

Modernizing LIMS Implementation: From Validation to Assurance



The unprecedented pace of new product development in regulated industries is increasing demands on quality organizations to quickly turn around massive volumes of testing without compromising quality or compliance. A modern laboratory information management system (LIMS) is transformative for any quality organization facing such demands. While the benefits that LIMS unlocks are well-understood, the prospect of implementing and maintaining a LIMS remains daunting.

Traditionally, the primary barrier to a timely and effective LIMS deployment was not only the effort required to configure the system to meet business requirements, but also to qualify that system and its underlying data. This effort includes the qualification of business process workflows, as well as the underlying configuration objects (referred to as “master data”) that are integral components of these system processes.

While the scope and complexity of master data vary from customer to customer, its development and qualification is universally considered to be one of the most important and time-consuming aspects of deployment — a factor which organizations often underestimate until they approach their target “go-live” dates. Further, change management processes for master data development and verification are extremely consequential. Even minor efficiencies gained through process optimization can lead to significant savings in time and effort when applied to many objects. It is critically important to right-size qualification activities to suit the risk and impact of the object under review.

This paper explores the evolving regulatory landscape and how the application of modern regulatory frameworks like computer software assurance (CSA) can dramatically accelerate the benefit-realization from a LIMS deployment through the enablement of modern tools and risk-based methodologies.



The Foundations of Digital Systems' Regulatory Guidance

The FDA's position on incorporation of digital records, key for modern LIMS solutions, into the Current Good Manufacturing Practices (cGMP) framework has been evolving since the mid-1990s and continues to update to keep current with emerging technology. The foundation of the FDA's relevant guidance is in the following documents:

01

21 CFR Part 820

Quality Management System Regulation (QMSR):

First issued in 1978, this document established the criteria for cGMP, which remains the backbone of quality management in regulated industries. The subsequent documents in this section, when properly applied, assure compliance with 21 CFR Part 820.

02

21 CFR Part 11

Electronic Records; Electronic Signatures:

Established in 1997, this document provides the definitive criteria for electronic records and signatures to be considered as reliable and trustworthy as pen-on-paper. This is the first regulatory guidance establishing the framework necessary for the digital revolution in FDA-regulated industries. In practice, this document opened a floodgate of questions from quality organizations and solution providers regarding the requirements set forth in the guidance and how to effectively and efficiently address those requirements. Consequently, organizations would stake out a position while implementing a digital quality system (such as LIMS), only to adjust their stance and systems in response to inspection comments and observations (FDA 483).

03

FDA-1997-D-0029

General Principles of Software Validation:

Initially released in 1997, this is a companion to 21 CFR Part 11. This document defines the requirements necessary for FDA-regulated industries to consider a digital quality system to be qualified for use. Further, this document introduces the concept of "verification" versus "validation."

Once again, this guidance left many critical points open for interpretation, requiring regulated entities to subsequently justify their responses.

04

DA-2022-D-0795

Computer Software Assurance for Production and Quality Management System Software:

First proposed in 2022, the "final guidance" on CSA provides a definitive distinction between:

- Initial validation of quality system software
- Verification procedures to manage object configuration (which is necessary for effective use and maintenance of these systems)

This paper discusses the distinction between "validation" and "verification," and the benefits of thoughtful application of these concepts in subsequent sections. The document also enshrined the concept of risk-based software assurance, a concept that regulated entities pushed for years.

The following sections describe the implications of these documents for the modern, digital laboratory.

The Shift: CSV vs. CSA

As the FDA’s understanding of the essential nature and accompanying risks of digital solutions in the quality domain has matured, its position on digital records has unmistakably evolved from early rigid frameworks to the current “least burdensome” approach. Although the first three documents listed above continue to evolve, they are nevertheless well-established and understood. The final document listed above (“Computer Software Assurance for Production and Quality Management System Software”) represents a sea-change in the FDA’s thinking and recognizes the fundamental distinction between “computer system validation” (CSV) and CSA while establishing the agency’s embrace of risk-based solutioning.

