Stealth BioTherapeutics, Inc 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: Vice President, Pharmaceutical Sciences and Technical Operations

Position Summary:

The Vice President (VP), Pharmaceutical Sciences and Technical Operations (PSTO) will be responsible for leading and executing all CMC (Chemistry, Manufacturing and Controls) and related activities from IND-enabling studies to NDA. S/he will be responsible for the development and implementation of efficient and effective CMC strategies to ensure excellent process and product development, including controls, in compliance with regulatory guidance.

The ideal candidate will be a highly motivated individual with substantial CMC experience in developing drugs from small organic drug substances, as well as have experience with therapeutic peptides. S/he will derive motivation from working in a small, entrepreneurial biotech environment, accepting the challenge of broad responsibilities and opportunities in a lean, matrix-focused can-do culture. A "hands-on" operational approach in a virtual biotech combined with the ability to effectively meet development and manufacturing objectives through contractors addresses a core responsibility.

Responsibilities:

- Develop and implement a sustainable and adaptable CMC strategy for each clinical candidate. Lead CMC activities from IND-enabling studies to late clinical development, ensuring full executive management engagement in key decisions and effective communications to all stakeholders.
- Build or adapt the operational tools, systems, and communication channels necessary for alignment of the PSTO department with program teams, as well as finance and legal practices, to achieve the goals and objectives of the Company.
- Provide input into the regulatory affairs strategy for the product portfolio; lead the development, review, and approval of all CMC sections in regulatory filings. Participate in meetings with the relevant global health authorities, conveying the appropriate compliance with GMP and other standards.
- Through Contract Manufacturing Organizations (CMOs), Contract Testing Organizations (CTOs), Contract Research Organizations (CROs), meet the needs of internal customers for appropriately packaged and labeled clinical supplies and, where applicable, commercial goods.
- Oversee the review of all CMC-relevant documents, such as technical reports, batch

records, protocols, and change controls to ensure compliance with all applicable regulations and industry standards for the development of drug substances and drug products.
- Lead, coach, mentor and further develop the PSTO team of scientists and managers and ensure alignment between individual, departmental, and corporate goals.
- Proactively identify potential risks to CMC timelines and deliverables and communicate/implement effective risk mitigation strategies.
- Directly manage external subject matter experts in the areas of CMC regulatory strategy, pharmaceutical development and manufacturing, and analytical development.

Requirements and Competencies:

- PhD in Chemistry, Chemical Engineering, Pharmaceutical Sciences or related technical discipline, as well as a minimum of 15 years' experience in the Biotech/Pharmaceutical industry, with 10+ years managing a CMC function. Small, virtual biotech experience preferred.
- Demonstrated ability to create and execute strategies for successful product. development through effective management of CMOs/CROs/CTOs.
- Substantial experience with cGMP manufacturing and testing of pharmaceuticals from early clinical development through product/process validation.
- Knowledge of cGMP regulations and CMC-relevant ICH guidance documents as well as experience in the preparation of CMC regulatory documents. Experience with pre-approval and other cGMP inspections and audits a plus.
- Strong proficiency in use of software to meet the key communication and data analysis and presentation objectives of the CMC function.
- Demonstrated general ability to apply fundamental scientific and engineering know-how to generate innovative and practical solutions to technical challenges.
- Skilled in clearly conveying complex concepts and study results in written and verbal form to a range of audiences, such as executive management, regulatory agencies, and intellectual property attorneys.
- Highly motivated self-starter with strong interpersonal skills, including experience in using influence and negotiation to successfully complete projects dependent on collaborators.
- Ability to manage and simultaneously advance multiple tasks and projects and "flex" between strategy and operational execution.