

Leading Pharma Company Meets Emerging Requirements for Serialization

This R&D-driven company seeks to create innovative new drugs and medical solutions by leveraging its core capabilities. The company manufactures a wide variety of drugs for treatments in the fields of cardiology, immunology, infectious disease, neuroscience, oncology, and urology.

The company chose Clarkston Consulting to help it meet emerging requirements for product serialization and aggregation in multiple countries in North and South America, Eastern and Western Europe, and in the Asia/Oceania regions. Clarkston Consulting was instrumental in helping the company develop the strategies, conduct the program management, and manage the projects to serialize products in time to meet the many different legal requirements. Clarkston Consulting also helped establish knowledge, documentation, and procedures to enable the company to meet future serialization requirements on its own.

Life Sciences Case Study

PROJECT OVERVIEW



COMPANY:

A leading Pharmaceutical Company

INDUSTRY:

Pharmaceuticals

PRODUCTS & SERVICES:

Cardiology, immunology, infectious disease, neuroscience, oncology, and urology drugs

EMPLOYEES:

18,000

REVENUE:

\$11 Billion annually

PRIMARY OBJECTIVES:

- Ensure products meet serialization requirements in all the countries in which the company conducts business.
- Link all business partners, including packaging plants, CMO's, 3PL's, wholesalers, and specialty pharma customers to the company serial number repository system.
- Assess and address the impacts of serialization on business and technical organizations including headcount, reporting structure, policies, procedures, and documentation.
- Transfer knowledge from the serialization implementation team to company business and technical resources to enable them to incorporate serialization activities into normal business processes.

RESOLUTION:

- Conducted a pilot program to prove concepts and technologies.
- Formulated a strategy of six core competencies to guide all serialization projects.
- Established a program management office to oversee and coordinate multiple, simultaneous implementation projects world-wide.
- Ensured artwork, labeling, and regulatory filing changes were conducted.
- Implemented a global serial number repository system.
- Integrated plants, CMOs, 3PLs, and customers.
- Fostered close and effective cross-functional cooperation to achieve serialization goals.
- Created "playbooks" to define serialization implementation procedures and outline serialization laws and regulations for specific countries.
- Enabled company business and technical personnel to estimate and plan for serialization impacts on their organizations.
- Transferred serialization knowledge from the Clarkston team to company personnel.

THE KEY BENEFITS:

- Products were serialized in advance of legal deadlines.
- Established templates for integrating future business partners.
- Established basis for ongoing serialization governance.
- Documentation made permanently available for future serialization activities.

ANTICIPATED BENEFITS:

- ▶ Recognition of the company as a leader in the serialization field.
- ▶ Achievement of all core competencies on schedule and within budget.
- ▶ Established basis for ongoing serialization governance.
- ▶ Sound basis for ongoing serialization management.
- ▶ More than 2,700 SKU's artwork and labeling revised to comply with serialization requirements
- ▶ More than 12 packaging lines serialized and aggregated
- ▶ Interfaces with more than 15 CMO's and more than 50 wholesalers and specialty pharma customers

