Life Sciences Case Study

PROJECT OVERVIEW

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Providing Computer Software Assurance (CSA) Guidance for LIMS for a Cell and Gene Therapy CDMO

The client is a biopharmaceutical company that specializes in cell and gene therapy, with a focus on lentiviral and cell therapy research, development, and bioprocessing. The company chose the development and delivery of new gene therapies for viral diseases, produced by the engineering of viruses based on lentiviruses and adeno-associated viruses (AAV), as its main target.

The client has more than 25 years of experience in viral vectors and has recognized leading solutions for the commercially approved lentiviral-based gene delivery system. With expanding GMP facilities, growing data, and the intention to deliver high-level products and boost laboratory efficiency, the company decided to implement a Laboratory Information Management System (LIMS) into the manufacturing process.

Clarkston Consulting was asked to partner with the company on their LabVantage LIMS project and ensure the solution implemented leveraged a risk-based approach to validation and Computer Software Assurance (CSA) guidance. The Clarkston team provided support in the development of the supporting documentation and testing of the LabVantage LIMS application to ensure it met all its intended business requirements.

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INDUSTRY:

Biopharmaceutical

PRODUCTS AND SERVICES:

Cell and Gene Therapy

PRIMARY OBJECTIVES:

- Leverage a risk-based approach to develop the risk assessment documents for the solution
- Assist the client in providing appropriate rationale and justification for risk assessment conclusions
- Set validation process guidelines with the continuous improvement plan to meet the current standards updates
- Collaborate closely with the IT validation team to ensure the development, review, and approval of the Validation Project Plan and documentation

RESOLUTION:

- Wrote and designed a validation plan
- Created risk assessment documents for the implemented software
- Generated Operational Qualification (OQ) and Performance Qualification (PQ) protocols and test scripts
- Executed a dry run of OQ and PQ scripts prior to formal execution by the end users
- Developed a validation summary report to provide an overview of the entire process
- Created the User Requirements and Specifications document
- Provided guidance on how to manage validation requirements after the final build

KEY BENEFITS:

- Ensured that the LIMS solution supports a repeatable process and expected results through the CSA model of documentation and testing

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KPIs

- Detailed analysis of the risk assessment conducted
- Validation Plan designed specifically to meet client's needs and FDA requirements
- OQ and PQ Test Scripts developed and tested through a dry run

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