

Pharmaceutical Commercial Operations... Validated, Controlled, and Audit-Ready: What It Takes to Manage Software Changes in a Regulated Environment



When pharmaceutical companies rely on software to support commercial operations, healthcare professional (HCP) data management, compliance activities, or regulated workflows, the question is not simply whether the system functions as intended. The more important question is whether the organization can demonstrate, through documented evidence, that it functions reliably, consistently, and in accordance with regulatory requirements.

In regulated environments, trust is built through validation.

Under FDA regulations such as 21 CFR Part 11, electronic records and electronic signatures used in regulated processes must be trustworthy, reliable, and equivalent to paper records. Organizations must be able to demonstrate that their systems are validated, changes are controlled, data integrity is maintained, and evidence is readily available for review during audits or inspections.

For companies operating in the pharmaceutical industry, software validation is not a one-time project. It is a structured lifecycle designed to ensure systems remain fit for their intended use throughout their operational lifespan.

The Foundation: A Risk-Based Validation Strategy

Effective validation begins long before testing occurs.

Most organizations establish a validation framework through a Validation Master Plan (VMP), which defines the systems requiring validation, the applicable regulatory requirements, and the documentation standards used across the organization. The VMP serves as the governing blueprint for validation activities, providing consistency and ensuring that risk-based decisions are applied across systems and processes.

Before implementation begins, systems are typically classified according to their regulatory impact and intended use. This classification helps determine the depth of validation required, the necessary deliverables, and the testing approach that will provide sufficient evidence of compliance.

Establishing this foundation early helps ensure that validation efforts remain aligned with both business objectives and regulatory expectations.

From Requirement to Release: The Validation Lifecycle

While validation methodologies vary by organization, mature pharmaceutical technology providers generally follow a structured lifecycle designed to create clear, defensible evidence at every stage.

The process often begins with a formal Change Request (CR) documenting the business need, scope, rationale, and potential regulatory impact. Whether introducing a new feature, modifying existing functionality, or implementing a new system, the objective is to clearly define what is changing and why.

A risk and impact assessment follows, evaluating how the change affects regulated processes, users, data, and downstream systems. This assessment determines the documentation, testing, and approvals required before implementation can proceed.

Once requirements are approved, development activities are supported by detailed specifications that define both business expectations and system behavior. These specifications become the foundation for testing and traceability throughout the validation effort.

Testing as Documented Evidence

One of the most misunderstood aspects of validation is that testing is not simply about finding defects. Testing is about generating documented evidence.

Operational Qualification (OQ) protocols are designed to verify that system functionality performs as intended under expected operating conditions. Each test step is documented, reviewed, executed, and supported by objective evidence demonstrating that requirements have been met.

The goal is not merely to confirm that the system works, but to create an auditable record showing how that conclusion was reached.

This distinction is critical during inspections and audits, where regulators often focus as much on the validation evidence as they do on the system itself.

The Role of Traceability

Traceability is what transforms a collection of documents into a complete validation package.

Through a Traceability Matrix, organizations connect business requirements to specifications, test scripts, results, and final conclusions. This linkage provides clear evidence that every requirement has been addressed and verified.

Without traceability, organizations may struggle to demonstrate that validation activities were comprehensive. With it, stakeholders can quickly answer one of the most important compliance questions: How do you know every requirement was tested and verified?

A well-maintained traceability process reduces ambiguity, supports audit readiness, and strengthens confidence in the overall validation program.

Bringing It All Together

The final stage of validation typically culminates in a Validation Final Report, which summarizes the activities performed, documents any exceptions or deviations, and provides formal confirmation that the system is fit for its intended use.

Only after all required approvals, testing activities, and deliverables are complete should a validated system move into production.

This documented conclusion provides organizations with the evidence needed to support operational use, regulatory inspections, and ongoing compliance requirements.

Why Validation Matters Beyond Compliance

Validation is sometimes viewed as a regulatory obligation that exists primarily to satisfy auditors and inspectors. In reality, its value extends much further.

A robust validation program helps organizations maintain data integrity, reduce operational risk, ensure consistent system performance, and support informed decision-making. More importantly, it provides confidence that critical business processes are supported by reliable technology.

In an industry where patient safety, regulatory compliance, and business continuity are closely connected, validation serves as a mechanism for establishing trust.

When regulators, clients, or internal stakeholders ask how a system has been proven fit for its intended use, the answer should not rely on assumptions or verbal assurances. It should be supported by a complete body of documented evidence demonstrating that requirements were defined, risks were assessed, functionality was tested, and results were verified.

That is the true purpose of validation: not merely proving that a system works but proving that it can be trusted.

About the Author

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