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/Sr. Director, Regulatory Affairs, CMC

Responsibilities:

- Responsible for the management and tactical execution of the regulatory CMC activities and ensuring that all applicable CMC-related regulations and guidelines are followed in the US and globally.
- Provide strategic guidance into the development of robust CMC strategies across all product life cycle.
- Perform regulatory assessment of change controls, deviations and GMP investigations. Manage multiple concurrent projects and provide project updates on set intervals.
- Manage timelines in cooperation with SMEs and project management to ensure on-time regulatory submissions.
- Assist with the planning, scientific writing and perform critical reviews of pre-INDs, INDs, IMPDs, NDAs, MAAs, annual reports, DSUR, amendments, supplements to ensure a high quality regulatory submission and approval.
- Assist in review of manufacturing change controls by cross-checking the description in regulatory filings in INDs/IMPDs, CTAs and BLAs/MAAs and to ensure that CMC related changes are reported to competent authorities in accordance with regulatory requirements.
- Support establishing, managing and maintaining a knowledge base of current and emerging CMC regulatory requirements and guidelines.
- Assist in tracking of CMC regulatory commitments for INDs/IMPDs, CTAs, and NDAs/MAAs.
- Participate, as needed, in planning, organizing and managing the CMC content of meetings with regulatory agencies.
- Participate in CMC project team meetings and provide current regulatory requirements that pertain to stability studies and analytical characterization tests.

Competencies:

- Self-motivated, detail oriented and strong problem-solving skills
- Ability to multi-task in a fast-paced environment with changing priorities
- Excellent verbal /writing skills and ability to influence across multiple functions
- Ability to work independently with a strong attention to detail
- Excellent written and verbal communication and collaboration skills

Requirements:

- Requires a Bachelor of Science degree plus a minimum of 8-10 years of industry experience in US regulatory CMC activities or equivalent combination of education and experience.
- Knowledge of global (US, EU, ROW, ICH, etc.) regulatory requirements.
- Recent successful NDA CMC submission experience preferred
- Must be able to demonstrate the ability to apply knowledge strategically and operationally across all projects.
- Experience working in a matrix environment: strong negotiation skills, able to communicate sound regulatory advice based on regulations as well as the business needs.
- Previous experience in providing regulatory assessment of change controls, deviations and GMP investigations.