Life Sciences Case Study

PROJECT OVERVIEW

clarkston CONSULTING

Supply Chain, Quality, and Regulatory Due Diligence for the Acquisition of Therapies

A pharmaceutical company was looking to acquire a portfolio of therapies. The client engaged Clarkston to conduct a supply chain, quality, and regulatory due diligence on the portfolio, which consisted primarily of IP therapies that were commercialized as well as therapies in the pipeline. They wanted to ensure that all risks involved in supply chain, quality, and regulatory aspects were identified, ultimately helping them decide whether to acquire these therapies and allowing for a fair acquisition price.

From a supply chain perspective, Clarkston reviewed the overall supply chain management to ensure it was in line with the acquirer's desired strategic outcome. The Clarkston team assessed the various levels – including active pharmaceutical ingredients (API) suppliers, contract development and manufacturing organizations (CDMOs), and third-party logistics (3PLs) – identifying risks at each level with the proposal of high-level solutions necessary to address any gaps. The team also detected areas where efficiency could be added.

The quality assessment consisted of documentation review, with a focus on quality elements, evaluating risk and potential impact on operations. The regulatory assessment focused on therapies that were yet to be commercialized, validating their regulatory pathway, taking into consideration different markets, and validating timings for launch.

The overall project allowed the pharmaceutical company to better understand various components related to the target company and ensure that the main risks related to supply chain, quality, and regulatory aspects were detected and that the right steps were taken to mitigate these risks.

Life Sciences Case Study

PROJECT OVERVIEW

clarkston CONSULTING

INDUSTRY:

Pharmaceutical

PRODUCTS AND SERVICES :

Manufacturing and distribution of therapies

PRIMARY OBJECTIVES:

- Review the acquisition of a portfolio of therapies in market and in the pipeline through supply chain, quality, and regulatory due diligence
- Perform a high-level assessment of the overall supply chain management
- Conduct an assessment of quality elements through a documentation review to ensure alignment with current regulatory requirements
- Evaluate quality-related risks for potential likelihood and impact on operations
- Validate the regulatory pathway and timings for launch of therapies in the pipeline

RESOLUTION:

- Ensured supply chain management was in line with the acquirer's desired strategic outcome
- Identified risks involved in the supply chain through an analysis of the company's inventory (focusing on demand for each SKU and on-hand inventory)
- Identified various risks at the API supplier, CDMO, and 3PL levels, proposing ways to mitigate these risks and increase efficiency
- Created high-level supply chain maps for each therapy illustrating the process from manufacturing to distribution, helping better visualize the overall supply chain per therapy
- Identified areas where value could be added through the acquirer's experience
- Detected issues in documentation practices through thorough review and proposed ways to ensure good documentation practices
- Identified gaps in the regulatory pathway of therapies in the pipeline with proposal for remediation
- Estimated launch dates for therapies in the pipeline

KEY BENEFITS:

- Provided a thorough understanding of the target company's supply chain
- Delivered step-by-step outlines to mitigate risks related to supply chain, quality, and regulatory aspects
- Proposed various short-term and long-term solutions to improve efficiency and profitability

CONTACT US

2655 Meridian Parkway | Durham, NC 27713 | Phone: 800-652-4274 | www.clarkstonconsulting.com