Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document provides document 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), intermediates (subsequent to the introduction of the API starting materials), drug products, medical devices or biologics.

1. For Direct Impact Systems, User requirements specifications (URS) should document what the system must do to meet internal specification, product and regulatory requirements. For standard systems, such documentation may be included in other documents (e.g., technical manuals, vendor documentation). The URS should be approved by the Validation Committee(VC). User wants and Business requirements may be included in the URS but should be differentiated from quality requirements and specifications.

2. For Legacy Direct Impact Systems, at a minimum, any documentation approved by the Quality Authority that describes what the system must do, (e.g., test protocol acceptance criteria) can serve as User requirements for all critical components.

3. For New Direct Impact Systems, Specifications should document the critical aspects of the system design, system functionality, hardware and software components and system configuration.
   For standard systems, such documentation may be included in other documents (e.g., technical manuals, vendor documentation, SOPs). Specifications for custom systems or configurable systems should be approved by a Subject Matter Expert (SME).
   Specifications for custom systems that serve as the basis for acceptance criteria should be identified and maintained to accurately reflect the system, in its current state.

4. 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.

5. Criteria to Consider When Conducting System Level Impact Assessments to determine if the system is a direct impact system include, but are not limited to:
   - System has direct product contact;
   - System produces a material or excipient that has direct product contact;

- Calibration.

16. Retirement Plans or SOPs should identify the activities and documentation required to fully decommission and remove a validated system from service. The plan should address disposal of the hardware, software, data, and documentation. The plan should be documented and approved by the responsible VC.

17. For Validated Systems Used to Store Electronic Records, the following should be addressed in the system retirement plan:
    - The archival and retention time of electronic records, including the application software;
    - Identification of records to be archived;
    - Procedures to access historic data; and
    - The migration of data into another system and the migration testing, if applicable.

