

Virtual manufacturer finds easy L4 solution

CASE STUDY



Virtual Pharma Manufacturers



CMOs



Product Serialization and Authentication

CUSTOMER PROFILE

Bayshore Pharmaceuticals, which works with contract manufacturing organizations (CMOs) to supply the generic drug market, needed to comply with serialization regulations. The growing New Jersey-based company achieved that—and more—thanks to OPTEL's serialization software.

CONTEXT

"Our target was to be compliant. We're a relatively small but rapidly growing company and are now adding new products every year. As we evolve, we wanted a package that would evolve with us," said John Schettini, Director, Supply Chain and Logistics, at Bayshore.

CHALLENGE

Because Bayshore is a "virtual manufacturer" working with multiple CMOs, the implementation of OPTEL's serialization solution had to be carried out according to multiple sets of specifications and guidelines. The company overcame the challenge, said Mr. Schettini, by having "a good solution architect and project manager who were very knowledgeable and who made it more streamlined than expected."

SOLUTION

The company chose OPTEL's serialization and authentication platform, which allows serialization down to the item level, creating parent-child relationships for all packaging levels.

The highly configurable platform is built on universal GS1 standards (e.g., EPCIS 1.0, 1.1, 1.2), supports any data communication protocol and can easily manage and validate connections to trading partners to exchange serialization data.

BENEFITS

Though it's simple to use, the real appeal of OPTEL's serialization software, according to Mr. Schettini, is the actionable, granular data it provides, which has allowed Bayshore to go beyond compliance with the Drug Supply Chain Security Act (DSCSA) and improve its overall operations.

"When you get down to such a granular level, it's just great data, from both an operational and financial perspective," he said. "It gives you that valuable, end-to-end perspective on your supply chain."

That end-to-end view of each individual item's journey along the supply chain helps Bayshore track the distribution of products to multiple wholesalers and efficiently manage returns and pricing variations thanks to OPTEL's ability to track and trace the company's products "down to the bottle." That's an important distinction, noted Mr. Schettini, since "there are certain things you just can't verify at the lot level. That's what makes the granularity of the data so valuable."

Another notable benefit is the flexibility and scalability of the solution, which Mr. Schettini compared to the customization of a passenger vehicle to which more and more features are added. In this case, he noted, the features are data that make the system "more and more savvy."

RESULTS

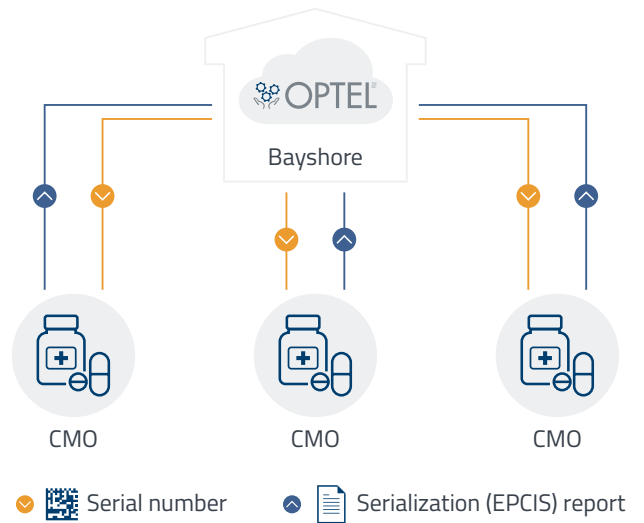
"The biggest difference is that we are meeting standards and timelines," said Mr. Schettini, adding the peace of mind the solution brings is bolstered by the positive partnership the company has established with OPTEL.

"I enjoy the relationship and the service," he said. "There's definitely a confidence level there."



The virtual manufacturer sends serial numbers to its CMOs.

The CMOs produce and serialize medications, and then send serialization reports, called EPCIS reports, to the virtual manufacturer.



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