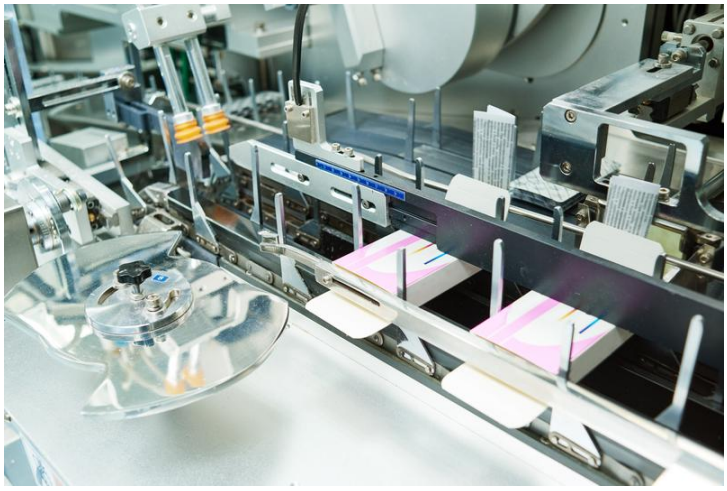
Case Study

Implementing a Serialization Program Successfully on the First Try

Service Areas: 3PL, Serialization, Supply Chain, Commercial Supply Chain Launch Readiness
Lifecycle Stage: Clinical



An emerging specialty biopharmaceutical company was preparing for the U.S. launch of their first drug product. Building out their supply chain would involve implementing a serialization program to meet Drug Supply Chain Security Act (DSCSA) requirements. While Supply Chain team members had commercial launch experience, they were not as familiar with serialization.

A successful serialization program requires biopharmaceutical companies, serialization solutions, packaging suppliers, and 3PLs to work in concert. Fortunately, this company's Supply Chain SVP had previous serialization experience and the company selected TraceLink as their serialization solution.

Converge Consulting joined as an implementation project management partner to oversee the serialization process from packaging through goods receipt at the 3PL.

Early Project Planning Eliminates Serialization Rework Later

Our consultants started by developing a serialization project plan that integrated each parties' activities and schedules.

Since packaging validation is a key driver of overall serialization program success, we worked very closely with their manufacturing partner responsible for the packaging. This company had limited experience with the US regulatory requirements for product packaging. As a result, aspects of this serialization setup were brand new for them.

We spent time building alignment between the different workstreams – clearly identifying what needed to happen and when, as well as communicating how and why these deadlines affect other workstreams. This detailed effort ensured that we addressed risks and resolved issues quickly. The timing fit together so that the company was ready for packaging validation in advance of the commercial launch.

(Note: Companies can conduct packaging validation before or during commercial launch. However, Converge usually recommends completing it beforehand to minimize the risk of delays during launch.)

Converge's project management support throughout the process included developing and managing an integrated project plan, tracking essential elements like activities, issues, and decisions, as well as building automated workflows to provide transparency for both task and milestone deadlines.

Relationship building with a deadline is challenging, but these close partnerships eliminated the need for rework later in the process.

Expanding the Serialization Initiative as the Portfolio Grows

Meanwhile, the company was also growing its portfolio through the acquisition of products nearing commercialization.

They bought a second product midway through ramping up the original serialization program. So as soon as Program 1 was underway, the Converge team also began serialization set up for Program 2.

Within months, a third product joined the portfolio. The relationship followed a similar course with setup beginning as soon as Program 2 was underway.

Both products joined the portfolio with packager relationships already in place. As a result, setup included evaluating the serialization capabilities of these added manufacturers.

Repeating the implementation process refined the organization's own processes for maintaining TraceLink over time and handling product verification requests. As new requirements for distributors are coming up, Converge is assisting the company with evaluating options to meet those requirements.

Our serialization program relationship also continues to include direct support for resolving errors and providing training on TraceLink.

Supply Chain Support Beyond Serialization

As the company's portfolio grew, supply chain management demands outpaced the bandwidth of their current team. What started as a single serialization implementation effort developed into multifaceted supply chain support.

- Supply Chain Planning – Our consultants designed and implemented an inventory management tool that included Materials Requirements Planning (MRP), the Sales & Operations Planning process, and allowed the company to convert sales forecasts into production plans. We also provided tactical and strategic support in preparing for new sales demand, MRP regeneration, capacity planning, inventory planning for new supplier sourcing, product cost scenario planning, and expiry management.
- Supplier Assessment – We helped the company find potential alternatives for manufacturing their drug substance so that they could end single stream reliance.
- Artwork Management – Converge team members collaborated on designing artwork management processes for use on new launches or changes to existing artwork.

Shipping Qualification – Recently, we started a gap assessment on shipping qualification protocols to ensure that new shipping lanes meet regulatory requirements.

Status Today

All three products have successfully launched into the commercial U.S. market with robust serialization programs in place. We are supplying ongoing serialization program management that includes addressing the evolving regulatory and industry environment on their behalf.

With a trusted serialization partner on board, the Supply Chain SVP is focusing internal hiring on other critical supply chain initiatives.

Converge Consulting *serves the Life Sciences industry with strategy, operations and execution expertise. We collaborate with biotech, pharmaceutical and cell/gene therapy companies to achieve important business objectives. The Converge approach focuses on bridging the gap between sound strategy and reliable execution. www.convergeconsulting.com*