Case Study

Managing the Unexpected in Commercial Launch Planning

2 Treatments, 1 Timeline

Service Areas: Commercial Launch, Supply Chain, Quality, Enterprise IT Solutions, Commercial Systems – CRM – Medical Affairs, Commercial Supply Chain Launch Readiness, Supply Planning
Lifecycle Stage: Clinical

Our client was an emerging biopharmaceutical company formed to commercialize a rare disease treatment in late-stage clinical trials. Essentially a startup, the company was scrambling to build the commercial operations and infrastructure needed to launch the treatment on an accelerated timeline and bring it to patients in need.

About 6 months prior to the PDUFA date, Converge was engaged to conduct a Launch Readiness Assessment, to identify any risks that may have been missed. Our quick-moving and structured approach was designed to identify risks to and gaps in the launch preparations across the commercial supply chain, manufacturing, quality, sales & marketing, medical, IT, accounting, and finance functions.

The assessment resulted in the identification of several important gaps, along with recommendations for addressing each area's specific needs. Converge worked closely with the client's own Commercial and Operations teams to accelerate internal preparation while maintaining the original launch schedule.

Working with the Converge Commercial Launch Team

To mitigate several critical risks, our Commercial Launch advisors helped the client form an integrated, cross-functional Launch Readiness Team with a mandate to ensure remediation and preparation in the time available.

Together we developed a unified launch plan that highlighted the critical tasks and inter-dependencies across functions, and our team conducted Day 1 and Contingency Planning sessions to synchronize the steps involved in producing and distributing the product within hours of receiving approval.

We also led cross-functional walkthroughs of both the patient and product pathways, which proved to be invaluable exercises since the treatment involved complex logistical challenges in moving, storing and administering the product, along with a high-touch patient services model focused on ensuring patient outcomes.

Adjusting to Unexpected Events

As launch preparations were taking shape, our client suddenly inherited a second late-stage product – a drug with approval anticipated on nearly the same timeline. Suddenly the company was planning a second launch to occur within a few months of their first.

With little infrastructure in place and few internal resources – all currently focused on the initial product launch, the client engaged Converge to support the build out of their commercial supply capabilities for the second treatment.

Providing experienced operations project managers for CMO and 3PL management, along with subject matter experts in cold chain logistics, global trade and commercial systems, we helped the client establish the supply chain for commercialization, including the necessary downstream order-to-cash processes, patient-focused CRM, and commercial and medical affairs analytics systems.

As the launch date for both products drew closer, our support shifted to execution of critical tasks to be launch ready.

Status Today

Our client won approval for both treatments and successfully launched in several countries, bringing their transformative treatments to patients and driving revenue and market value for the emerging company. Converge continues to serve as a trusted partner, providing strategic guidance, operational support and execution resources supporting the commercial teams, Technical Operations, Quality, Finance and IT as the company expands access into new markets and grows their internal organization.

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*