Historically, CSV was akin to “validation by-the-pound,” focusing on exhaustive, scripted documentation to mitigate quality and audit risk. This approach used a broad brush, treating every system and every component object of these systems with the same level of rigor. As a result, the time and effort required to deploy and maintain a digital quality system was often cost-prohibitive.

As digital quality systems have matured, a distinction has evolved between the validation of a system and the verification of subsequent updates to that system.

This evolution has been codified in the recently released guidance, “FDA-2022-D-0795: Computer Software Assurance for Production and Quality Management System Software.” This document has fundamentally flipped the script from a historically indiscriminate approach to validation to the laser-focus of “effort based on assessed risk.” A high-level description of these approaches (and their implications) is tabulated below:

Feature	Traditional CSV	Modern CSA
Qualification Strategy	Validation	Validation or verification, as merited by risk
Qualification Driver	Documentation-centric	Risk-based assurance
Testing Guidelines	Strictly scripted	Flexible, unscripted, or automated
Evidence of Compliance	Screenshots and manual logs	Native digital records and audit trails
Overall Philosophy	“Validate everything”	Critical thinking and “right-sized” documentation

Implications for Digital Quality Systems Implementation

With the release of FDA-2022-D-0795, system vendors and regulated entities alike are now encouraged to make risk assessment a fundamental consideration in procedural decisions regarding system development and deployment. While it may seem like the assessment of risk adds a layer of effort to the change management process, consider that there are broad classes of changes (and object classes) that can be assessed without controversy.

With respect to LIMS, changes to the definition of objects (such as storage locations, conditions, and orientations, for example) can be considered low risk without concern, thereby streamlining their deployment process. This frees-up resources to focus on more complex, highly consequential changes. The potential efficiencies gained by facilitating the categorization and subsequent treatment of master data by complexity and impact accelerates LIMS deployment significantly and greatly simplifies post-deployment maintenance activities.

Thoughtful definition of change control procedures with respect to the quality systems in scope is necessary for proper designation of risk category for a change. The subsequent validation or verification of the change will consequentially be “right sized,” and defensible on audit. Prior to the final guidance, such decisions were made out of necessity which (prior to regulatory support) required a defensive posture during an audit. Conversely, it is now reasonable to assume that in future audits an inspector may focus less on adherence to a uniform set of validation practices, and more on risk/impact assessment and the procedural response to the perceived risk.

Implications for Your Veeva LIMS Strategy

The FDA’s risk-based guidance explicitly extends to vendors and subscribers to SaaS deployments, reducing the burden for companies developing or adopting modern cloud-based LIMS solutions. Consequently, Veeva has adopted a validation/verification stance that embraces risk-based assessment and distinguishes between the platform’s validation state and the verification of customer-specific master data.

1. System qualification and acceptance

- a. Quality system integrity:** Veeva adheres to a strict software development lifecycle regimen in alignment with regulatory guidance and industry best-practices to properly develop, document, and deploy customer-facing systems. Customers routinely conduct audits and Veeva considers their feedback for incorporation into internal procedures.

- b. Release qualification:** Veeva maintains the platform's qualified state through risk-based testing and comprehensive documentation of changes to the released system, as well as comprehensive regression testing prior to every release.
- c. Release acceptance:** Veeva provides customers with comprehensive release notes outlining the changes in every new release of Veeva LIMS. Veeva encourages customers to adopt a risk-based acceptance strategy, e.g.:
 - Scope determination: Release documentation is reviewed to determine the nature of applicable changes (if any) that require qualification prior to implementation.
 - Scripted user acceptance testing (UAT): For new or high-risk functionality.
 - Unscripted UAT: For moderate-risk changes to confirm the system performs as documented.
 - Regression testing: For confirmation that critical customer workflows impacting product quality or patient safety function as expected.

2. Master data verification

Veeva categorizes the qualification of master data as 'verification,' distinguishing it from platform-level validation, heavily reducing LIMS customers' compliance burden. It is evaluated across two dimensions: complexity and impact.

