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

Position Title: Director/Sr. Director, Pharmaceutical Sciences and Technical Operations

Position Summary:
The Director/Sr. Director, Pharmaceutical Sciences and Technical Operations (PSTO) will be responsible for meeting the company's drug product needs from pre-IND to commercial distribution. Reporting to the Senior Vice President, PSTO, primary responsibilities include planning and leading drug product research, development, manufacturing, and validation activities by identifying, engaging, negotiating with, and managing Contract Development Manufacturing Organizations (CDMO's).

The ideal candidate will be a self-starter with substantial experience in drug product research, development, manufacture, and process validation, with emphasis on sterile products. Experience in GMP and management of CDMOs are essential. The individual will be motivated by working collaboratively with internal and external stakeholders in a small, entrepreneurial biotech environment, embracing the challenge of broad responsibilities and opportunities in a lean, matrix-focused, can-do culture. A “hands-on” operational approach combined with the ability to effectively meet development and manufacturing objectives through contractors addresses a core responsibility.

Responsibilities:

- As the internal subject matter expert for drug products, develop and implement related short-and long-term strategies, in collaboration with internal and external stakeholders.
- In partnership with the SVP of PSTO, develop budgets and timelines to implement CMC strategies internally and externally.
- Manage contracting process with CDMOs (CDA, RFP, proposal evaluation/ recommendation/selection) and internal legal team.
- Oversee drug product activities at CDMOs, providing technical support and troubleshooting as needed.
- Review and approve technical documents including batch records, manufacturing deviations, investigations, protocols, reports, and change controls. Prepare and review CMC documents as needed.
- Manage inventories (expiry dates, retesting, resupply, disposal).
- Lead and facilitate cross-functional CMC meetings in partnership with key internal stakeholders (eg. QA, Regulatory, Discovery, IP.)
- Provide drug product expertise to support Regulatory activities.

- Work collaboratively with Quality to ensure cGMP compliance.

Competencies:

- Highly motivated self-starter and team player with strong interpersonal skills, including experience in using influence and negotiation to successfully complete projects dependent on collaborators.
- Ability to effectively provide oversight and management of CDMOs.
- Ability to anticipate and proactively resolve issues, applying fundamental scientific and engineering know-how to generate innovative and practical solutions to technical challenges.
- Excellent communication skills with the ability to facilitate alignment across internal and external stakeholders.
- Ability to simultaneously manage and advance multiple tasks and projects in operational execution.

Requirements:

- B.S. in Chemistry, Chemical Engineering, Pharmaceutical Sciences, or related discipline. Advanced degree preferred. Minimum of 10 years' formulation/operations experience in Biotech/Pharma, with an emphasis on sterile product experience.

- Substantial experience with cGMP manufacturing of pharmaceuticals from early clinical development through process validation. Experience with pre-approval and other cGMP inspections and audits is a plus as is experience in tablets, capsules or subcutaneous depot.

- Strong proficiency using software to meet key communication, data analysis, and presentation objectives of the CMC function.

- Experience working remotely in small biotech is preferred, along with the ability to travel up to 25% both domestically and internationally as needed.