

Sai Life Optimizes Its Global Data Management Through Collaboration With STARLIMS

ABOUT SAI LIFE

Sai Life Sciences is one of India's fastest growing Contract Research, Development, and Manufacturing Organizations. As a full-service CRO and CDMO, Sai Life works with over 100 global innovative pharmaceutical and biotechnology companies to accelerate the discovery, development, and commercialization of their New Chemical Entity (NCE) small molecule programs. Today, the organization has over 2,500 employees across its facilities in India, the UK, and the USA.

- 100+ molecules across different clinical phases
- USFDA and PMDA certified
- 100% track record of successful inspections across R&D and manufacturing facilities
- Customer base in highly regulated markets, including the USA, EU, and Japan
- Over 70% of GxP activities are governed within electronic systems

SAI LIFE BUSINESS CHALLENGES

Sai Life owned a variety of quality control laboratory management systems and hundreds of instruments on its manufacturing sites.

- Existing GMP-Pro LIMS lacked instrument interfacing capabilities
- Huge amounts of manual activities and document management
- Data transfer from application software to LIMS increased compliance risks
- Difficult to achieve progressive laboratory digitalization
- Absence of data centralization and scalability

WHY STARLIMS SDMS STANDALONE SOLUTION?

In search of the optimization and standardization of instrument data, results, and file storage, Sai Life wanted to

have a comprehensive and centralized data management tool to work together with their existing systems without the need of replacing them, including their document management system. They thoroughly researched and evaluated various SDMS solutions in the market. Sai Life selected the STARLIMS SDMS Standalone solution based on a comprehensive set of standards. This choice was motivated by a high level of flexibility and adaptability of the STARLIMS SDMS solution to the business needs; the global deployment capacity of STARLIMS SDMS technology; implementation expertise and excellent customer support from the STARLIMS team.

For Sai Life, apart from the flexibility STARLIMS Standalone SDMS offers, while working with an existing LIMS solution, other major benefits include:

Equipment Data Capture

- Interfaces with all types of equipment results
- Data extraction of Port/RS232, TCP IP, file types of all sorts, CDS software
- Both standalone and networked equipment interface
- Interface with raw data image capture
- Generation of custom reports
- Creation of custom documents and approval workflows

Files Storage, Search, Archival

- Store all types of files generated, including SOP, Masters, MSDS, calibration, maintenance, training, etc.
- Equipment handling data sheets, raw data sheets, COA, reports, equipment raw and processed data, images, graphs, etc.
- Upload from multiple sources or automatic capture from various sources
- Define meta tags and search criteria to search documents and data inside documents
- Archive original raw data files from the instrument, as well as a standardized representation in XML format
- Search, reporting, and trending

Interface with LIMS, ELN, and Worksheets

- Extract, transform, and transfer instrument data and results to GMP-Pro LIMS without human intervention
- Receipt of sample information
- Handle request and dispatch of the raw data file

Data Integrity and Compliance

- Assure the highest data integrity in document capture, storage, processing, search, and archival of all types
- 100% 21CFR Part 11 envelope
- Password-protected and role-based access to files
- Retention policy rules
- Document lock-down and revision control and full traceability during the validation process

CUSTOMER TESTIMONIAL

“When you have multiple application software where reporting templates are different, capturing those data in a harmonized way and pushing data into a LIMS should be customized. How easy it is to customize is a game-changer for the implementation timeline. STARLIMS brought us a very good system and helped us to customize the reports easily.”

Dr. M. Damodharan, Chief Quality Officer & Head of Global Quality and Regulatory Affairs

Sai Life's Challenge	STARLIMS Solution	Sai Life's Result
Equipment integration: It was difficult for Sai Life to get all the raw data from equipment and analytical software. Manually pulling data was time-consuming.	STARLIMS SDMS offers one tool to handle all types of interfaces with complete integrity and increased efficiency.	Significant savings on investing in additional middleware and multiple data storage systems.
Data entry errors: With the electronic systems Sai Life was using, data entry errors were generated from manual tools, thus undermining data integrity, and causing compliance risks.	STARLIMS SDMS is an automated solution that can be used to eliminate manual errors. It can capture data in real-time, back up data, protect it from deterioration and loss, and maintain the raw data as the original record.	Reduced errors in data entry and other measurables with an automated solution, ensuring data integrity.
Sharing of files: It was a big challenge for Sai Life to share files between different systems and across manufacturing sites.	STARLIMS SDMS supports file sharing for review by team members and provides and maintains version control.	Efficient and harmonized file sharing across various systems and manufacturing sites to support global business growth.
Workflow routing: Various process mapping was a major challenge in a manual system, including sample receipt, sample allocation, analyst qualification, test methodology, document management, integration, material release, etc.	STARLIMS SDMS supports the definition of workflows in various scenarios. It allows users to create workflows for the retrieval and approval of documents. Steps include actions like email, export to PDF, synchronization to LIMS, etc.	Huge time saving from workflow automation. Less turnaround time and reduced errors.
Data centralization: Sai Life found it difficult to store data for a long period while maintaining appropriate connections without data centralization.	STARLIMS SDMS supports data repositories in a single system. Instead of file servers and local computers, the SDMS database can store all instrument data.	Data in a single centralized storage system with easy access and retrieval. Enterprise application allows users to view or access data from different locations and sites with predefined permissions.
Documents searching and locating: Searching and locating documents was time-consuming for audits.	With STARLIMS SDMS, documents are indexed and easy to search and retrieve.	Time and cost-savings on document searching and locating, readiness for audits.