

Developing COGS Models for a Biotechnology Firm

This client is a publicly listed, clinical-stage biotechnology company focused on discovery, development, and commercialization of biotherapeutics for treatment of cancer and various autoimmune and inflammatory diseases.

In advance of Biologics Licensing Application (BLA) filing with the FDA, commercialization and growth planning, this client engaged Clarkston to develop operations data models central to their strategic finance and supply decision-making. Informed by the current state processes as well as commercial future state, strategic planning and process modeling tools were developed to be leveraged for additional pipeline assets as well as to enable and inform the implementation of an ERP solution.

This included the development of a strategic supply/demand planning model, (Cost of Goods Sold) COGS models for the client's two lead drug candidates, the build-out of Bill of Materials and a part numbering scheme for those products, and the documentation of as-is clinical and to-be commercial supply chain process maps.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Biotechnology

PRODUCTS AND SERVICES :



Develops therapeutics for the treatment of cancer, autoimmune, and inflammatory diseases

PRIMARY OBJECTIVES:

- Develop COGS models for robust, sustainable and scalable maintenance and adaptability for future commercial products.
- Develop and document supply chain process maps for late-stage clinical/leading commercial drug candidate.
- Develop and document bills-of-material and part numbering scheme for late-stage clinical/leading commercial drug candidate.
- Support the commercialization of late-stage clinical/leading commercial drug candidate as well as future pipeline assets.

RESOLUTION:

- Developed COGS models for robust, sustainable and scalable maintenance and adaptability for future commercial products.
- Created supply chain material flows for both clinical (as-is) and commercial (to-be) drugs, using both 2 drug substance and 2 drug product CMOs.
- Developed and documented product numbers as well as bill-of-material scheme leveraging lot and part numbering standard operating procedures (SOP) within the quality management system (QMS).
- Identified and documented key future-state process flows to support company growth.
- Developed and delivered a strategic supply and demand planning model for leading commercial drug candidate with adaptability for future pipeline assets.

KEY BENEFITS:

- Improved supply chain visibility, planning and decision-making for changes in demand based on outsourced manufacturing capacity.
- Enhanced finance visibility and planning relative to changing demand and impact on costing.
- Increased understanding of cost elements, standard cost development as well as alignment among Finance and Supply Chain stakeholders.
- Improved financial and supply planning and decision-making using strategic supply models for what-if scenario planning.
- Better tools to aid in the development of commercial supply agreements with strategic partners.
- Expanded understanding of future state end-to-end supply chain, product costing, transportation lanes, lead-time, supply partnerships – transportation, storage/warehousing, etc,

CLARKSTON CONSULTING



Improved visibility into supply chain and financial operations



Enhanced tools and models to empower decision-making



Increased organizational understanding and alignment on key activities relative to supply and demand planning

