




LIMS&SOFTWAREVALIDATION

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# LIMS & SOFTWARE VALIDATION

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**OUR SUBJECT MATTER EXPERTS.**



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# LIMS & SOFTWARE VALIDATION

Supporting key features of a modern laboratory's operations, a Laboratory and Information Management System (LIMS) is an essential component of sound quality management in FDA regulated industries such as medical device and life sciences. Along those lines, manufacturers must validate the software deployed in various medical devices to ensure the safety of products before they reach the open market. The process-centric approach to quality management applies to validating a LIMS' software, similar to the approach employed by manufacturers across many different industry verticals. Focusing on the criticality of validating a LIMS' software, IQS offers software validation services to FDA regulated manufacturing industries.

## DEFINING A LIMS

Software vendors tailor a LIMS to the specific challenges of operating a modern laboratory. For instance, the software configurations of a LIMS deployed in academic research or pharmaceutical development are quite different from a LIMS' configurations used in the medical device industry. As such, a LIMS' central purpose varies among disciplines. With respect to manufacturing quality management systems, a LIMS essentially is the most business-critical repository of quality-related workflow records, data tracking support, IT architecture and data exchange interfaces.

## THE CHALLENGE OF SOFTWARE VALIDATION

To mitigate risk by using the most cost-effective techniques, manufacturers rely on software validation projects to satisfy market and regulatory requirements. Failures can originate at any stage in the product development life cycle, and software-based root causes are still far too common. Studies have implicated software failures in as many as 8% of all medical device malfunctions. With proper validation of a software's functionality, reliability, usability, efficiency, maintainability and portability, FDA regulated manufacturers can mitigate the risk of deploying new software in their production designs to bring reliably safe products to fruition.

## IQS'S SOFTWARE VALIDATION SERVICES

A LIMS can serve many purposes. Tailoring software validation projects to the unique characteristics of a LIMS is critical to safe product design, implementation and proper regulatory auditing. Regulatory pressures contribute greatly to the challenge of validating a LIMS' software, so IQS focuses on employing risk management and process analysis techniques to identify the critical steps and functions, focusing efforts on what

really matters to a specific laboratory. These critical facets of sound quality management have a direct impact on total cost of quality, which the IQS solution seeks to manage.

IQS's software validation solutions offers manufacturers the opportunity to fine tune a LIMS' efficiency to streamline data entry procedures, record retention and auditing trails, three essential components of regulatory compliance. In the past, paper-based software validations failed to identify errors and faults adequately to prevent medical device failures. The IQS solution affords manufacturers the flexibility to deploy an automated quality management system, which integrates well with a LIMS' critical processes within the context of an enterprise-wide framework. By doing so, manufacturers in the medical device industry can mitigate the high cost of device failures.

The purpose of a LIMS' in FDA regulated industries (such as medical device and life sciences) varies from company to company. To ensure that a LIMS' output satisfies regulatory pressures, software validation is a critical facet of sound quality management.

> "The process-centric approach to quality management., applies to validating a LIMS' software, similar to the approach employed by manufacturers across many different industry"

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