

Expanding LIMS Functionality with LabVantage: Advanced Analytics for a Gene Therapy Company

The global client operates as a biotechnology company, focusing on the development, commercialization, and licensing of recombinant and adeno-associated virus gene therapy, serving customers worldwide. Its 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.

The client continues to engage Clarkston Consulting to support and expand on the implementation of their selected LIMS solution, LabVantage. Their existing LIMS solution was becoming increasingly difficult to maintain and update. The LabVantage deployment expanded on the initial implemented lab processes within their Analytical Development/Quality Control for Raw Materials department, with an integration of Oracle as the main Enterprise Resource Planning (ERP), as well as within their Bioanalytical departments to include Biobanking and LabVantage Analytics.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Biopharmaceuticals

PRODUCTS AND SERVICES :



Cell and Gene Therapy

PRIMARY OBJECTIVES:

- Expand functionality to a validated LIMS solution to meet the business requirements and facilitate the execution of the laboratory processes for Raw Materials and Biobanking
- Partner with the client to guide business process design and provide project management
- Capitalize on opportunities to enhance process flows and efficiencies where the LIMS solution could serve as the catalyst
- Create master data supporting the creation of Raw Material batches and Biobanking
- Support the interfacing of the client's ERP solution to the LIMS solution using the API for inventory management
- Collaborate with the vendor to configure and customize the Advanced Analytics module with a write back of data to LIMS

RESOLUTION:

- Established, managed, and executed the project plan and scope using the proven Clarkston methodology
- Ensured LIMS application design aligned with master data configuration
- Developed and managed the Master Data Delivery plan, cutover plan, and hyper-care support
- Provided technical insight to inform and develop a business process strategy
- Executed build, review, and migration of master data objects for Biobanking and Raw Material setup
- Supported validation efforts of master data and system configurations
- Provided technical LIMS guidance and API knowledge in support of the ERP interface for product batch creation of Raw Material
- Collaborated with vendor to use the Advanced Analytics module (LVA) to create calibration curves and plate analysis with a write back of statistics to LIMS

KEY BENEFITS:

- Raw Materials, and eventually Manufacturing Lots, automatically created in LIMS using an ERP interface
- Plate (Array) Methodology and Biobanking capability in a more robust LIMS, allowing for streamlined processes
- Analytical calculations done through Advanced Analytics with Artificial Intelligence (AI) capabilities
- Foundational processes and procedures that will scale with the client and desired throughput
- Reduced risk of error for both end users as well as the team maintaining the system by having calculations automatically perform statistics and calibrations in the analytics module



KPIs

- Supported the importing of manifests to Accession multiple Biobanking samples, saving time and resources.
- Interfaced the ERP to create Raw Material lots in LIMS, reducing risk of error and saving time
- Added 69 product configurations for Raw Materials
- Enhanced trending of Biobanking data using Advanced Analytics and artificial analysis to predict failures or out-of-range possibilities
- Enabled faster statistical analysis and calibration curves on plates (arrays) done seamlessly

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