

Multi-facility Business Process Mapping Design and Execution for a Pharmaceutical Company

This pharmaceutical company provides high-quality, low-cost pharmaceuticals through ultramodern, U.S.-based advanced manufacturing processes. They plan to use continuous manufacturing to produce essential medicines through Active Pharmaceutical Ingredients (APIs) to Finished Drug Products. In addition, this company maintains a warehouse that will help to support medical emergency response capabilities by keeping a reserve of critical APIs for the health of all the country. Through manufacturing and the warehouse reserve of APIs and Finished Drug Products, the company hopes to fortify the domestic supply chain and prevent future drug shortages.

The company launched as a response to pandemic shortages in the supply of essential drugs and are hoping to use end-to-end pharmaceutical manufacturing processes and apply green chemistry to reduce costs and waste.

Clarkston was asked to collaborate with the client to identify, analyze, and develop business process maps and related procedures and digital artifacts (process support tools) for three distinct areas – a pilot-scale manufacturing facility, a large strategic API reserve warehouse, and a large-scale hybrid manufacturing facility. Clarkston facilitated workshops to help build and document business processes for the new facilities, supporting

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Pharmaceutical

PRODUCTS AND SERVICES:



Active Pharmaceutical Ingredients (APIs)

PRIMARY OBJECTIVES:

- Conduct business process mapping across two production facilities and one warehouse facility
- Collaborate with contract partner manufacturing facility
- Update the current SOPs
- Develop new SOPs and artifacts to support processes
- Create new Work Instructions and Forms

RESOLUTION:

- Developed business process maps and process support tools/artifacts to support the business processes for two different manufacturing facilities
- Conducted business process mapping for the warehouse in conjunction with the use of SAP from one site and a different ERP system from another partner site
- Analyzed and identified the SOP gaps, updated current SOPs, and created new SOPs
- Developed nine work instruction documents and nine SOPs for the warehouse operations
- Collaborated with contract partner manufacturing site to create a holistic overview of business processes

KEY BENEFITS:

- End-to-end business process analysis and design
- Creation of new or modified processes to ensure the facilities had processes to adhere to for operations
- Analysis and development of the new or existing SOPs and artifacts to support the client manufacturing processes optimization and growth
- The bridging project between SAP Phase 1 and SAP Phase 2 implementation, which allows the client to move forward with manufacturing processes and warehouse operations and be ready for the next implementation phase, was developed
- A holistic view of all business processes and SOPs that support those processes



KPIs

- Developed 66 business process maps across 10 key functional areas for manufacturing and warehouse facilities
- Developed 36 significant artifacts to support the business processes for three different facilities
- Created more than 10 unique artifacts (process support tools) and developed one artifact for future use

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