

Supply Chain Commercialization Roadmap

A clinical-stage biopharmaceutical company that designs transformative medicines to treat patients who suffer from genetic diseases and cancers partnered with Clarkston to develop a global supply chain commercialization roadmap. The company is filing for an NDA (New Drug Application) in 2023 and preparing its supply chain to go commercial in 2024. This will be quickly followed by submission in Europe for approval to sell in key markets. In advance of their planned commercial filing, the client needs to evolve their supply chain capabilities to support a global commercial operation. As they undertake this evolution, they want to leverage current clinical supply chain practices and avoid unnecessarily “reinventing the wheel.”

The client needed to understand the gaps between current capabilities and the capabilities needed for a commercial entity, considering aspects of the “process, people, and technology” framework. They engaged Clarkston to help realize these capabilities and develop a two-year commercialization roadmap.

Clarkston’s approach to the project began with conducting interviews and visioning exercises with key stakeholders. Clarkston then performed a current state gap analysis to determine the framework needed for commercial supply chain readiness. This approach allowed Clarkston to better understand the strategic approach and impacts of clinical and commercial timelines.

Clarkston identified over 25 capabilities the client would need to develop for long-term success and future global supply chain stability. Moving from a clinical to a commercial operation requires more rigorous processes, especially around supply/demand planning, inventory management, supplier management, serialization, quality release, and finished goods distribution. In consideration of these new capabilities, Clarkston was able to build a supply chain roadmap for short- and long-term planning and develop a supply chain strategy activation plan needed for a robust commercial supply chain. The two-year roadmap incorporated the supply chain capabilities, required processes and standard operating procedures (SOP), cross-functional interactions, departmental ownership, and commercial supply chain flow with key milestones and deadlines.

Clarkston helped the client understand the impact of implementing these capabilities on the organization’s people, processes, and technologies. This provided the client with a path forward in evolving and preparing their supply chain to go commercial in 2024.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



Pharmaceuticals

PRIMARY OBJECTIVES:

- Develop an actionable roadmap that positions the supply chain organization to support the company's global commercialization strategy and future growth, as well as retain a competitive advantage
- Assess current people, processes, and technology through stakeholder interviews/vision exercises and process analyses
- Develop a supply chain strategy activation plan composed of supply chain capabilities and actionable recommendations

RESOLUTION:

- Documented understanding/assumptions of current and future state people, processes, and systems
- Conducted interviews/visioning exercises with key stakeholders
 - Identified and reported key themes and observations
- Created a strategic Supply Chain Capabilities Map with a breakdown of every function required to develop a commercial supply chain successfully
 - Each function identifies ownership, SOP development requirements, and current/future state technology utilization
- Developed a future vision supply chain flow with key supply chain metrics and targets to achieve for every step in the supply chain
- Established a supply chain commercialization roadmap that defines capability gaps in the strategy, prioritizes opportunities and sequencing, recognizes key milestones, and provides a tangible activation plan

KEY BENEFITS:

- Cultivated a culture of cross-functional collaboration among executive leaders in separate departments
- Established a path forward with sequential steps and actionable recommendations
- Provided milestones and critical deadlines to be met for future commercial demand in Q4 of 2024
- Created a Supply Chain Capabilities Map composed of 28 capabilities required to bridge the gap between clinical and commercial operations
- Conducted workshop and knowledge-sharing meetings with the client to deep dive into critical supply chain controls to help them gain a better understanding of the impact they have on the overarching supply chain strategy
- Provided recommendations on how to approach U.S. vs Ex-U.S. markets
- Created a sense of urgency around key supply chain capabilities that need to be prioritized
- Provided guidance on meeting management, cross-functional collaboration, and setting cadences with critical internal partners
- Conducted a spans and layers assessment with a supply chain re-organization recommendation
- Initiated key discussions around technology planning and the cadence to consider in ERP and serialization implementations, with suggestions for a strong business case to support any technology needs



KPIs

28 supply chain capabilities created and assessed

25 critical milestones identified over a two-year period

11 executive leader interviews/vision exercises conducted

"These meetings we have with Clarkston, discussing our future supply chain, are the most exciting conversations we have in a day. It makes me both excited and anxious for the future."

- CLIENT

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