How **TruPharma** Gained Control of **DSCSA Compliance** with OPTEL's **VerifyBrand**™ in under 4 Months

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Traceability technologies for a better world

TruPharma™

Jennason
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CUSTOMER PROFILE

TruPharma was founded in 2012. TruPharma distributes a broad range of pharmaceutical products in the U.S. market.

CONTEXT

As the US Food & Drug Administration (FDA) continued its implementation of the Drug Supply Chain Security Act (DSCSA), TruPharma recognized the importance of evaluating its internal processes and ensuring it had the right systems in place to meet the regulatory requirements.
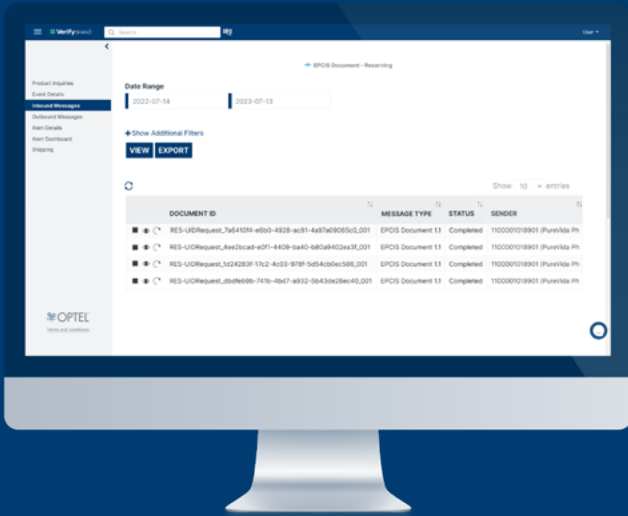
CHALLENGES

For many years, the company leveraged the serialization capabilities of its supply partners and outsourced serialization and data management tasks to a third-party. As more of its downstream customers were demanding compliance on advanced timelines, TruPharma decided to proactively assess whether additional steps or tools would enhance its compliance strategy.

In late 2023, TruPharma initiated an internal evaluation to identify a solution that could provide the flexibility and control needed for exchanging serialized T2 data with downstream customers. While the DSCSA enforcement had been delayed a year, some of TruPharma's key trading partners set their own earlier timelines, underscoring the importance of having a robust and reliable serialization system in place.

Understanding the business-critical nature of implementing a serialization system, the team at TruPharma reached out to Scott Pugh, a renowned expert in product serialization and supply chain traceability at Jennason LLC. Scott has 16 years of experience working with all types of pharmaceutical companies on their journey to DSCSA compliance.

"We had roughly four months to choose a technology platform, implement it, train the TruPharma team and start exchanging T2s with customers. The goal was to finish everything by March or April 2024 to meet key TruPharma trading partners data exchange expectations." noted Scott.

SOLUTION

Counting on Pharmaceutical Product Traceability Specialists

As a first step, TruPharma evaluated a select number of vendors. The selection criteria included the speed of execution, comprehensive validation approach and the system's ability to manage DSCSA daily operations. "I knew OPTEL could deliver," Scott explained. The reason? He had previously implemented OPTEL's VerifyBrand™ with other clients. VerifyBrand™ provides serialization and traceability capabilities for L4-L5. Another contributing factor?

Scott elaborated on the decision-making process: "We needed a partner who could deliver quickly both in deploying and validating the system. OPTEL's team was equipped to handle much of the heavy lifting, from authoring key documents like the User Requirements Specification (URS) and Controlled Software Design Specification (CSDS) to Installation Qualification and pre-executed and pre-validated Operational Qualification (OQ) protocols. To minimize impact on TruPharma resources, we were able to lean on OPTEL's documentation as much as possible to ensure a comprehensive validation package focused on TruPharma's specific implementation. We also had to ensure the vendor's architecture and version control wouldn't require constant release reviews and risk assessments as the resourcing needed to cover such ongoing tasks simply wouldn't be feasible."

Another decisive factor was OPTEL's integration with the Trust.med service layer, which manages connections to downstream customers. TruPharma's 3PL had already established some connections with Trust.med, and Scott had recently completed a project connecting OPTEL to Trust.med for another client.

"Knowing that OPTEL was already connected to Trust.med was a game-changer," Scott said. "We could leverage OPTEL's extensive list of existing connectors, which saved us development time and eased implementation efforts."

With the vendor selected, the team moved swiftly into implementation. OPTEL'S team prioritized the validation process, authoring TruPharma-specific documentation and streamlining the review process.

Kyle Rentz, Senior Accountant of Serialization Operations at TruPharma, appreciated the efficiency. "The way we got through the validation process was remarkable. Scott's summaries made it manageable, and the OPTEL team was incredibly responsive. It was a collaborative effort that made a daunting task achievable."

Another significant part of the implementation involved a complex data migration effort. The team needed to acquire historical serialization data from the 3PL and import it into VerifyBrand™ to ensure continuity.

Scott described the data migration challenges. "We had to ensure that all historical data was correctly imported to avoid any shipment disruptions. It was a meticulous process, but essential for maintaining the traceability integrity."

