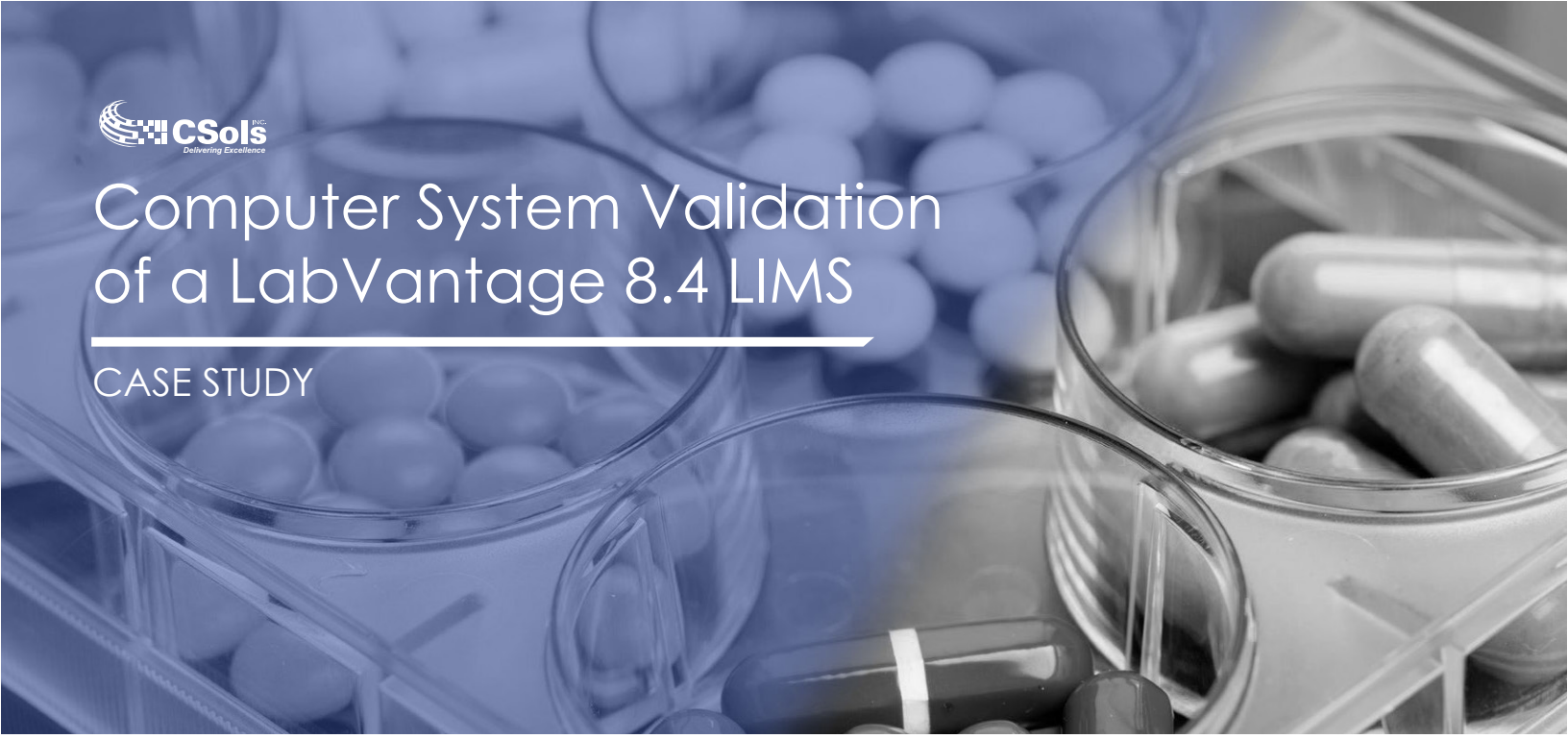

Computer System Validation of a LabVantage 8.4 LIMS

CASE STUDY

PROJECT AT A GLANCE

Business Sector:
- Pharmaceutical
- Contract Lab

Informatics Systems
- LabVantage 8.4 LIMS

Service Offering
- Implementation Validation

Elements:
- 1 Site
- 1 Testing lab
- 2 Months
- 2 CSols Team Members

The client is a pharmaceutical contract manufacturing and stability testing company focusing on providing rapid contract testing and long-term stabilitytesting for their clients. They are planning to transition away from paper recordkeeping by implementing a LabVantage LIMS to support their Quality operations and long-term growth.

The pharmaceutical contract manufacturer had selected LabVantage 8.4 LIMS for their analytical laboratory and the implementation was completed successfully by the vendor. Due to personnel constraints, the client wanted to support their internal validation efforts with an expert LIMS consulting company that has experience with IT Computer System Validations (CSV).

As a partner of LabVantage Solutions, CSols was brought on the project to provide validation deliverables such as the Validation Plan, the Functional Requirements Specification (FRS), the User Requirements Specifications (URS), the Functional Risk Assessment (FRA), the Configuration Specification (CS), the Trace Matrix (TM), Test Scripts (IQ/OQ/PQ), and reports that are required by the U.S. Food and Drug Administration (FDA).

The LabVantage organization knows thatCSols has a team of validation experts with an excellent track record of delivering validation documentation and testing to keep clients compliant and their systems defensible in an FDA audit. LabVantage staff suggested CSols for the validation part of the project. CSols was also tasked with writing supporting documentation such as the client's standard operating procedures for LabVantage LIMS.

The client agreed that CSols was the right consultancy to achieve the objectives defined for validating this LIMS in an FDA-regulated industry.

Objectives and Challenges

The client required the development of standard validation deliverables

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per its guidelines and to comply with FDA regulations. The client was also interested in developing all the supporting work instructions (WI) required for the LIMS.

If the effort was not completed, the client would not be able to support/improve the productivity in the contract testing and stability area of their business. They would continue to face an unmanageable amount of paper records, which has been inefficient and prevented growth. The tracking, traceability, and audit trail of the data would continue to be difficult for quality management.

To achieve these objectives, there were a few hurdles to overcome:

- The client required additional resources to help move the validation portion of the project forward.
- The client did not have specific validation procedures and those needed to be developed along with the documentation.
- In the middle of the project, the client was acquired by another company, which brought in additional procedures that needed to be met.

CSols's Role in the Solution

The CSols and LabVantage partnership often results in advantageous collaborations for clients. CSols has built a depth of experience with LabVantage validations upon which the LabVantage team knows they can rely. For this client, CSols consultants helped with the validation project planning by reviewing the vendor documents to identify any gaps and develop the CSV deliverables as follows:

- Validation Plan
- Identifying/gathering /documenting requirements
- URS
- FRS

- TM
- FRA
- CS
- OQ/PQ test scripts
- Summary reports

CSols then supplied resources to move the validation work forward, providing expertise in developing the required documentation. CSols used a risk-based approach to follow the GAMP5 guidelines for validation of configurable systems. CSols consultants helped the client adapt to the additional procedures necessitated by the recent acquisition.

Benefits

The benefits the client received by having CSols deliver on this project included the ability to more rapidly identify and rectify system deficiencies. A deployment model for client products (generic templates) was developed that can be populated easily for additional products. The validation test scripts were easy for the client to execute successfully.

The in-depth knowledge of LabVantage LIMS that the CSols team brought to the project added value for the client by simplifying the path to future system growth. The end result was a full suite of validation deliverables and timely completion of the project, within budget, facilitated by the CSols project leader with input from the client.

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