

A STARLIMS Implementation for a Canadian Pharmaceutical Contract Manufacturing Organization

CASE STUDY

PROJECT AT A GLANCE

Business Sector:

- Pharmaceutical
- Contract Manufacturing

Informatics Systems:

- STARLIMS 12.3

Service Offering:

- Implementation
- Project Management
- Business Analysis
- Validation

Elements:

- 1 Site
- 1 Lab
- 24 Months
- 4 CSols Team Members

A global pharmaceutical contract manufacturer located in Quebec, Canada, had purchased facilities from another global pharmaceutical company and needed to implement a new LIMS as a result. Mergers and acquisitions are a common source of LIMS implementation work. The client has recently signed an agreement to partner with a primary supplier of critical medicines in Canada, which provided a justification to upgrade their labs. As part of the work, the previous owner's SAP instance used for record keeping needed to be disconnected from the informatics system.

CSols Inc. was selected to implement and validate STARLIMS QM v12 at the client's facility due to our knowledge of STARLIMS and its interfacing with SAP, our status as a Canadian entity, and our ability to communicate with the end users in Canadian French.

Objectives & Challenges

The client needed to separate their systems from the previous owner's systems and implement STARLIMS to make it easier for their lab to handle larger sample volumes.

The project faced several challenges. The STARLIMS system was new to the users, so they had limited knowledge of the system and its capabilities. The client lacked dedicated IT resources. Throughout the project, there were multiple changes in the client's assigned resources (subject matter experts, project managers, etc.). During the project, the client got cyberattacked, which made them anxious about adopting new software. Lack of familiarity with STARLIMS added to the client's concerns.

The language barrier (Canadian French from the client, English from some of the CSols resources) occasionally caused misunderstandings.



CSols' Role in the Solution

CSols adopted an Agile approach to deliver the STARLIMS QM v12 implementation and validation. Due to the client's greater-than-usual misgivings about implementing new software, CSols undertook numerous configuration changes (including data uploads and reuploads) throughout the project. This helped to resolve the initial misunderstandings of the system by the client and of the client's data by CSols.

Extra test script reviews were conducted because the client was unsure of the distinction between system validation (for which CSols was not responsible) and requirements validation testing.

CSols provided a project manager, a business analyst, developers, and validation consultants to achieve the project's goals and enable the client to achieve greater laboratory efficiency. Specific tasks undertaken by CSols resources included the following.

Project Management

The Project Manager (PM) created, defined, and executed the overall implementation and validation project. This included:

- Create, communicate, and update the detailed project schedule (Microsoft Project and PDF)
- Communicate project status to key stakeholders on a regular and timely basis
- Manage schedule and budget, project resources, deliverables, and issue and risk logs
- Go-live plan—review and input

Business Analyst

The Business Analyst (BA) worked with the PM, stakeholders, and the client's team to provide expert guidance and feedback throughout the project. Specific tasks that the CSols BA participated in included the following:

- User Requirements gathering—reviews and input
- Functional Requirements documentation—review
- Process workflow development on current and future processes
- Design and Configuration documentation—review
- Static and Dynamic Data Gathering
- Participation in, and review of, up to 5 prototype sessions for new, replacement, or existing upgraded functionality
- Static Data Load Verification
- Bug Fixes—reviews and input

LIMS Developers

The Developers were responsible for the execution of the following:

- Iterative, agile-style development with demonstrations of functionality as it is completed
- Functional Requirement and detailed Design Specification documents
- Peer code reviews of CSols-developed STARLIMS scripting
- Implementation of hypercare support for up to 20 days after go-live

Validation Services

The Validation Consultants used GAMP 5 best practices and their extensive regulatory experience to follow a risk-based approach that ensured the right level of documentation, testing, and verification to mitigate the client's audit risk

- Validation plan development
- SOP review
- Functional risk assessment
- 21 CFR Part 11 compliance assessment
- Data integrity assessment
- Audit trail review risk assessment
- Trace matrix development
- Write, update, and dry run LIMS PQ test scripts
- PQ execution
- Leverage STARLIMS vendor IQ and OQ documentation
- Validation summary report

Other ways the CSols team added value:

- Being proactive to identify potential problems/issues before they cause problems and recommend opportunities for efficiency.
- Knowing the subtleties of the system and being able to quickly provide answers, implement solutions with or without customization, and describe possible short- and long-term impact.

The lack of client familiarity with STARLIMS required extensive training and hypercare from CSols experts to dispel frustrations and help the client understand the system's capabilities. This was achieved with continual informal training and demos throughout the project on the different modules and configuration approaches.

CSols experts were constantly available to answer questions, reassure the client, explain what functionality is used for which purpose, and offer different options to fit the client's needs and deliver a helpful system.

The presence of native Canadian French speakers among the CSols resources was a definite plus when situations or discussions involved ambiguity.

Benefits

Beyond the expected efficiencies and security gained from implementing and validating STARLIMS QM v12, this client also gained a strong understanding of the system.

Their end users are now confident in their abilities to administer the system, set up the data, and configure the different modules to achieve the results they need.