

Project Leadership, Implementation, and Validation of LabWare LIMS™

Situation

Rapid growth of a global biopharmaceutical company led to multiple instances of LIMS, one per site, with substantial customization. The complexity of supporting many customized instances and combining data became a major challenge for this company. The client envisioned the development of a single, core LIMS which was less customized and more configurable for all site needs. This strategy would allow for easier system upgrades and facilitate data sharing across sites. Deployment of a more standardized, multi-site system would provide greater efficiencies for the future. Therefore, the client undertook a project to deploy a highly configured but less customized version of LabWare LIMS™ to all sites. Based on CSols' demonstrated expertise on other lab informatics projects, the client chose CSols, Inc. to lead the deployment of the LIMS from the initial site to the remaining sites.

Objectives and Challenges

The client began their project by building a core LabWare LIMS and deploying it at one site. Following the initial deployment, each additional site was engaged, and the core system was further adapted through minimal customizations and site-specific configurations to prepare for deployment at each of the additional four sites in three different countries. Site extensions to the core LIMS included the addition of an Environmental Monitoring (EM) module and interfaces to the Empower™ 3 Chromatography Data Software (CDS).

The client's staffing model utilized relatively few full-time employees with a substantial number of contractors. The client wanted to run the site deployments while minimizing the input required from client resources. The client also desired to complete the site deployments within a limited time frame.

CSols' Role in the Solution

CSols was engaged to manage the site customizations/configurations and lead the multi-site rollout program. CSols provided resources for project leadership, LIMS development and configuration, SOP writing, and validation support. CSols' work involved the following major areas:

- Project Leadership Services
 - Project Management to ensure that staff were prepared for system implementation
 - Created and maintained open communication lines between all sites
 - Coordinated scheduling of site rollouts, ensuring training was completed and site rollouts were properly coordinated and sequenced
 - Managed resources from multiple vendors, including the product vendor
 - Developed status reporting for senior level management
 - Appraised senior management of challenges requiring their attention

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PROJECT AT A GLANCE

BUSINESS SECTOR:
Biopharmaceutical

INFORMATICS SYSTEM:
LabWare LIMS v6

SERVICE OFFERING:
Project Leadership
Implementation
Validation
Standard Operating Procedures

ELEMENTS:
5 Sites
3 Countries
Multiple Labs
6 CSols Team Members

(Continuation...)

- Development and Configuration Services
 - Added enhanced functionality to the core system (e.g., EM)
 - Performed development work for configuration and customization to fit site specific requirements
- SOP Writing
 - Wrote SOPs for the LabWare LIMS
- Validation Support
 - Wrote test protocols and scripts for the client's customized LabWare LIMS implementation, using accumulated expertise with the system
 - Wrote test scripts for the LabWare to Empower 3 interface
 - Updated the set of masters (URS, FRS, TM, RA, and DS) based on the revisional release protocols, in conjunction with approved change controls

Benefits

- Under CSols' project leadership, on-time deployment of core LabWare LIMS to all sites was achieved. Through the role of a CSols Project Leader, the client also benefited from strong communication and centralized support throughout their project.
- The client's IT Sponsor's time was efficiently utilized by not needing to be consumed with all aspects of the complex effort. This was possible because the CSols Project Leader took the detail work and only escalated significant issues to the IT Sponsor.
- Seamless management of the multi-vendor team by the CSols Project Leader provided the IT sponsor with confidence that the project was being managed effectively.
- Procedures, scripts, protocols, and change controls were developed by the CSols implementation experts.
- The client achieved their strategy of a more harmonized system across all sites for improved information sharing, increased efficiency and reduced cost, and an available future upgrade path due to the implementation expertise provided by CSols developers.