Examples of complexity-level assessments:

- **Low:** Simple builds with no calculations or picklists (e.g., base tables like Locations).
 - ✓ Suggested verification methodology includes documenting the new object(s) and comparing the object to source documentation.
- **Medium:** Builds involving picklists and simple calculations without subroutines.
 - ✓ Suggested verification includes documentation of the object and unscripted functional testing by a qualified SME.
- **High:** Any builds or fixes involving complex logic or subroutines.
 - ✓ Suggested verification includes full documentation and comprehensive, scripted functional testing, including negative/edge-case testing.

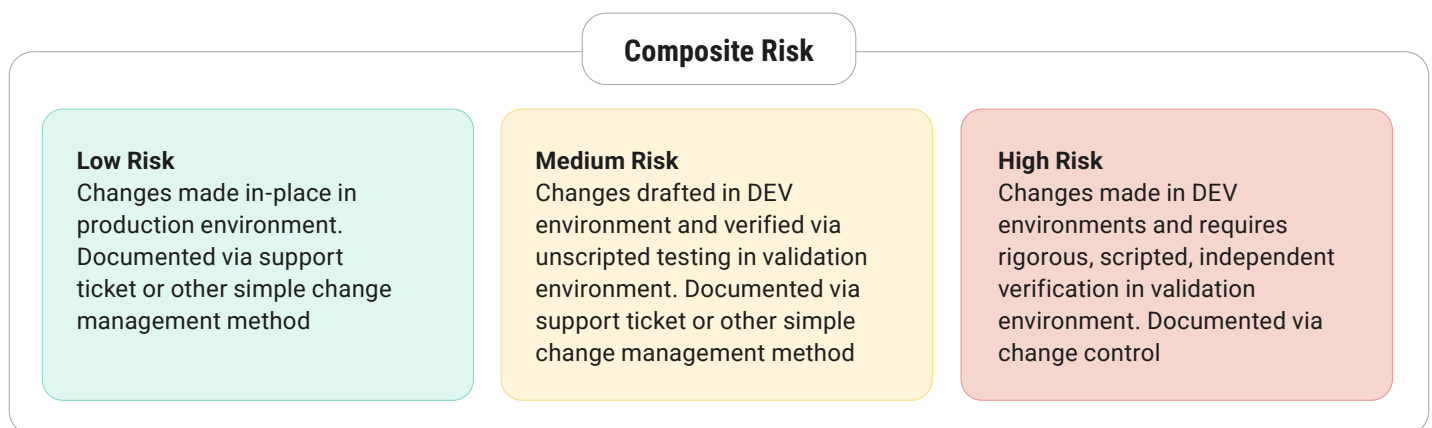
Examples of impact levels:

- **Low:** Minimal impact on patients, compliance, or business.
- **Medium:** Tangible potential impact; often tied to minor deviations.
- **High:** Direct impact on patient safety or product quality; often tied to major investigations.

Composite risk rating:

The rubric shown below describes a proposed composite risk model associated with “complexity” and “risk” assessments, which allow for an estimation of the overall risk (along with examples of verification methodology):

Low / Low	Low / Medium	Low / High	Low Complexity Simple typos, cosmetic changes, Base tables	Complexity ↓
Medium / Low	Medium / Medium	Medium / High	Medium Complexity New or significant changes to design data. No complex calculations. No code	
High / Low	High / Medium	High / High	High Complexity Complex calculations, coded subroutines, logic gates, custom configuration	
Low Impact	Medium Impact	High Impact		
Scope / Impact →				



Ultimately, the composite risk assessment, as well as the level of verification associated with the composite risk category, is at the discretion of the customer's quality organization.

AI Considerations

As with nearly every aspect of digital life, artificial intelligence (AI) holds the prospect of fundamentally changing the way that Veeva develops and deploys customer-facing systems, as well as customer's methodology for configuration and qualification of the system. While the potential for use of AI in all aspects of the digital quality domain is nearly limitless, this discussion will focus exclusively on AI considerations for master data development and verification.

▶ AI as a tool for master data development

Bulk development of master data objects generally occurs in unregulated sandbox (DEV) instances of customers' LIMS systems and is not typically subject to regulatory scrutiny. Therefore, it should not be surprising that AI has a potential part to play. System integrators are already using AI to "scrape" source documents, or their legacy LIMS systems, and using the data from these activities to build new master data in the target systems' DEV environments. Using AI as a drafting tool in this manner greatly increases the accuracy, efficiency, velocity, and consistency of the master data build process. While drafting master data in unregulated sandboxes is not technically within the purview of regulatory documents, it merits mentioning here because this process moves the critical path downstream to the verification process, which is very much in scope.

