

Stealth BioTherapeutics is an innovative biopharmaceutical company committed to bringing patients mitochondrial targeted therapies to treat both common and rare diseases. Driven by a desire to help patients with unmet treatment needs, our team collaborates with well-recognized institutions, physicians and scientists to develop the next generation of therapies focusing on mitochondrial dysfunction in many diseases.

Position Title: Director, Clinical and Commercial Supply Chain Operations

Position Summary:

In this newly-created position, the Director, Commercial Supply Chain Operations will coordinate all activities and relationships required to ensure the timely and compliant delivery of product for commercial distribution through contract manufacturing organizations (CMO's) and Commercial Packaging Organizations (CPO's), in preparation for upcoming commercial product launch. Reporting to the VP Pharmaceutical Sciences and Technical Operations, the role will partner extensively with cross-functional stakeholders internally, as well as with multiple contracted vendor organizations externally.

Responsibilities:

- Provide expertise in packaging technology, especially as pertains to compliance with global regulatory requirements for serialization and Unique Device Identifier technology
- Develop, implement, and maintain processes (including software) to translate demand into a rolling supply forecast and firm production orders. Align inputs from business processes with technical operations to ensure optimal performance in clearly defining demand and necessary revisions in supply plans.
- Negotiate and create or amend commercial supply agreements with CMO's, CPO's, and third party logistics companies to establish reliable, flexible, and efficient supply chain operations that achieve production goals.
- Develop, maintain, and communicate plans, timelines, and budgets with internal and external stakeholders. Effectively collaborate with cross-functional teams including Quality, Regulatory, Commercial, Technical Operations, Finance, Legal, and IT.
- Develop and implement continuous improvement processes and manage control documentation to address needed changes at CMO's, CPO's and/or key component suppliers, in collaboration with Tech Ops.

Competencies:

- Strong communication skills (both written and verbal)
- Detail-oriented, self-starter with an innovative, quality-focused approach to problem-solving
- Ability to nimbly “flex” between strategy and operational execution
- Ability to anticipate and proactively resolve issues, applying sound judgement
- Team player skilled in collaboration and facilitation, especially with regard to contractor relationships
- Flexibility in making course corrections in response to changes in plans
- Strong business knowledge of biotech/pharma manufacturing operations; technical proficiency in commercial supply chain technologies and processes, as well as in related pharmaceutical regulations for world-wide commercial distribution
- Ability to use software or develop spreadsheet-based algorithms to enable the core function of forecasting and tracking production schedules

Requirements:

- BS/BA in a scientific discipline, MS or MBA preferred, with 10 years of related pharma experience, including 7+ years’ experience working in supply chain management
- Demonstrated experience in building-out a commercial sterile product supply chain to enable product launch and to sustain supply, in conjunction with CMO’s, within a cGMP-regulated environment
- Advanced knowledge of US and EU commercial drug supply chain and distribution processes; working knowledge of the processes for US and EU regulatory drug approval processes and cGMP manufacturing operations
- Travel domestically and internationally, as needed