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/Senior Director, Process Chemistry R&D**

Position Summary:

Reporting to our VP, Pharmaceutical Sciences and Technical Operations, this position is responsible for developing phase-appropriate drug substance manufacturing processes for small - organic-molecule and peptide drug candidates from research through registration, including technology transfers and process validation, in partnership with contract development and manufacturing organizations (CDMOs).

The position requires in-depth process chemistry experience in development and manufacturing settings and demonstrated experience in building strong, collaborative relationships with both internal and external stakeholders.

Responsibilities:

- Plan and manage phase appropriate API development and manufacturing activities at CDMOs from process research through development to commercialization, with an emphasis on regulatory compliance and cost-effective operations.
- As Stealth's primary subject matter expert, operate at a detailed technical level, delivering on functional, program, and corporate goals within a prescribed budget. It will be essential to effectively convey information and make recommendations to executive management through drug substance development updates, data interpretation, technical recommendations, contractor selections, etc.
- Effectively build and manage professional relationships with CDMOs, placing appropriate focus on communication, planning, risk assessment, and escalation of issues.
- To meet deliverables, lead internal cross-functional or external task-focused teams.
- Lead and/or participate in the writing and review of scientific reports and regulatory submission documents. Hold primary responsibility for the chemistry sections of global regulatory filings. Document and archive data and reports from CDMOs.
- Develop plans and manage implementation of process qualification, process validation, and technology transfer activities to meet regulatory agency and quality expectations. Integrate quality by design and risk management principles based on prior experience.

- Work directly with Analytical colleague(s) to define and implement effective process control requirements and with Formulation colleague(s) to address clinical requirements and API properties in formulation and drug product development activities.

- Partner with medicinal chemistry team in the development of pipeline molecules and in the selection of lead candidate molecules. Work closely with internal and external colleagues to move development candidates into the IND enabling stage.

Competencies:

- Excellent written and verbal communication skills

- Ability to effectively manage and report complex information to facilitate agreement on process and control strategies.

- Demonstrated collaboration skills that have led to productive vendor relationships and ability to anticipate and proactively resolve issues critical for production of APIs

- Ability to "flex" between strategy and operational execution. High competency in making course corrections in response to changes in plans.

- Proficiency in applying analytical chemistry principles to ensure adherence to quality standards

Requirements:

- Ph.D. in Organic Chemistry, or related field with strong knowledge of pharmaceutical process chemistry.

- 10+ years' relevant experience in pharmaceutical process chemistry and GMP-compliant process development with emphasis on managing complex process chemistry projects in the biotech/pharmaceutical industry.

- Travel sufficient to build and manage strong partnerships with CDMOs (estimated at approximately 30%).