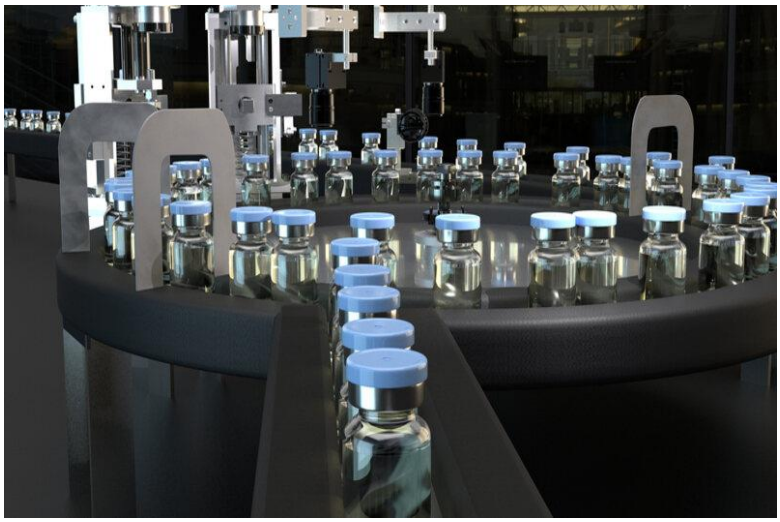
Case Study

Commercial Launch Planning on an Accelerated Timeline

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

An emerging European biotech company was preparing to commercially launch its first product in the US. The FDA granted the innovative product a priority review given the potential for significant benefits to patients.



As a result, the company faced a compressed timeline to build their US commercial supply infrastructure. Company leadership had established a US-based subsidiary and hired a US Commercial Lead. However, few existing employees had participated in a commercial launch before and none with a US launch.

Companies preparing for US commercial launch must prepare a great deal of operating infrastructure, business processes and systems. These range from commercial packaging & labeling, artwork management, warehousing and distribution to serialization, logistics and demand/supply planning. Furthermore, when the drug product is manufactured outside the US, additional questions must be addressed. These include determining the commercial packaging location, import/export compliance, and aligning operations with the tax and legal entity strategies.

With priority review, this company did not have the time to hire all the expertise in-house. Instead, roughly five months before the targeted PDUFA date, they partnered with Converge Consulting to establish the commercial supply capabilities required for their unique product to reach patients in need.

Rapid Planning for US Commercial Launch

Converge's experienced team began educating key client stakeholders on the full scope and timelines required for US commercial launch readiness. They also clarified the impact of the accelerated review timing. Working collaboratively with the client, we conducted a Readiness Assessment to determine which launch preparation activities were already underway and their progress against the target timeline. Results led to identifying key priorities and client agreement on short-term tradeoff decisions to ensure the product would be ready for delivery upon approval. These priorities and decisions were documented in a commercial supply chain launch strategy and time-phased roadmap.

The roadmap was a blueprint showing the initiatives, timing, and sequencing required for success. It delineated activities necessary for submission, pre-approval inspection (PAI), launch, and longer-range planning purposes. It also included the tools, investment, and hiring requirements.

Building the US Commercial Supply Chain

Our initial planning activities quickly shifted to tactical execution as we built out the commercial supply chain infrastructure. The client used the roadmap and Converge's senior advisors to efficiently delegate work. Together, we identified which activities the client would handle directly, which ones Converge would support, and which activities Converge would lead and execute.

Converge provided support to the client's US management as the Project Manager for the launch readiness effort. This included meeting weekly with Supply Chain, Quality, Regulatory, and CMC stakeholders, as well as supporting vendor meetings. In this role, we kept the overall effort on track.

Additionally, Converge mobilized experienced practitioners and subject matter experts to execute a range of launch-related workstreams. For example, one such workstream was Commercial Packaging, Labeling and Artwork. Converge led discussions with the packaging vendor to finalize artwork for the label and carton, as well as develop artwork management processes and governance. We built detailed T0 tactical launch-day plans and contingency plans to ensure label revisions and printing without delay. This included coordinating reviewer availability during the middle of the night and accessibility of printers on a Sunday morning to ensure the drug would be available to patients as fast as possible after approval.

We also selected the best fit 3PL for our client's commercial model, working with the 3PL and packager to establish the serialization program and distribution procedures to ensure compliant patient delivery.

Our planning experts conducted a Supply & Demand Analysis, providing insights that helped the client decide how much drug product to package for launch and also for retains and other needs. We helped the client establish a formal Sales and Operations Planning process to manage overall supply chain planning in a way that accounted for significant demand uncertainties and risks.

Additionally, Converge's trade compliance experts assisted in obtaining state licenses and evaluating whether to import utilizing a PLAIR or FTZ. Our logistics experts developed and executed the shipping solutions and qualification studies to ensure the integrity of the product was maintained.

Successful Results

Working together as a fully integrated team, Converge helped this European biotech build and manage a US commercial supply network in under six months despite the added stress of the accelerated review timeline.

When approval was granted, our team supported the successful launch of the client's first product into the US market with commercial product available within five business days of FDA approval.

Our client documented their appreciation:

> "This is a massive moment for us, and we wouldn't be here without the support and expertise of Converge. You guys guided us through to the finish line! …We did this together and we did it right. Most of all, I'm very proud of our collective professionalism."

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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*