▶ AI as a tool for master data verification

Automated tools have long been employed for creating master data objects from manually created build-sheets and subsequently verifying that system objects created match the source specification. The logical extension of this concept is to employ advanced AI-driven tools to perform verification against the source documentation used to build the objects in the first place.

Taken a step further, agentic AI is an excellent option for unscripted testing of simple to moderately complex master data (and the boundaries are ever-expanding). CSA regulatory guidance allows for this bold use of machine learning as long as:

- A realistic assessment of the risk is made in advance
- Rigorous oversight accounts for the inherent risk of the objects under scrutiny, and the methodology being used for verification.

Critical Considerations for Veeva LIMS Implementation Customers

The FDA's new CSA guidance encourages stratification of risk, including for SaaS-based implementation. This stance supports Veeva's approach to the qualification of system updates, which is to offload the system qualification from the customer (and onto Veeva) to the greatest extent possible. Veeva's validation management team executes extensive, transparent risk assessment of the system releases, and performs qualification activities commensurate with the risk associated with the change.

Veeva encourages customers to adopt the new FDA strategy when performing their due diligence prior to accepting new functionality into their production environments. The cornerstones of a customer's pre-acceptance activities should be:

- Vendor audit: Veeva customers are encouraged to audit the quality systems, processes, and documentation associated with their systems of interest.
- User acceptance testing / performance qualification (UAT/PQ): Prior to deployment of systems (or system updates), Veeva encourages customers to do the following:
 - ✓ Review pertinent release documentation
 - ✓ Assess the risk associated with new / updated features and processes and impacts to training, technical architecture, and other pertinent validation documentation requiring updates
 - ✓ Execute UAT/PQ on the new features and processes according to their assessed risk
 - ✓ Perform regression testing of highly-critical functionality, if such functionality might have been impacted by the release.

Finally, it should be noted that Veeva's SaaS architecture mitigates the need for customer execution-of-server qualification, software installation qualification (IQ), and infrastructure scaling to accommodate releases or scope expansion. Veeva manages these technical and regulatory requirements.

Final Considerations

In summary, with its release of final CSA guidance, the FDA has provided regulated industries and vendors of quality system software (such as LIMS) with a powerful tool. This framework encourages all parties involved in the development, deployment, and governance of such regulated systems to focus on the most impactful, high-risk components during qualification. At a time when regulated industries face ever-increasing financial pressures and compressed timelines, this approach frees critical resources to pursue innovation while seamlessly adopting modern, digital advancements from platforms like Veeva LIMS with minimal effort.

To maintain data integrity while supporting unprecedented product development, quality leadership must fundamentally transition away from traditional, cost-heavy compliance models. It is time to treat the quality organization not as an operational cost center, but as a strategic profit center capable of unlocking massive organizational efficiency. Organizations must challenge their current system qualification practices: are current QA processes truly cutting-edge, or are manual, semi-digital bottlenecks quietly eroding margins and delaying revenue?

Quantifying the exact ratio of time spent on rote administrative documentation versus high-value quality risk management is the critical first step. By embracing the new FDA guidance during LIMS implementation, organizations can greatly accelerate the ROI of a digital quality transformation. Right-sizing compliance activities can dramatically increase the velocity of deployment, drastically accelerating the readiness of critical systems, and unlocking market share ahead of the competition.

The path to a highly profitable, modern quality system starts today.

Next Steps for Your Transformation

If you are looking to build a business case for this transformation, Veeva offers resources to help quantify the ROI of modernizing your lab. You can explore these further through:

- [The Veeva Business Consulting Page](#): Where you can connect with experts who advise on digital transformation strategy.
- [Veeva LIMS Product Page](#): For specific product features and customer success stories.
- [Resource Center](#): To download executive guides, such as "Learn, Confirm, Then Scale: A Leader's Guide to Transforming Quality Control."



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