

Life Sciences Case Study
PROJECT OVERVIEW

CLARKSTON
CONSULTING

LIMS

SOFTWARE

SYSTEM

DESIGN AND

VALIDATION

Founded over 100 years ago, the client develops and produces medicines and vaccines for a wide range of medical disciplines, including immunology, oncology, cardiology, endocrinology, and neurology.

The organization faced significant challenges with their laboratory automation platforms, used to support and optimize ongoing laboratory operations. Differing technology strategies and multiple mergers and acquisitions led to dynamic, site-specific business processes and laboratory information management systems (LIMS) configurations. Furthermore, the current LIMS were approaching end-of-life status with the vendor. As a result, the costs of maintenance, support, and compliance for their LIMS platforms were continuing to rise.

Clarkston Consulting collaborated with the client to achieve process harmonization, requirements definition, system configuration, and validation of a global LIMS system, leading to one of the most advanced, integrated, and standardized laboratory automation and global quality data warehouse systems in the world.

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PROJECT OVERVIEW



COMPANY:

One of the world's largest pharmaceutical manufacturers

INDUSTRY:

Pharmaceutical Manufacturing

PRODUCTS & SERVICES:

Discovers, develops, manufactures and markets medicines for humans and animals, as well as consumer products.

EMPLOYEES:

96,500

REVENUE:

\$52.8B (Globally)

PRIMARY OBJECTIVES:

- Harmonized business processes, data structures, and best practices across sites
- Improved operating efficiency utilizing standardized master data configurations and improving real-time data analytics
- A foundation for future adaptation of paperless labs to reduce human error
- Simplified and streamlined global LIMS IT landscape

RESOLUTION:

- Used individual, tightly-integrated teams focused on each business process to migrate global business requirements from legacy platforms to a single LIMS solution
- Developed a fully configured core solution, including standard lab business processes, chain of custody, instrument interfacing, and SAP interfacing allowing for lot generation and usage decisions
- Designed reporting and analytics utilizing both the standard queries and reports in LIMS, as well as the data warehouse
- Validated the core solution using an agile, lean and risk-based verification methodology
- Produced global training materials and delivery methodology
- Prepared and executed the deployment methodology to sites

KEY BENEFITS:

- Harmonization of business processes, master data, and reporting from disparate processes and unique site data
- Further integration of laboratories from previously acquired companies
- Reduction of site-specific system documentation maintenance through use of harmonized global standard operating procedures (SOPs)
- Greater consistency across labs and reduction of errors
- Improved test and lot cycle times within the laboratory
- Visibility to key quality metrics for reporting and decision making as part of the data warehouse
- Broader availability of LIMS data to the organization so it may be integrated with other datasets for additional insights/information, such as ERP and QTS data
- Consolidation of relevant LIMS information across the organization
- A robust and simplified ad-hoc reporting platform
- Cost savings due to increased efficiencies and enhanced compliance in the laboratory
- Ability to plan for the retirement of aging and unsupported platforms

ANTICIPATED BENEFITS:



Reduction in test cycle times and elimination of manual verification and housekeeping checks



Enhanced Right First Time performance and data integrity through audit-trail control



Advancement towards centralized licensing and infrastructure by decommissioning of platforms

