Validating a Laboratory Information Management System (LIMS)

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This article is intended as a concise guide for those looking to validate a LIMS. A fuller paper covering these points in more detail can be requested from the author.

LIMS Validation is important in regulated industries to prove your system operates as intended and meets GxP (Good Laboratory/Manufacturing Practice) regulatory requirements. This imposes specific controls and procedures throughout the development and operation of the system as global regulated industries require that LIMS are validated. As a LIMS can be configured (using configuration tools) and/or customised (writing custom code), this part of the lifecycle must be carefully controlled and documented.

For commercial LIMS, the PQ step of system validation is always done by the user organisation at their site, using their system architecture and data. The supplier can help by providing technical resources to implement and validate the system, and by allowing an assessment of the supplier's quality system.

You can also get help by using Google to search for 'LIMS Validation consultants' and by using LinkedIn (try the LIMS4U LinkedIn group which has over 3,700 members, many knowledgeable in validation practices).

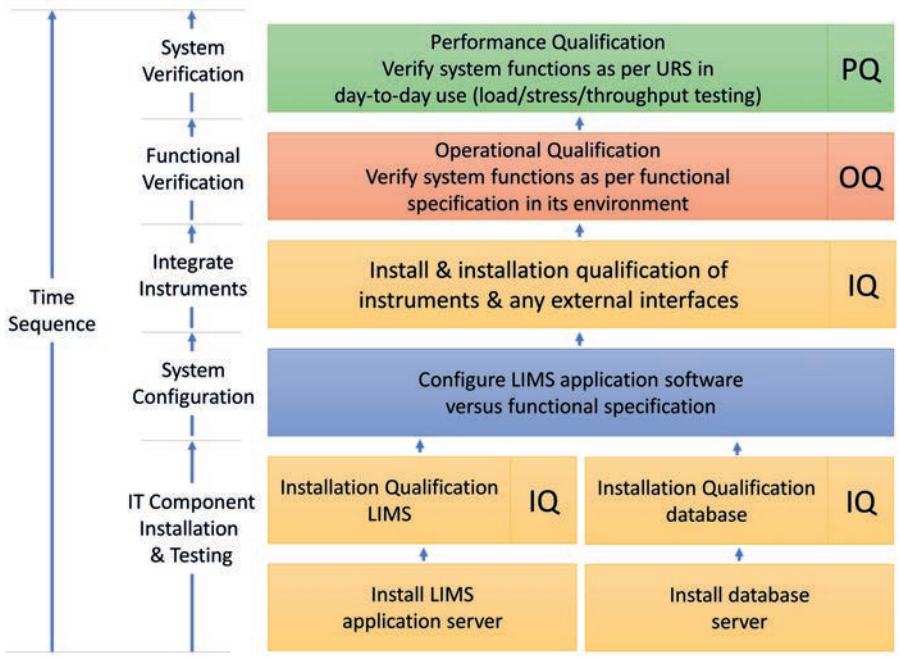

Figure 1. Validation Process Overview

Validation shows that the LIMS functions as intended. Proving this to the authorities can be crucial during a regulatory audit. Typical steps towards validation include:

- Creation of a User Requirements Specification (URS) to define the operational requirements, and regulatory compliance constraints. The URS helps LIMS vendor selection by defining must/should/could have' requirements.
- Assessment of the supplier's quality system, and how they develop their software.
- Development of Functional Specifications (FS) describing the system features to meet the URS.
- A risk assessment of the system, requirements, and development methodology to assess risk levels and the amount of validation needed to address them.
- Creation of a Validation Plan (VP) to identify what needs to be validated, who is involved, their responsibilities, and documentation required. A project plan should be created and maintained to log progress.
- Installation Qualification (IQ) to check that the LIMS application has been successfully installed in the specified environment.
- Configure (or customise) the system against functional specification. Note that the risk assessment may differ between the two methodologies. GAMP 5 {Ref.1} stipulates configurable solutions, whose code does not change during LIMS configuration, are a lower risk than customised solutions that do write software code to modify functionality. This directly affects the risk and therefore the amount of validation that needs to be performed.
- Operation Qualification (OQ) to verify that the functionality of the software is operationally fit to be deployed and can be handed over to the laboratory.
- Performance Qualification (PQ) to verify the system performs as expected under real-world conditions. In practice, with Autoscribe Informatics configured LIMS solutions, PQ and OQ can be performed in parallel as the underlying modular functionality is already tested before the software is released. By design this is unchanged by configuration and therefore deemed a lower risk by the risk assessment.
- The creation of a traceability matrix, If needed, to ensure traceability of any regulatory requirements.
- Development of risk-based change control procedures to ensure system re-validation after changes.
- User training and updating of standard operating procedures to include the LIMS.
- Agreement with IT for backup and recovery of data, and planning for disaster recovery should issues occur.
- A Final Validation (FV) report to review all activities undertaken against the validation plan, document any exceptions, and release the system for its intended use.

The final step is customer sign-off and acceptance of the system.

Reference

1. https://ispe.org/publications/guidance-documents/gamp-5-guide-2nd-edition
GAMP 5 - A Risk-Based Approach to Compliant GxP Computerised Systems

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