, while integrated with associated systems, operates in the final production and/or validation test environment according to SOPs, and meets predetermined acceptance criteria.

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