Implementation of STARLIMS v11 at a Global Pharmaceutical company

CASE STUDY

PROJECT AT A GLANCE

Business Sector:
- Pharmaceutical
- Consumer Health

Informatics Systems
- STARLIMS v11

Service Offering
- Implementation

Elements:
- 4 Global Sites
- 4 Testing labs
- 12 Months
- 2 CSols Team Members

A large pharmaceutical company had a LIMS in place for their largest sites and wanted a solution to harmonize all of the smaller sites, some of which had no LIMS and some that had an older LIMS that lacked support. An internal team was put together by the client to look for a new solution. This team conducted a full product selection process including software demonstrations from vendors based on the client's user requirements.

The STARLIMS solution was selected for its flexibility and, not insignificantly, because the client already had STARLIMS expertise on site (CSols consultant and client employees) with multiple years of experience. Their previous work was a result of a recent merger with another company's consumer health business. Therefore, it was a natural choice to have CSols perform this STARLIMS implementation.

Objectives and Challenges

The objective of this work was to provide the client's smaller sites with a simplified STARLIMS application to support both the pharmaceutical and consumer health businesses. The client needed to replace the older LIMS that lacked support and harmonize the smaller sites, as well as set those sites up for any future divestment. The implementation team needed to ensure that the software could provide business support for the manufacturing processes and also needed to roll out the application to two sites every six months. The client's current system had been taking too much time for evaluation and identification of the root cause of production defects. Extracting the necessary data could take as long as 3 hours.

The client also wanted the static data segregated by site to help

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support the sale of individual sites in the future after a potential merger. The technical design for that request was done by CSols, ensuring that the system remained a global one and that, if need be, all the data for a specific site could be extracted, scrubbed from the production database, and moved somewhere else.

Many challenges were faced in completing the first two of the four sites; some of which involved enabling the printing of certificates of analysis (CoAs) in multiple languages, instrument interfacing, customer base data loading, training, and validating two production environments (for the pharmaceutical and consumer health business units). After the successful implementation at the first two sites, the scope of the project changed slightly. For the next two sites, the client wanted to build an interface with SAP for batch creation and usage decision reporting and to develop a packaging material test module. This added a layer of complexity.

CSols's Role in the Solution

The CSols technical consultant created the user requirements specification (URS) and completed an analysis to identify gaps in the proposed system based on the URS. Any data migration from older systems to STARLIMS was also done by the CSols consultant. Four environments were created in STARLIMS to facilitate the implementation: development, validation, production, and sandbox; with design specifications for each.

The CSols resource acted as the technical lead for all aspects of the STARLIMS implementation, and configured the system to meet the URS by creating calculations and adjusting modules and dashboards.

The CSols technical developer also acted as a deputy for server maintenance and reviewed server

access requests. The CSols consultant was responsible for ensuring that updates to the server application and/or database did not affect the system. The CSols consultant built and set up the development and validation environment, including the following responsibilities:

- Procure servers as per specification found in the design document
- Start draft Installation Qualification document while setting up the environment
  - Internet information services, Database client, application software, directory security, etc.

After go-live, the CSols consultant traveled to individual sites to provide training and hypercare support. Once each site's implementation was complete and moved to support, the team moved on to the next sites to implement. New modules or functionality were also evaluated and planned, e.g., Stability module, SAP interface, new reports, KPIs, etc. After the plan was set, the whole process started again with identification of gaps, documentation, customization, testing, approvals, and go live.

CSols developed a custom continuous process validation (CPV) module that used moving ranges, Nelson rules, and other statistical calculations. Now

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the user can go to the CPV module and provide search criteria such as the manufacturing date, product number, etc. The returned results set can be filtered and records excluded by categories such as material code, analyte, or manufacturing date. Once a user is satisfied with the dataset, the user clicks on the graph icon and the statistical information for moving ranges and normal probabilities are shown in graphs with the option of printing the graph and its supporting dataset. This allowed the client to quickly find trends with production issues. This was a major reason for implementing STARLIMS at the smaller sites.

The CSols technical resource was also responsible for runtime upgrades to the system. Using the sandbox, the team was able to assess the impact of the upgrade and plan accordingly. This meant that they would start a new change control and coordinate with the Oracle database group and the Windows Server group to develop the upgrade plan for these machines (if necessary). The upgrade plan would highlight modifications that needed to be reapplied and identify with the client's BA the regression script to run. If no regression scripts were available the appropriate regression testing document was written; for example, for the interface with SAP.

Benefits

The client received a state-of-the-art system that replaced older software and, in some cases, a mix of spreadsheets and paper. With the batches being created directly from SAP, the turnaround for testing was improved.

The process of identifying the root cause of production defects, which had previously taken as long as three hours, was significantly improved. The CPV module that the CSols consultant developed brought the process down to as little as 30 minutes.

CSols made improvements to the environmental monitoring module by scanning all the rooms and developing a pointand-click interface to allow the user to define a sampling point directly on the map.

To help support the production labs, CSols developed a Lab ePlanning tool.

- The tool interfaced with Outlook to plan analysts' work based on their availabilities (by a scan of the Outlook calendar) and their roles, task definitions, and other parameters.
- Touch-screen displays were installed in the labs for access to the ePlanning tool, replacing the traditional whiteboard meetings. Managers could drag and drop tasks from one day to another using their fingers.
- Big-screen monitors in the labs showed the various states that testing tasks were in, using different colors for the status and percent completion. Various key performance indicators were also available, to track lab performance.

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