

A Roadmap to Transitioning to Insourcing Clinical Supply Chain Operations

A clinical-stage biotechnology company that designs new immunotherapies to address life-threatening diseases reached out to Clarkston to help them navigate an upcoming transformation to their supply chain network. The client recently decided to transform its supply chain by insourcing its clinical supply warehousing and distribution. In support of this transition, they partnered with Clarkston to complete an assessment of their current and future state operations.

Clarkston's approach to the assessment included three phases: Discover, Assess, and Deliver. Document reviews, stakeholder interviews, and site visits were utilized to develop observations and understand their landscape. First, the Clarkston team conducted an in-depth review of the client's documents, including SOPs, work instructions, forms, policies, reports, and governance. Then stakeholder interviews were conducted with a focus on three key topic areas: People, Processes, and Technology.

As a result of Clarkston's discovery phase, over 25 critical challenges were identified across six categories, including standardized procedures, facilities management, cross-functional collaboration, employee training, technology advancements, and 3PL transition. Based on all the findings, Clarkston built recommendations with priorities for each of the six categories of observation. To support a long-term plan that ensures all recommendations are addressed appropriately, Clarkston developed four strategic initiatives. The initiatives were aligned with the client's business intentions and provided them with a plan to successfully transform their supply chain with little to no disruptions.

Clarkston helped the client understand the importance of addressing the critical challenges to establish robust internal processes in sync with making a significant transformational change to their distribution network. This provided the client with a clear path forward to transform their supply chain network with minimal disruptions to their business.

Life Sciences Case Study

PROJECT OVERVIEW



INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



Biotech

PRIMARY OBJECTIVES:

- Conduct an assessment of current and future state operations
- Document findings and recommendations in a report with clear identification of areas in need of remediation
- Develop an action plan and roadmap to close gaps identified and ensure a smooth supply chain transformation

RESOLUTION:

- Conducted interviews and site visits with key stakeholders
- Identified and reported key themes and observations
- In-depth reviews of the client's documents, including SOPs, work instructions, forms, policies, reports, and governance
- Uncovered over 25 critical challenges that would have significantly hindered the client's ability to successfully insource their clinical distribution network
- Documented all findings with examples and clear priorities for action
- Provided recommendations to directly address each of the critical challenges
- Proposed four comprehensive initiatives to address all recommendations

KEY BENEFITS:

- Gained confidence in the investment in the first therapy suite, which has potential upside over a five-year period
- Ascertained insight that the non-tablet market is stealing market shares from the tablet market and is projected to continue to expand over the next five years
- Provided conflicting evidence for the second therapy's investment thesis due to market saturation.
- Obtained a realistic timeline for the FDA's approval of the new DS therapy which helped adjust the launch projections accordingly
- Informed on ways to improve future processes and procedures based on actionable quality and compliance recommendations

KPIs

- **26 in-depth document reviews**
- **7 interviews and vision exercises with leaders**
- **6 categories of observation**
- **27 critical challenges uncovered and evaluated**
- **4 comprehensive initiatives proposed**

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