Stealth BioTherapeutics 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 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: **Executive Director, Process Development and Controls**

Position Summary:

We are seeking a seasoned professional with strong collaboration skills to provide technical and strategic leadership of key CMC operations to successfully pioneer the application of small molecule therapeutics in mitochondrial disorders. Reporting to our VP, Pharmaceutical Sciences and Technical Operations, the ideal candidate will develop phase-appropriate drug substance manufacturing processes, analytical methods, and quality controls for small organic and peptide drug candidates. With a lead peptide candidate advancing through Phase 3 trials and a pipeline of compounds either in or approaching clinical development, responsibilities in both analytical and process chemistry span from research to registration, including required GMP-compliant development activities, technology transfers, process and method validations, and commercial API manufacturing and controls.

A reliance on multiple partnerships with contract development and manufacturing organizations (CDMOs) requires this individual to have demonstrated experience in effectively building, aligning, and managing relationships with both internal and external stakeholders. Also required is a working knowledge of analytical methodology applied to both injectable and oral drug product development for the purposes of product registration.

Responsibilities:

- Plan and manage phase appropriate API development and manufacturing and controls activities at CDMOs from process research through development to commercialization, with an emphasis on regulatory compliance and cost-effective operations.
- Deliver on functional, program, and corporate goals within a prescribed budget, fluidly flexing between operating at a strategic and detailed technical level. Effectively convey information and make recommendations to executive management through drug substance process and method 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.
- Lead internal cross-functional or external task-focused teams to meet agreed upon project deliverables.
- Lead and/or participate in the writing and review of scientific reports and regulatory submission documents. Hold primary responsibility for the chemistry, method

development, specifications and stability sections of global regulatory filings. Review and approve documents 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, where appropriate, based on prior experience.
- Define and implement effective process control requirements and work with Pharm Sci and Tech Ops colleague(s) to address clinical requirements and API properties in formulation and drug product development activities.
- Partner with Medicinal Chemistry in the development of pipeline molecules and in the selection of lead candidate molecules. Work closely with internal and external colleagues to move new development candidates through 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. Ability to effectively manage and align people around the achievement of functional goals.
- Demonstrated ability in project management, objective setting and plan execution; ability to work on multiple initiatives simultaneously and effectively prioritize workload.
- Demonstrated proficiency in applying collaboration skills that have led to productive vendor relationships
- Ability to anticipate and proactively resolve issues critical for production and testing 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 and rationally create suitable specifications for products

Requirements:

- Ph.D. in Organic Chemistry, or related field with strong knowledge of pharmaceutical process chemistry.
- 20+ years' relevant experience in pharmaceutical process chemistry, analytical chemistry, and development of GMP-compliant chemical manufacturing processes with emphasis on managing complex projects in the biotech/pharmaceutical industry.

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