RESULTS

Better Serialization Management In-house Allowing for Reduced Consultant Costs

Within four months, TruPharma successfully went live with the OPTEL VerifyBrand™ solution and successfully met data exchange deadlines imposed by large wholesalers.

Operationally, Kyle Rentz took on the responsibility of managing TruPharma's serialization activities, overseeing the quality of incoming serialization data, monitoring for processing failures, and handling DSCSA exceptions when exchanging data. Despite not having prior experience with a traceability platform, he found VerifyBrand™ very user-friendly.

"The solution does most of the work," Kyle said. "It's basically in and out. Now, I focus on managing exceptions rather than getting bogged down in the details."

Training was another critical component. Scott's familiarity with VerifyBrand™, combined with OPTEL's training, enabled Kyle to quickly become proficient.

"Scott already had extensive experience with VerifyBrand™, so onboarding me was smoother," Kyle noted. "But even without that, the platform is intuitive, and the OPTEL team was always available to help."

The impact of implementing VerifyBrand™ was significant. TruPharma gained control over its serialization process, reducing its reliance on third parties. This autonomy allowed them to integrate new CMOs more efficiently and manage serialization without outside contractors.

Scott emphasized the strategic advantage: "The goal was for TruPharma to eliminate dependence and costs for external serialization resources. Now, the company can manage serialization independently, which is a huge step forward."

Since going live, TruPharma has transmitted thousands of T2 notifications and managed millions of serial numbers. This achievement in such a short time frame underscores the effectiveness of the solution and the team's efforts.

"We went from being largely depending on third-parties regarding serialization data management to having full control," added Kyle. "It's empowering. You need the right systems and build the knowledge set internally to upskill in-house teams. If I can do it, anyone can."

He also stressed the value of expert guidance. "I recommend partnering with an expert like Scott. His experience was invaluable, not just for us but also in coordinating with our CMOs, 3PL and OPTEL. Without him, I have no idea where we would be."
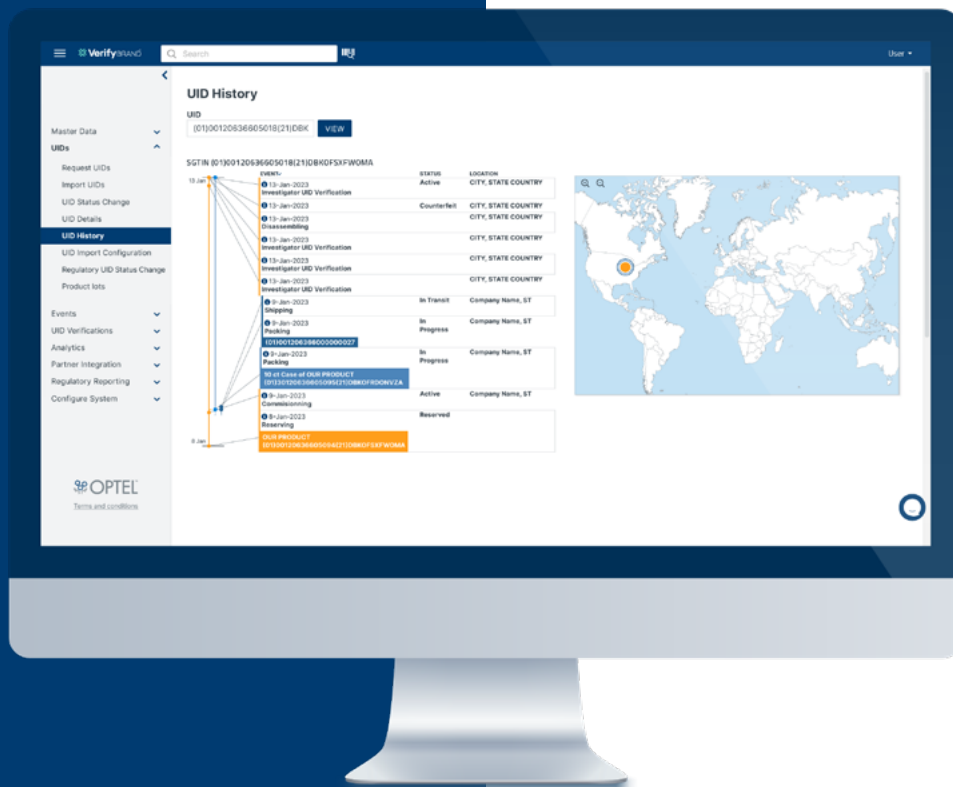
CONCLUSION

The project also presented a compelling return on investment (ROI). By building internal capabilities and reducing reliance on external consultants and third-party services, TruPharma positioned itself for long-term efficiency and cost savings.

Scott encourages other companies to consider this approach. "I hope more companies take the time to understand what drives their support needs and recognize that getting on a better path means first getting the right systems in place."

In an industry where regulatory landscapes and market demands are constantly evolving, TruPharma's success story serves as an inspiring blueprint. It demonstrates that pharmaceutical companies can navigate complex challenges efficiently with decisive action, agile collaborations, and a focus on building internal expertise.

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