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, Analytical Development

Position Summary: Primary responsibilities include leading the development, validation, and implementation of appropriate methods for analysis of peptide and small molecule API's, as well as a broad range of drug products and depot formulations. These responsibilities are performed through supervision of contractors to conduct all laboratory-based activities, and currently the position has no direct reports.

Responsibilities:

- Develop and qualify HPLC methods through contract research organizations (CROs) to determine stability and performance of small molecular weight API's and dosage forms
- Develop and qualify through CROs non-HPLC methods to measure other key properties (e.g., spectroscopy for proof-of-structure, dissolution of solid oral dosage forms)
- Establish protocols to qualify, validate, and/or transfer analytical methods
- Outsource specialized testing of new API's and excipients, as required
- Develop in-process, near-line, or in-line process monitoring methods
- Develop novel analytical techniques to increase product or process knowledge for pipeline compounds
- Assess precision of drug delivery technologies applied to proprietary compounds
- Lead efforts to define regulatory specifications for development compounds and dosage forms
- Supervise GMP stability and reference standard qualification programs including identifying and qualifying outside testing labs, managing a comprehensive stability database, and conducting data analysis (trending) for all stability programs
- Write sections of regulatory filings pertinent to analytical chemistry
- Manage inventory of reference standards and related authentic substances
- Serve as the company-wide expert in ICH and USP methods

Competencies:

- Strong communication skills (both written and verbal)
- Self-starter with solid analytical and problem solving skills
- Demonstrated ability to effectively manage vendor relationships
- Team player with strong collaboration skills
- Flexibility in adapting to change

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Requirements:

- PhD degree in Chemistry, Analytical Chemistry, or related field
- 10 years industry experience with an emphasis on supervising CRO's to effectively develop and implement analytical methods for cGMP operations
- Experience with the following:
    - Analytical method development with depth of knowledge in HPLC purity methods
    - Oversight of contract laboratories generating analytical data under cGMP's,
    - Quality control operations consistent with international regulatory guidance documents
    - Analytical aspects of cGMP documentation including method validation protocols and reports, technical report writing, and preparation of regulatory submissions
    - Availability for an average of 10% travel time