

Launch Planning Strategy and Management for a Biopharmaceutical Company

The client is a biopharmaceutical company focused on developing and commercializing innovative therapeutics in medical dermatology.

The client was looking to commercialize their first product in the U.S. market and engaged Clarkston to realize their goal of building a commercially mature organization from early on.

Clarkston provided the client with end-to-end support, which encompassed activities including 3PL and serialization strategy, vendor selection, launch planning support, S&OP business support, supply chain BA support and risk assessment, transportation and launch support, as well as SAP/Post-Go-Live Enhancement.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



Biopharmaceutical organization dedicated to developing and commercializing innovative therapeutics in immuno-dermatology

PRIMARY OBJECTIVES:

- Review and update existing cross-functional tactical launch plans and processes for CMC
- Collaborate with functional leads to update deliverables and timing
- Identify gaps, interdependencies, risks, and mitigation planning
- Create a comprehensive launch playbook to facilitate and manage the launch for their first product as well as for future launches
- Conduct scenario and contingency planning for launch
- Facilitate launch dry runs and mock sessions to ensure transparency across the matrix with internal as well as external stakeholders

RESOLUTION:

- Conducted comprehensive review of existing cross-functional tactical plans to gain perspectives on current state and identified areas where plan needs to be built out further
- Updated the current plans to include a holistic view encompassing all functions of CMC, including deliverable timing, priority, and ownership
- Worked with internal and external stakeholders to validate and socialize these launch plans
- Developed a launch playbook leveraging the Smartsheet tool to track launch progress, as well as highlight interdependencies and launch status
- Conducted multiple launch dry run sessions prior to launch to ensure transparency and consistent flow of data across teams
- Proactively managed risks and created contingency scenarios and highlighted critical path items
- Set up a command center and deployed resources during the launch week to ensure seamless execution

KEY BENEFITS:

- The client was able to successfully commercialize their first product within 48 hours of FDA approval
- Our idea of bringing the product to the U.S. prior to approval enabled the client to get product in channel two weeks ahead of original plan
- The comprehensive launch playbook that Clarkston created for the client can be used as a foundation for their future launches as well
- The client was able to maximize their opportunity and drive sales faster by entering the market earlier than anticipated
- Due to proactive management of risks and contingency planning in advance, there was minimal need for any fire drills during/close to launch date



KPIs

Helped the organization realize their goal of being commercially mature on Day One

Developed a comprehensive launch playbook for CMC activities for current and future launches

Enabled client to launch their first product successfully within 48 hours of receiving FDA approval

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