

TRACELINK IMPLEMENTATION CASE STUDY

Serialization Strategy for a Pre-Commercial Company

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES:



Pharmaceuticals for genetic
diseases and cancers

BUSINESS TRANSFORMATION STORY & BUSINESS CHALLENGE

The client is a pre-commercial biopharmaceutical company that develops medications for genetic diseases and cancers with genetic markers. They were progressing toward their first commercial launch, and as part of the preparation, needed to be Drug Supply Chain Security Act (DSCSA) compliant.

The client had already selected TraceLink as their serialization provider, but still needed to implement the solution, including supporting data and business processes. Clarkston helped them to determine a serialization strategy that could support their first significant commercial launch as well as future country launches. Given that serialization was only one workstream in their roadmap to commercialization, cross-functional alignment was key to a successful solution.

Clarkston's serialization subject matter experts were engaged to lead this initiative. The team was responsible for defining the strategy, managing the project, drafting supporting documentation, leading validation efforts, testing the solution, and coordinating efforts with TraceLink and the client's partners, including CPO and 3PL.

PRIMARY OBJECTIVES:

- Develop a sustainable serialization strategy to be compliant with the DSCSA
- Stand up serialization-related business processes and write supporting documentation
- Create Master Data, ensuring alignment with SAP Material Master
- Implement a validated TraceLink environment, including conducting validated testing with business partners



SOLUTION:

- Worked with cross-functional teams to understand their business needs and developed a serialization strategy, including system administration
- Created a project plan and hosted regular check-ins to monitor progress
- Authored System and Business Process Documentation via SOPs and Work Instructions
- Completed Computer System Validation Plan & Reports
- Conducted Validated Testing with CPO and 3PL
- Created all Master Data (*aligned to SAP Material Master*) and loaded it into the client's TraceLink
- Oversaw the TraceLink configuration and production go live
- Drafted Business Go-Live Readiness Checklist to prepare the client for serialization in line with commercial launch



KEY BENEFITS:

- A validated and tested serialization solution that allows for the commercialization of the first product in compliance with DSCSA requirements
- A platform for moving into the next phase of serialization needs to support future market launches and requirements
- A pragmatic, executable serialization strategy to address short- and long-term xdbusiness needs
- Detailed serialization requirements aligned with industry best practices
- Cross-functional alignment on business processes and system administration



KPIs

- Authored and led review sessions for 10 systems and business process documents
- Wrote 28 system requirements to support business needs and align with best practices
- Created and executed end-to-end test scripts