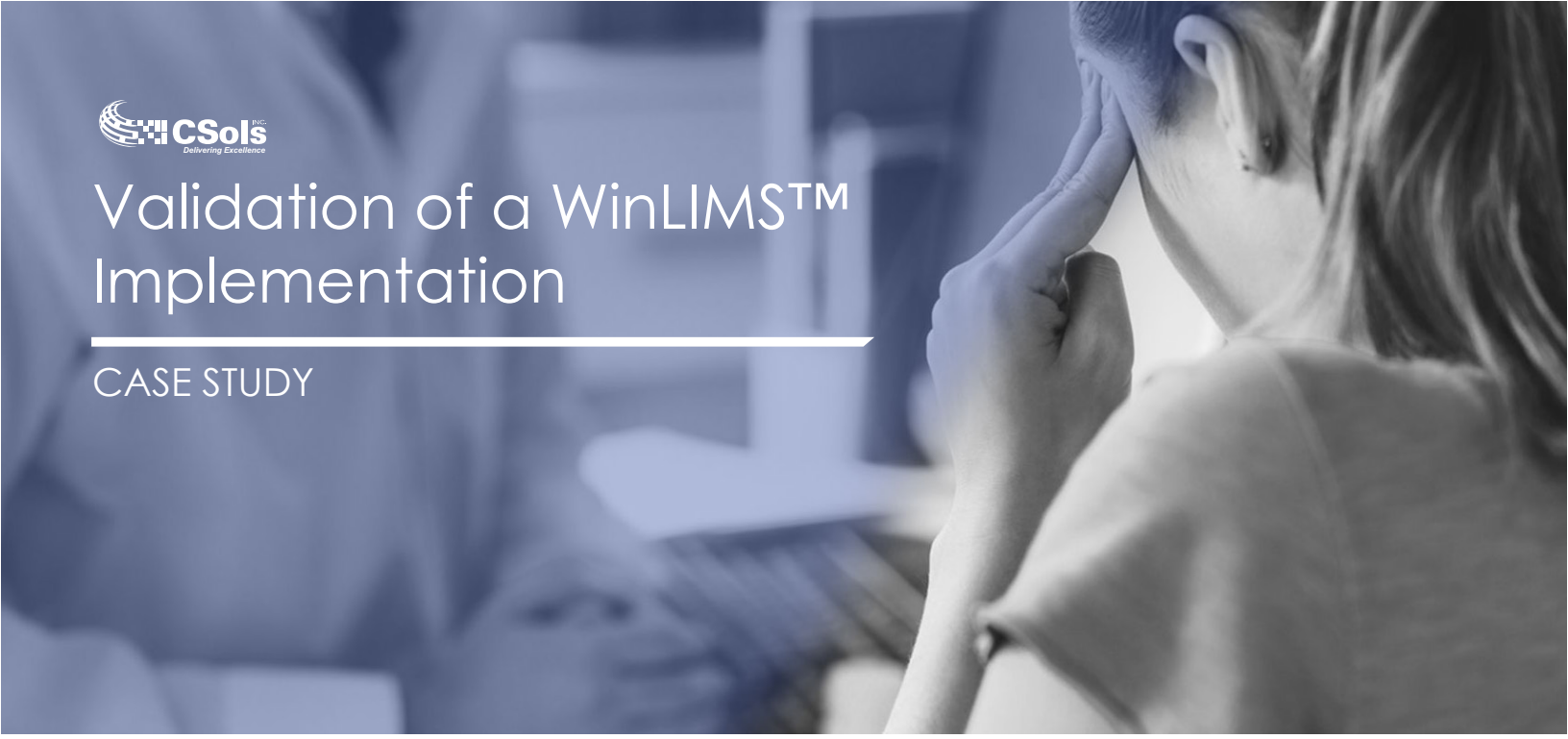

Validation of a WinLIMS™ Implementation

CASE STUDY

PROJECT AT A GLANCE

Business Sector:
- Pharmaceutical R&D

Informatics Systems
- WinLIMS v9.01

Service Offering
- Validation

Elements:
- 1 Site
- 3 Months (part-time)
- 1 CSols Team Member

In support of its internal effort to improve productivity in the research and development (R&D) and Quality laboratories, a clinical-stage biopharmaceutical company planned to transition away from paper record-keeping and implement a laboratory information management system (LIMS) from the LIMS software provider, Quality System International Corporation (QSI).

The vendor completed the implementation successfully; however, they did not have sufficient resources to complete the validation activities required of software used in a GxP environment. The client also faced internal resource constraints.

QSI knew CSols as a company that could complete the testing documentation effectively and efficiently and introduced CSols to the client. As a result, CSols was ultimately chosen, as a premier LIMS consultancy with expertise in LIMS validation to achieve the defined validation objectives for the new WinLIMS implementation.

Objectives and Challenges

This client was experiencing a significant loss of time and efficiency by using a paper process in their laboratory. They would continue to accumulate an unmanageable amount of paper records, which had been inefficient and was preventing growth, if they continued on their current path. The tracking, traceability, and audit trail maintenance for the data would continue to be difficult for quality management.

The goal of this project was to validate the QSI LIMS product, WinLIMS, by creating standard validation deliverables per the client's guidelines. In addition, the client was also interested in developing all the supporting Standard Operation System (SOPs) required for the LIMS.

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There were a few hurdles to overcome to achieve these objectives:

- Neither the client nor QSI had sufficient experience in computer system validation. Therefore, the client hired CSols to provide validation oversight and create the required validation deliverables.

- The client also needed some additional project leadership assistance to help keep the project moving forward. CSols provided that leadership to accomplish the validation tasks in the time allocated in the SOW.

- The client did not have existing software validation procedures. CSols provided the guidance and associated templates to use for all deliverables and tasks, following a risk-based approach.

CSols's Role in the Solution

After QSI completed their implementation of WinLIMS, CSols joined the project to perform computer system validation services. CSols followed GAMP5 guidelines for configurable systems and practiced a risk-based approach for software validation. The first step was to request Functional Requirements Specifications, IQ, and OQ documentation from QSI to identify gaps.

CSols developed the following standard CSV deliverables to support the validation effort.

- Validation Plan
- User Requirements Specification
- Functional Risk Assessment
- OQ and PQ Protocols

Benefits

By bringing in CSols to complete the computer software validation, the client received the following benefits:

- Expert validation project leadership that helped the client understand the validation process and ensure a complete set of documentation that the client can defend

- An on-time project completion that allowed the client's staff to continue their day-to-day jobs

- Validation documentation that can be re-used for future changes to the system, allowing for quicker turn-around times and less re-work

- A trusted partner that knows their system

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