OPTEL™
Traceability technologies for a better world

Achieving compliance and gaining efficiencies with OPTEL's Verify Platform

CASE STUDY

Pharma | Medical Devices | Product Serialization and Authentication

SITUATION

Our client is an international pharmaceutical manufacturer that collects and fractionates blood plasma to produce and distribute plasma-derived therapeutic products for use in treating serious diseases, disorders and conditions such as hemophilia and immune-system deficiencies.

Because the products are lifesaving and crucial, the mandate was to get the serialized product to the patient in the acceptable packaging on time.

The client also needed to comply with the European Union's Falsified Medicines Directive (EU FMD) and the U.S. Drug Supply Chain Security Act (DSCSA), as well as Russian and Saudi Arabian regulations.

The company was seeking a cost-competitive solution with full-service implementation.

COMPLIANCE/ITEM-LEVEL SERIALIZATION

The company chose OPTEL's SWIFT implementation framework, which includes project initiation, configuration and validation, go-live training, hand-off, customer support and ongoing account management.

Our Verify Platform software has enabled the customer to establish parent-child relationships for all packaging levels within its serialized (EPCIS) data. The platform also allows the company to receive EPCIS inbound and outbound shipping events from its 3PL.

FEATURES

STANDARDS-BASED PARTNER INTEGRATION CAPABILITIES: OPTEL's Verify Platform is built on GS1's universal standards (e.g., EPCIS 1.0, 1.1, 1.2) to enable greater connectivity to the largest network in the world. The platform supports any data communication protocol and can easily manage and validate connections to trading partners to exchange serialization data.

FLEXIBLE PLATFORM: The platform is highly configurable, which lets us quickly integrate into our clients' business operations without disruption. This flexibility means we configure our platform to work with existing systems, and it also allows our customers to expand their data sets at any time. In addition, we created Verify Platform to reduce our customers' validation resources and efforts—they only upgrade the software when they need or want to. (By contractual agreement, we keep our customers current with country-specific regulations.)

DIRECT CONNECTION TO EU HUB

Unlike our competitors, who use a third-party service to connect to the European Union Hub, our platform can connect and pass all customer data directly from the marketing authorization holder to the EU Hub, resulting in fewer failure points and greater data security for our clients.

FIXED-COST INVESTMENT

Our pricing structure is completely transparent, with no hidden fees or costs.

USER-FRIENDLY REPORTING AND ANALYTICS

OPTEL's Verify Platform comes with built-in advanced reporting tools designed to help improve our customers' business operations. They have the ability to examine the capacity of a line or trading partner, determine the persistence of a product in their supply chain from commissioning to order and evaluate returns by customer, location and market.

RESULTS

OPTEL's proven software, automated implementation tools and time-tested project management framework rapidly and efficiently ensured that this pharma company was able to check the compliance box before the EU FMD deadline. Their next step will be to undertake VRS implementation and then take steps to ensure compliance with the U.S. DSCSA as well as Russian and Saudi Arabian regulations.

In addition, the software will help the company maximize its serialization investment by delivering analytics and insights that will increase operational efficiencies and create a smarter supply chain.

OPTEL's Verify Platform is **highly configurable**, which lets us quickly integrate into our clients' business operations **without disruption**.

CONTACT US

To learn more about OPTEL's solutions, contact us at **optelgroup.com/contact/**

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