Top 10 Pharmaceutical Company Improves Laboratory Productivity

Employing thousands of people worldwide, this top ten pharmaceutical company operates research and development, manufacturing and distribution facilities in a multitude of countries on four continents. Bulk products are shipped from pharmaceutical plants around the world where they are used as the key ingredients in the production of injectables, tablets and capsules.

Business challenge and objectives

In an effort to reduce the cost of maintaining and supporting multiple home-grown LIMS, the company sought to consolidate onto one corporate standard across all sites with the following objectives:

- Business integration with IT systems such as ERP, MES, LIMS and other enterprise and laboratory software applications

- Laboratory automation with instruments and other data systems

- Global harmonization and standardization of best practices

- Paperless lab, reduced costs and improved quality

Requirements

Thermo Scientific™ SampleManager™ LIMS software was selected was selected not only for its products' rich functionality and extensive deployment history in Pharmaceutical QA/QC, but also for its services capabilities to implement, validate and provide language support across multiple sites and continents. With SampleManager LIMS software, the company had all of the tools necessary to meet its integration, automation and harmonization objectives.

Thermo Fisher
S C I E N T I F I C

Phase 1

The project initiated at the Active Pharmaceutical Ingredients (API) production facility to support both the Quality Control (QC) and In-Process (IP) laboratories. The implementation of SampleManager LIMS software in their new facility presented a number of requirements, including meeting strict deadlines for completion to coincide with production initiation.

In terms of functionality, the fundamental requirements of the LIMS were clearly outlined at an early stage. They needed a system that would allow users to store, manipulate and retrieve information relating to samples and laboratory processes. In addition, the LIMS needed to act as a centralized repository storing all analytical data for release and stability testing purposes, along with environmental monitoring.

Phase 2

The project team also identified the need to interface the LIMS both within the laboratory and to external systems to automate their workflows, improve efficiencies and facilitate communication. Inside the laboratory, the LIMS needed to integrate with their analytical instrumentation — from simple instruments such as balances and pH meters, to more complex instruments that collect and process the results, such as chromatography and mass spec data systems. The LIMS also needed to act as the conduit to connect the lab to external systems and interface with the companies Enterprise Resource Planning system (SAP) specifically for QC, Electronic Laboratory Notebook and Operations Management software applications.

In addition, it was necessary for Thermo Fisher Scientific to develop and implement a comprehensive training program for the large number of staff to ensure the smooth running of the system from the outset.

Phase 1 LIMS implementation was to be used as a prototype system for future rollout to other global sites.

The solution

In order to meet the key challenge of such aggressive timelines, Thermo Fisher assisted with the gathering and standardizing of business requirements across multiple sites. This was followed by customer workshops aimed at training and determining gaps in the workflow. Gaps were transformed into a design specification that formed the basis for system implementation and configuration.

Phase 1 implementation included validation Performance Qualification (PQ) and stability testing. The system was configured to meet all of the requirements including sample login via ERP interface, test assignment, label generation, worksheets, results entry and review, batch disposition, certificate of analysis, stability testing, environmental monitoring and management reporting and trending among many other items.

The SAP interface enabled the QC function to automatically login samples based on goods received into the warehouse and goods issued by production. The interface also addressed the requirements for automatic login of samples for materials approaching retest (expiration) date.

The local and on-site presence of the Thermo Fisher services team for the entire duration of the project also ensured faster progress of the project through continuous access to all of the project team. Additionally the active involvement and "hands on" approach of both organizations enabled quick decision making and document turnaround. Thermo Fisher's SAP expertise was critical to the success of this project.

To facilitate remote deployments, Thermo Fisher leveraged a broad partner network to provide resources to help configure local data and train end users in their native language. Orbis Labsystems works exclusively with Thermo Fisher products and its services include LIMS justification and cost benefit analysis, design, implementation and support. Orbis also provides LIMS integration solutions for instrumentation, CDS, business and manufacturing systems.

With Thermo Fisher's ongoing partnership and support, the LIMS is now implemented across twelve sites and four continents.

Business benefits

The implementation of SampleManager LIMS software has resulted in a number of clear benefits including:

- Enhanced data quality, integrity and availability by eliminating manual, error-prone and time consuming paper-based processes
- Reduced the cost of ownership by eliminating high overhead and inefficient home-grown applications
- Optimized workflows by harmonizing and standardizing on unified methods, SOPs, specifications and other laboratory practices across all laboratories
- Consistent global deployment by leveraging network of Thermo Fisher staff and partners
- Better flexibility to adapt to evolving business processes
- Improved productivity and efficiency by automating and integrating systems and instruments
- Operators trained via on-demand multi-lingual eLearning
- Manufactured lots traceable directly back to raw material and EM data

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Partnering with Thermo Fisher Scientific

Thermo Fisher Scientific is the worldwide leader in laboratory software and related services, providing enterprise-wide, multi-laboratory solutions that have become the corporate standard at leading pharmaceutical organizations. Our LIMS, CDS, SDMS and other informatics solutions control manufacturing quality data at many of the world's leading pharmaceutical companies. To support our global customers, we provide implementation, training, maintenance and support from the industry's largest worldwide informatics services network.

To support customers worldwide, Thermo Fisher offers comprehensive professional services ranging from implementation and validation to support, training and education. Deploying and maintaining LIMS and CDS software raises many challenges from defining your initial project requirements and implementing/validating your solution, to ongoing support and training.

Expert knowledge to help make the right decisions, targeted assistance with deployment, and a clear understanding of the software and how it integrates in your application, all combine to help yield the long term benefits you look for when buying software.

Our comprehensive range of implementation and validation services is delivered via a unique approach that integrates software deployment, project management, consulting, and instrument and systems integration. With a global network of some of the most highly experienced professionals dedicated to delivering the best informatics services in the industry, Thermo Fisher's LIMS and CDS deployments are smooth and predictable.

Find out more at **thermofisher.com/digitalscience**

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