Global LabWare 7 LIMS Implementation for a Chemical Company

CASE STUDY

PROJECT AT A GLANCE

Business Sector:
- Chemicals

Informatics Systems:
- LabWare 7.02

Service Offering:
- Implementation
- Project Management
- ERP & Instrument Interfaces
- Post Go-Live Support

Elements:
- 7 Global Sites
- 15 Months
- 10 CSols Team Members

A multinational chemical manufacturing company was growing exponentially but still had numerous sites using paper-based processes. The client needed a single way to manage, track, and report sample testing for their quality assurance (QA), quality control (QC), and operations staff. They chose to implement LabWare 7 LIMS to harmonize with existing sites, interface with their enterprise resource planning (ERP) system, automate sample submissions, provide result entry via instrument interfaces, and standardize workflows to meet the anticipated volume of product testing.

Five sites in the United States and two in South Korea needed to be added to the existing LabWare 7 LIMS. This would allow Certificate of Analysis (CoA) generation through an ERP system in the United States and the generation of CoAs out of the LIMS in South Korea. External lab results would need to be imported into the LIMS from a client subsidiary lab.

System performance issues led to low end-user adoption and the failure to go live with the initial implementation. To turn the implementation around, the client needed lab informatics technical leadership, project leadership, and business analysis experience in addition to LabWare LIMS expertise.

The client chose CSols to work with them on their second attempt at the LIMS implementation. CSols was brought in to determine how to salvage the existing LabWare implementation, perform a gap analysis, and complete the stalled configuration, deployment, and validation efforts. The client wanted the comprehensive assistance of a full-time project manager, as they had underestimated the necessary internal activities that exacerbated their issues.

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Objectives

The goal of this project was to ensure a functional, well-documented, global LabWare 7 LIMS implementation with instrument and ERP integration across multiple sites and manufacturing processes. Their prior experience had made the client realize that a different deployment approach was needed to ensure widespread end-user adoption and satisfaction with the LIMS. Additionally, a standardized approach to sampling, testing, nomenclature, data reporting, and business processes across all sites would increase efficiency. The client wanted to improve their in-house understanding of LabWare 7 so that they could maintain their LIMS as it evolved.

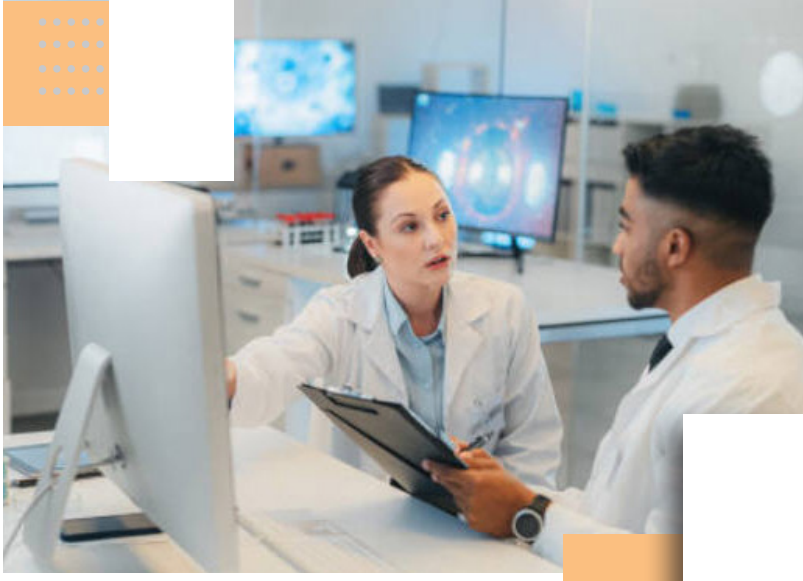
Challenges

The expected challenges (magnified by the project size), included the following:

- No in-house expertise or standard operating procedures for the instruments to be integrated, which led to challenges with data files and testing.
- Incomplete and changing master data across multiple development environments.
- Client unfamiliarity with Agile methodology and limited LabWare LIMS knowledge.

Some of the unexpected challenges that caused significant delays included:

- The COVID-19 pandemic made travel impossible and exacerbated the difficult time zone difference with the Korean sites.
- The staggered LIMS rollout frontloaded development and requirements gathering. The client expected that the subsequent sites would be drop in, but they were not. Some use cases had to be modified to work for subsequent sites.



- A transition to a new SAP ERP started during the LIMS project, straining client resources who used both systems and requiring two development systems

CSols Role In The Solution

CSols was engaged to provide a senior project leader for this global project in collaboration with the client's internal IT project manager.

The CSols resources elicited the requirements; defined the use cases; and configured, built, and tested the system for deployment, using a modified Agile approach. **The Agile methodology** allowed the work to proceed in increments and would allow for corrections if needed before the work advanced too far down an inappropriate path. All activities (not just those assigned to CSols) were examined to determine the approach, identify the proper communication tools, and manage timelines using grouped site gap analyses. Agile development broke the project down into a series of milestones with sprints.

A documented set of use cases was created to serve as the backbone of project planning. This resulted in achievable sprint goals and for expectations to be met by all.

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The CSols consultants helped to smooth the transition to virtual meetings during the pandemic because they had extensive remote work experience.

- Project Leader
  - Ensure the project plan/timelines were met; updating the schedule as needed
  - Strategic advisement, risk management, and change management
  - Guide the client to establish their user acceptance testing (UAT) process
  - Manage and execute Agile configure/ build/test process
- Technical Lead
  - Work with the Project Leader to plan the work for each Agile milestone and sprint
  - Oversee all development work and provide technical leadership
  - Coordinate LIMS environment installs
- Lead Business Analyst/Tester
  - Lead user requirement workshops and gap analysis sessions to understand client needs
  - Write all use cases and functional requirements, updating them as necessary
  - Oversee the system testing and training processes
- Developer
  - Develop/configure the system according to the use cases/FRS and LIMS coding best practices
  - Develop design specification
  - Prioritize, organize, and assign resources to development tasks and perform phased deployments to each environment (development, test, production)
- Lead Business Analyst/Tester
  - Write and execute testing scenarios to ensure use cases and functional requirements are met
  - Develop and deliver end-user and master data training
  - Investigate and resolve UAT system tickets and bug fixes
- Quality Manager
  - Review all CSols documentation (e.g., use case/FRS, milestone summary reports, etc.) to ensure they meet CSols quality requirements

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Benefits

Having a dedicated CSols project leader provided this client with the expertise necessary to guide their implementation to success. The LabWare knowledge that the project leader brought to this engagement was crucial for reigniting the client's passion for this project and ensuring that their team was prepared to manage the system for many years to come.

The successful, global LabWare 7 LIMS implementation and go-live after a failed one gave the client renewed confidence in their LIMS abilities from management and among the team. They gained experience and discipline in a project structure/approach (Agile), which they are now using on other projects in the company.

The detailed training materials CSols provided will allow the client to modify the materials and use them to train additional future users. The work has greatly reduced manual data entry/errors.

This implementation increased data standardization and sharing between sites and enabled reporting with a consistent CoA format.

LabWare LIMS provides standardized QC and QA Batch Release processes, including automated sample tracking with barcodes and results entry. Instrument integrations and an increased QA presence increased efficiency using a single system to track specs and audit history.

Data is now housed in one place and can be used for trending. Workflows are configured by role and function with two, grouped site configurations. This allows different site-specific processes and interactions with the ERP.

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