

Supporting a Serialization and Traceability Program for a Biotechnology Company

The client is an American-based biotechnology company committed to helping address serious infectious diseases globally through the discovery, development, and delivery of innovative vaccines to patients around the world.

The client had launched a COVID-19 vaccine under multiple pandemic programs, including Operation Warp Speed (US), COVAX (World Health Organization), and Vaccine Drive (UK) under Emergency Use Authorization (EAU). Now the client must transition their supply chain to enable serialization in accordance with the US Drug Supply Chain Security Act (DSCSA) and EU Falsified Medicines Directive (FMD) requirements.

Having worked with Clarkston Consulting on an SAP S/4HANA implementation, the client engaged Clarkston for support developing a serialization strategy aligned with their new product launch.

The Clarkston team worked with the client to learn about their business strategy, timeline, and concerns with how serialization could impact commercial operations, as well as to understand the risk of failure. Together, they developed a multi-year plan that included developing a serialization strategy, selecting a serialization system, preparing the business, implementing serialization with supply chain partners, and providing post go-live support.

As a result of the engagement, the client has launched multiple commercial products on time and compliant with serialization guidelines on a global scale. This successful partnership continues as Clarkston supports the traceability program and daily serialization alert monitoring.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES:



Discovery, development, and delivery of innovative vaccines

PRIMARY OBJECTIVES:

- Oversee the set up, testing, and implementation of the serialization alert system
- Supervise the TraceLink stabilization and EU Hub integration
- Direct the US, EU, and APAC SKU serialization master data and data specification setup and approval
- Manage the serialization process capability readiness (*i.e., documentation, partner readiness, alert monitoring*)
- Develop and lead the daily alert monitor process, spearhead resolution investigations, and report findings to the appropriate authorities

RESOLUTION:

- Collaborated with client's IT team and TraceLink to ensure the system was set up, connectivity was tested, and transmissions were successfully sent/received with the EU Hub, NMVOs, CMOs, CPOs, and 3PLs as needed to support client business requirements
- Drafted all serialization documentation for TraceLink, managed SKU-based serialization master data, and created all serialization content in the client's document management system (Orion)
- Created the serialization data specification template and managed the collection of relevant master data across nine functional organizations (*i.e., Manufacturing, Commercial, Regulatory, Supply Chain, Quality, IT, CMO/CPO*) and dozens of countries to drive process efficiency and standardization
- Worked with CMOs, CPOs, and 3PL to ensure successful processing of serialization data to meet DSCSA and EU FMD requirements
- Formed the process and documentation required to monitor, resolve, and report on serialization alerts to EU MAH, client pharmacovigilance, client leadership, EMVO, and applicable NMVOs

KEY BENEFITS:

- Successfully enabled process compliance of the US supply chain to the DSCSA and to the EU FMD serialization
- Added value by optimizing the serialization process and providing subject matter expertise that wasn't resident in the client's organization
- Allowed the client to keep focus on building other areas of supply chain necessary to support multi-product, multi-market New Product Introductions by fully staffing the Traceability Program



KPIs

- **Supplier Compliance: 100%** *supplier compliance with traceability requirements*
- **Alert Identification: 100%** *identification of alerts in TraceLink*
- **Alert resolution: 100% resolution** *of EU alerts to EMVO and subsequently to the NMVO*
- **Alert reporting: 100% reporting** *of any serialization alerts*

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