Business Sector: **BIOBANKING**

CASE STUDY:

LabVantage LIMS Biobanking Validation for a Contract Research Organization

OVERVIEW: A contract research organization (CRO) providing full-service clinical development services to biopharmaceutical and medical device sponsors was interested in implementing one centralized system to manage their biorepository. They choose to install the LabVantage pre-packaged LIMS designed for biobanking (LabVantage Biobanking), as this system is pre-configured to address all aspects of biorepository management.

The customer worked with LabVantage Professional Services to implement LabVantage Biobanking into their laboratories with no customization of the system. Once LabVantage Biobanking was installed, it needed to be validated. As a premier LabVantage consulting partner, Astrix Technology Group specializes in validation services for LabVantage LIMS. The customer therefore decided to partner with Astrix to fulfill its LabVantage Biobanking validation requirements.

SERVICES PROVIDED: Astrix provided two primary resources to the customer to accomplish the necessary validation activities for LabVantage Biobanking:

- **Validation Manager** – This resource had overall responsibility for all validation services performed and worked to keep validation activities within budget and in alignment with the overall LabVantage Biobanking implementation project plan. The Validation Manager interfaced with both the LabVantage Project Manager and customer resources.
- **Validation Analyst** – This resource was responsible for the planning, construction and execution of all validation-related Services.

The work the Astrix Team did on this project included:

Validation Plan. The Astrix team created a Validation Plan document that defined the objectives of the validation, the approach for maintaining validation status over the full software development lifecycle (SDLC), and satisfied all regulatory policies and industry best practices (e.g., GAMP 5). The Validation Plan detailed the following:

- **Project Scope** – outlined the parts of the system that needed validation (those parts of the system that would be utilized by the customer), along with deliverables/documentation for the project.

The Astrix team created a Validation Plan document that defined the objectives of the validation, the approach for maintaining validation status over the full software development cycle, and satisfied all regulatory policies and industry best practices.

- **Testing Approach** – Defined the types of data that would be used for testing, along with the kind of scenarios that would be tested.

- **Testing Team and Responsibilities** – Listed the members of the validation team, along with their roles and responsibilities in the validation process.

- **Acceptance Criteria** – Defined the requirements that need to be satisfied before the system is considered suitable for use in regulated activities.

Requirement Gathering. The Astrix Team gathered the necessary information regarding the customer's intended use of the system that would be used to guide a risk-based approach to validation testing. The following documents were finalized in this phase:

- **User Requirements Specification (URS)**. The Astrix Team worked with the customer to author the URS, which clearly defined what the system should do, along with any operational (regulatory) constraints.

- **Functional Requirements Specification (FRS)**. The Astrix Team worked with the customer to review/revise the FRS, which defined how the system will look and function for the user to be able to achieve the user requirements.

- **Design Specification (DS)**. The Astrix Team reviewed the LabVantage Biobanking DS that were created by the implementation team.

Risk Management. The Astrix Team conducted an analysis of failure scenarios to determine scope of validation efforts. A risk management plan (RMP) was created to document the findings and recommendations which came out of the analysis.

System Qualification and Interim Reports. All installation qualification protocol (IQ) activities associated with infrastructure of the hardware, software, and instrument interfaces were completed by the customer with the assistance of other third-party vendors. The Astrix Team reviewed IQ documentation, and conducted the following qualification activities:

- **Operational Qualification Protocol (OQ) with Test Scripts** – Wrote test scripts at subject matter expert (SME) level and conducted the testing.

- **Performance Qualification Protocol (PQ) with Test Scripts** – Wrote test scripts at SME level and conducted the testing.

- **Traceability Matrix** – Documented the OQ and PQ results in a Traceability Matrix

Closure & Deviation Management. The Astrix Team worked to document the results of the project by authoring the following documents:

- **Validation Summary Report (VSR)** – A review of all activities and documents against the Validation Plan.

- **System Release Document** – Documentation that validation activities are complete and that the system is available for intended use.

RESULTS DELIVERED: The contract research organization (CRO) engaged with the professional services group at LabVantage to install and configure the pre-packed LIMS for biobanking Astrix Technology group then created a Validation Plan document that defined the objectives of the validation, the approach for maintaining validation status over the full software development lifecycle (SDLC), and satisfied all regulatory policies and industry best practices. The validation plan detailed the project scope, testing approach, testing team responsibilities, and acceptance criteria. Additionally, Astrix provided the Validation Manager and the Validation Analyst resources to perform the necessary validation activities.

The Astrix Team then gathered the detailed information regarding the customer's intended use of the system that was used to guide a risk-based approach to the validation testing. The documentation provided during this phase of the project included the User Requirements Specification (URS), Functional Requirements Specification (FRS) and Design Specification (DS).

During the final phase of the project, the Astrix Team conducted an analysis of failure scenarios to determine scope of validation efforts. A risk management plan (RMP) was created to document the findings and recommendations which came out of the analysis. The system qualification was managed in two stages. The IQ was completed by the customer with the assistance of other third-party vendors. The Astrix Team reviewed the IQ documentation, and conducted the OQ and PQ, with all and results documented in a traceability matrix. At the completion of the validation, the Astrix Team provided a Validation Summary Report (VSR) and the System Release Document indicating that all validation activities were completed, and that the system was available for intended use.

The LabVantage validation performed in this project by the Astrix Team met the customer's needs which resulted in significant improvements to operational efficiency, regulatory compliance and data integrity for their centralized LabVantage LIMS and biobanking system. The customer was extremely satisfied with the results of this project having accomplished all of the intended business goals.

The LabVantage validation performed in this project by the Astrix Team met the customer's needs which resulted in significant improvements to operational efficiency, regulatory compliance and data integrity.

ABOUT US:

Astrix Technology Group Astrix Technology Group has over 25 years' experience helping scientific organizations architect, select, implement, integrate and validate laboratory informatics technologies. Our experienced professionals have the skills necessary to help your laboratory turn data into knowledge, increase workflow efficiency, improve quality and facilitate regulatory compliance.

Visit astrixinc.com for more information.

astrix TECHNOLOGY GROUP
CORPORATE HEADQUARTERS
125 Half Mile Rd, Suite 200
Red Bank, NJ 07701
732-661-0400