

Case Study

Building the Downstream Commercial Supply Chain for Launch

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

An emerging pharmaceutical company was preparing for its first commercial product launches with two products progressing through the clinic. Approvals and launch events were targeted within one year of each other. The products were similar in technology and formulation. The first anticipated approval was for a relatively smaller indication. The second was for a much larger mass market. This timing leveraged the smaller-scale launch to prove out the commercial supply chain for the larger one.



Our client gated hiring like many clinical-stage firms. As a result, they hired a Head of Manufacturing & Supply just prior to NDA submission. He would need to execute all aspects of the supply chain buildout for launch. This included building the initial supply network to support both products with a very lean team and newly hired staff.

Fortunately, the industry veteran understood the complexity. It spanned startup and validation of commercial packaging operations, 3PL selection and setup, serialization implementation, supply chain planning, and shipping qualification. He also recognized that his team did not have the in-house expertise or capacity to execute everything internally.

Ensuring Cross-Functional Commitment to 3PL

The client directed their limited internal resources toward the commercial packaging effort. Meanwhile they engaged Converge to [support the execution of other important PAI readiness activities including 3PL, serialization and shipping qualification](#).

First, we led a structured process for selecting the 3PL partner. Our methodology involved building a cross-functional team with the quality, finance and commercial groups represented. The team screened 3PL candidates able to meet the client's needs based on an initial set of high-level business requirements.

A formal RFP process followed where we documented how each remaining candidate would or would not meet the requirements. Everyone had clear visibility on where gaps existed and agreed on what was needed to fill those gaps.

The approach resulted in alignment across the team and commitment to the recommended direction. Converge provided guidance through the negotiations with the selected partner and led setup of warehouse and order-to-cash activities.

Setup timing coordinated with important packaging line and serialization activities.

Setting up Serialization Simultaneously

In parallel, Converge led the implementation of serialization capabilities to comply with DSCSA regulations across packaging, warehousing and client operations. Although these parties deployed different solutions, our experienced serialization specialists negotiated the multisolution environment by brokering common understanding between the client team, packager, and 3PL.

Open dialogue addressed questions regarding key business processes, timing of data sharing and expectations for data aggregation. This revealed operational variation across the parties that could be resolved in advance.

The process also brought visibility to important differences in GS1 standards conformance. Following our practical guidance, the client avoided performing time-consuming updates on the packager and 3PL systems that did not impact critical supply chain and compliance processes for the files shared between the systems.

Our multidisciplinary reach provided crucial coordination. This included managing the efforts and interdependencies between the commercial packaging validation, 3PL setup, and serialization solution implementation. The approach ensured everyone was working toward the same goals, operating to the same plan, and avoiding local decisions that might compromise launch success.

Status Today

The client successfully gained approval and launched their first U.S. product. Full commercial packaging, serialization, warehouse, order-to-cash, and logistics capabilities supported the launch.

They are currently anticipating FDA approval for the second product launch. The company also intends to leverage many of the capabilities, partners and lessons learned from the first launch. In addition, they plan to expand operations to scale with the increased commercial demand.

Our relationship with this client has grown into a long-term partnership. It now spans internal manufacturing and supply chain teams, packaging and 3PL partners, and the serialization solution vendor.

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