

# **Serialization Implementation: Ensuring Compliance for Product Launch**

The client, a clinical-stage immuno-oncology company, discovers and develops leading-edge targeted treatments to address the unmet needs of patients with various types of cancers.

The client, in preparation for their initial product launch, needed to be compliant with the US Drug Quality and Security Act (DQSA) – specifically, Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA) – and to implement a serialization solution to address both the serialization business processes and supporting technology solution.

The client was looking for a partner specializing in the unique needs of a pharmaceutical manufacturer preparing for commercialization and engaged Clarkston Consulting as the system integration partner for their serialization implementation. To support the client's product launch, the Clarkston team helped the client ensure compliance with the DSCSA requirements, as well as serialization laws and regulations to meet future products and markets.

# Life Sciences Case Study

## PROJECT OVERVIEW

### INDUSTRY:



Life Sciences

### PRODUCTS AND SERVICES :



Discovery and development of antibody therapeutics

### PRIMARY OBJECTIVES:

- Implement the TraceLink Life Sciences Cloud to support the distribution of serialized drug product and exchange serialized data with client's trading partners to ensure full U.S. market compliance with DSCSA and FDA regulations
- Create and promulgate the serialization SOPs and work instructions based on best practices, FDA guidance, and DSCSA regulations to enable the organization to incorporate serialization into the entire product release and distribution process
- Support full integration of client's CMO and 3PL trading partners with DSCSA data exchanges
- Implement a fully validated serialization solution including validation documents, work instructions, and SOPs

### RESOLUTION:

- Provided serialization subject matter expertise (process and solutions), including industry and DSCSA knowledge and strategic decision-making with best practices and industry guidance
- Guided the client through solution implementation and provided project management support
- Supported integration and deployment activities with TraceLink and client's Trading Partners (CMO and 3PLs)
- Developed GxP SOPs and Work Instructions through a series of workshops to support serialization actions being incorporated into the normal business routine
- Facilitated transfer to full business readiness with all stakeholders
- Supported full preparation and execution of validation testing, including documentation that was fully incorporated into client's quality organization
- Organized support for system deployment and trading partner transition from testing to full production
- Developed, prepared, and delivered serialization training in preparation for system go live

### KEY BENEFITS:

- Installed validated serialization solution in compliance to Title II of the US Drug Quality and Security Act (DQSA) of the Drug Supply Chain Security Act (DSCSA)



### KPIs

- Serialization capabilities in compliance with DSCSA
- Deployment in advance of commercial launch readiness activities
- System validation, including creating documentation and SOPs in adherence to client's standards
- Project managed within scope and on budget

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