

CASE STUDY:

LabVantage LIMS Functional Expansion in a Rapidly Expanding Biotechnology Company



OVERVIEW: A rapidly expanding biotech company focused on drug discovery and drug development for vaccines, oncology and other diseases was using LabVantage LIMS in its analytical development and quality control laboratories. The LabVantage system was initially rolled out as a “results only” deployment for their Drug Substance and Drug Product Analytical Development departments. Following this initial deployment, the company decided to expand the functionality in their LabVantage system to support tracking and processing test data from clinical trials of their drug candidates. The company hired Astrix to help with the buildout and deployment of these enhancements due to our extensive experience with the LabVantage platform.

BUSINESS CHALLENGE: Since the initial Phase I “results only” deployment for LabVantage LIMS in 2017, the company experienced significant expansion. As a result, the LabVantage system needed to be enhanced to accommodate expanded use cases, an expanding and changing user base, and new functionality. Specifically, the enhancements required were:

■ Expanded Use:

- ▶ AQC Module
- ▶ LES Worksheets for AQC and test method analysis
- ▶ Instrument integrations
- ▶ Reagent Lot/Reference Standard Lot Module

■ Expanding and changing user base:

- ▶ New user training
- ▶ Training on new functionality

The company’s business goals for this project included:

- Eliminate use of Electronic Lab Notebooks
- Eliminate use of spreadsheets for data calculations and reporting
- Eliminate copy/paste or duplicate data entry of result data from instrumentation to LIMS

SERVICES PROVIDED: The work the Astrix Team did on this project included:

■ **Configuration**

- ▶ Built out full test methods from SOPs (deployed 150+ test methods, including parameter lists, and specifications)
- ▶ AQC Module configuration (deployed 60+ QC methods)
- ▶ Configured LES Worksheet templates (Test method LES Worksheets, AQC method LES Worksheets)
- ▶ Managed demonstration/feedback and review/approval processes
- ▶ Defined reagent types and inventory tracking parameters
- ▶ Configuration migration from DEV (method development) to QUAL (verification) to PROD environments

■ **Instrument Integrations**

- ▶ Chromeleon driver testing and evaluation
- ▶ HPLC Data File configuration
- ▶ Parameter Instrument Field mapping
- ▶ File Result transfer testing

■ **Training**

- ▶ Developed training materials and training plan for new functionality
- ▶ Scheduled and delivered training to 25+ end users in groups of 5-10
- ▶ Combined process overview, LIMS application instructions, demonstration and hands on exercises in training sessions
- ▶ Retrained users as new or modified processes were deployed
- ▶ Maintained training materials as functional modules were deployed/improved

■ **Application Experience / Best Practices**

- ▶ Recommended and developed solutions for user needs/requirements
- ▶ Used the power of the LabVantage LIMS toolkit to develop creative solutions to unique problems
- ▶ Shared LabVantage LIMS knowledge and experience with the rest of the project team

■ **Vendor Support**

- ▶ Logged issue tickets in vendor support system
- ▶ Worked with vendor staff to document and provide supporting information to investigate and solve issues
- ▶ Tested and Implemented recommended solutions to address issues

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RESULTS DELIVERED: Given the rapid pace of growth, the customer required rapid deployment and fluid design to meet the ever increasing business demands. The LabVantage enhancements implemented in this project met these needs and resulted in significant improvements to operational efficiency, regulatory compliance and data integrity in the company laboratories.

The customer was very happy with the results of this project. All the customer's business goals were accomplished on a rolling basis - as the individual method solutions were verified and moved into production, the use of the ELN and spreadsheets were eliminated for that method. This project was also one of the first implementations of LabVantage LIMS AQC LES Worksheets, functionality that was released in LabVantage LIMS version 8.3.