

Executing the Global Deployment of LabVantage LIMS for a Biopharmaceutical Company

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES:



Vaccine and antibody
therapeutics development
and manufacturing

BUSINESS TRANSFORMATION STORY & BUSINESS CHALLENGE

The client is a global specialty biopharmaceutical company that develops vaccines and antibody therapeutics for infectious diseases. The client initially engaged Clarkston to propose an IT strategy roadmap for their global implementation for a LabVantage (LV) LIMS solution for their R&D, Clinical, and Quality laboratories across 10 sites. Clarkston provided a multi-phase approach along with a detailed project plan.

While in the initial project phase, which comprised of implementing the Environmental Monitoring functionality at their manufacturing sites, Clarkston transitioned into a project management role. Working with the project management leadership, the Clarkson team led business process mapping, system requirement gathering, deployment activities, and an overall governance strategy for validation, training, and system adoption.

The project had several challenges and setbacks to mitigate throughout the three-year deployment. The site deployments were designed to be multi-phase rollouts, but this proved challenging due to the resource and time commitment disparity between single product smaller sites vs. large sites with multiple products as well as serving as a contract manufacturer with multiple clients. The client also experienced layoffs, site closures, and divestitures, which directly impacted committed resources, budgets, and timelines.

The three-year project implemented a validated global LV LIMS platform that integrated end-to-end laboratory processes across their laboratory network, delivering multiple process improvements and digital enhancements. The project established a global master data governance model consisting of test methods, specifications, and certificates. All sample creation, resulting recordings, and generation of certificates are now managed by the LV LIMS platform. With all testing data present in the LIMS database, data visualization is now possible by leveraging dashboards and reports linking to statistical tools for process capability and stability modeling. During this transformation, laboratory manual processes were eliminated, and legacy LIMS solutions were decommissioned, strengthening data integrity and compliance risks under the LV LIMS solution.



PRIMARY OBJECTIVES:

Project Management

- Execute the strategy deployment plan within specified timeline, resources, and budget
- Build a central team comprising of client, Clarkston, and LabVantage (LV) resources to execute the deployment plan
- Establish a global governance model and provide oversight for system configuration and customization, master data build, validation activities, and migrations through the project and production environments
- Coordinate activities between the client and LV technical services to meet business requirements and validation of the LV system

Business Processes

- Implement a validated global LIMS solution to integrate end-to-end laboratory systems and processes across R&D, Clinical, and Quality laboratories
- Reduce manual processes to mitigate data integrity and compliance risk
- Leverage a global LIMS solution to develop harmonized laboratory process to drive operational improvement and efficiencies

Site Deployment

- Oversee site go-lives with minimal disruption to the site's business activities
- Develop training materials and facilitate end-user trainings
- Collaborate with the sites to coordinate the cutover, along with hyper-care and maintenance activities

RESOLUTION:

Project Management

- Developed, managed, and executed a 3-year project plan within scope and budget using the proven Clarkston methodology
- Established a master data governance model consisting of test methods, specifications, and certificates
- Created a master data analyst team who collaborated with site resources to evaluate, build, and validate master data

Business Process

- Conducted requirements gathering and harmonization workshops across R&D, Clinical, and Quality organizations
- Provided technical insight into the business processes and system development and integration
- Managed the build, review, validation, and migration of master data objects across project and production clients
- Ensured the design of the LIMS solution aligned with master data configuration
- Delivered a LV-SAP interface to further streamline the processes between generation and release of laboratory data
- Recorded all testing data in the LV LIMS and generated certificates
- Produced a global certificate of analysis generated from the LV system dashboards and reports to improve reporting and laboratory operations
- Eliminated manual data recording procedures to strengthen data integrity compliance

Site Deployment

- Drafted and refined training plans for end users, subject matter experts (SMEs), and administrators
- Formed and managed the master data delivery plan, cutover plan, and hyper-care support
- Harmonized laboratory process for sample generation, resulting recording, and data reporting

KEY BENEFITS:

- Enhanced data integrity procedures with a validated global LV LIMS solution that integrated laboratory systems and processes across 8 global sites
- Implemented the LabVantage Platform consisting of environmental monitoring, sample management, results recording, investigation reporting, Lab Execution System (LES), LV/SAP interfacing, and dashboard/Jasper reporting
- Ensured a standardized approach for documenting laboratory investigations and Acceptable Quality Levels testing within the LV solution
- Established a Master Data Governance module and Change Management procedure

KPIs

- Built a high-performance team consisting of over 50 resources from client (central and site), Clarkston, and LV resources to execute the project plan
- Deployed ~29,202 master data objects across 12 site-specific deployments, leveraging a successfully trained and managed staff of 22 client subcontracted resources at varying levels of Global Master Data Management
- Decommissioned 2 legacy LIMS with the replacement of a global LV LIMS platform
- Streamlined the generation of testing certifications from 1,000 product-based templates to 5 global LIMS templates