

Supporting a LabVantage Implementation for a Gene Therapy Company

The client operates as a biotechnology company, focusing on the development, commercialization, and licensing of recombinant and adeno-associated virus gene therapy, and serves customers worldwide. Their gene therapy product candidates are designed to deliver genes to cells to address genetic defects or to enable cells in the body to produce therapeutic proteins that are intended to impact disease.

Following a successful vendor selection, the client has continued to engage Clarkston Consulting to support the implementation of their selected LIMS solution, LabVantage. Their existing LIMS solution was becoming increasingly difficult to maintain and update. Additionally, there were still Excel sheets in place that had been flagged for replacement. This deployment transitioned the lab processes within their Analytical Development/Quality Control (AD/QC) and BioAnalytical departments from their current custom-built LIMS to a more stable and robust platform.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Biopharmaceuticals

PRODUCTS AND SERVICES :



Cell and Gene Therapy

PRIMARY OBJECTIVES:

- Provide a validated LIMS solution to meet the business requirements and facilitate the execution of the laboratory processes
- Partner with the client to guide business process design and provide project management
- Configure master data for both the QC laboratory as well as the BioAnalytical group, including test methods, instruments, consumables, biobanking, and products
- Develop and define change management processes and training materials as well as facilitate end-user training
- Capitalize on opportunities to enhance process flows and efficiencies where LabVantage could serve as the catalyst

RESOLUTION:

- Established, managed, and executed project plan and scope using the proven Clarkston methodology
- Ensured the design of the LIMS solution aligned with master data configuration
- Developed and managed the Master Data Delivery plan, cutover plan, and hyper-care support
- Provided technical insight into business process strategy
- Executed build, review, and migration of master data objects
- Supported validation efforts of master data and system objects
- Developed training plans for end users, subject matter experts (SMEs), and administrators
- Facilitated “Day in the Life” workshops and “Train the Trainer” sessions
- Assessed potential for an ERP interface for product batch creation (*successfully completed next phase*)

KEY BENEFITS:

- More robust LIMS solution with additional features and capabilities from legacy system
- Enhanced sampling plans and labeling, leading to efficient sample management
- Ability to capture data in a more streamlined approach throughout the laboratory
- Easier tracking of identifying consumables for use in LIMS within the laboratory
- Allowed identification of testing from different labs within AD/QC department
- Foundational processes and procedures that would scale with the client and desired throughput
- Reduced risk for both end users as well as the team maintaining the system



KPIs

- **Converted 294 test methods from legacy system to new LIMS**
- **Added 91 products for GxP and development batches**
- **Implemented 271 consumables with expiration and container tracking**
- **Simplified way of logging batches utilizing sampling plans**