

## 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, 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:
  - Analytical Quality Control (AQC) Module
  - LES Worksheets for AQC and test method analysis
  - Instrument integrations
  - Reagent Lot/Reference Standard Lot Module
- Expanded Use:
  - Expanding and changing user base
  - New user training
  - Training on new functionality

**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

### 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

## ■ 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

**RESULTS DELIVERED:** Due to the significant growth that the company was experiencing, the customer required a rapid deployment and fluid design of the LabVantage LIMS to meet the ever increasing business demands. The LabVantage enhancements implemented in this project met these needs and resulted in substantial improvements to operational efficiency, regulatory compliance and data integrity in their analytical development and quality control laboratories. All of 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.

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## ABOUT US:

**Astrix** has been an industry leader for over 25 years in helping scientific organizations implement and integrate improved informatics systems in the laboratory. Our experienced team of expert informatics consultants bring together technical, strategic, regulatory and content knowledge to provide the most effective solutions to problems faced by scientific organizations. Our domain experts have helped hundreds of companies globally effectively navigate their digital transformation journey. Visit [astrixinc.com](http://astrixinc.com) for more information.



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