

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:** Associate Director/Director, ADME/PK

**Position Summary:**

We are seeking a highly motivated self-starter with strong problem solving skills and demonstrated experience in drug metabolism and pharmacokinetics to provide support for our Discovery pre-clinical and early-clinical development stage projects. The successful candidate will be responsible for overseeing ADMET-DMPK strategies in a multidisciplinary team environment, providing PK, in vitro/in vivo drug metabolism, and PK/PD modeling and analysis for small molecule and peptide projects. Additionally, this individual will establish and maintain effective strategic alliances for outsourcing, managing and reporting DMPK programs and studies.

**Key Responsibilities:**

- Provide strategic oversight for DMPK including quality and performance of all DMPK activities, including interactions with CROs and external project support.
- Identify and implement appropriate assays and technologies relevant to ADME-DMPK characterization for assessment of small molecule and peptide therapeutics for drug discovery and early development projects.
- Oversee all DMPK data analysis, PK/PD modeling & simulation and prediction.
- Integrate, interpret and report data to Clinical teams and management.
- Prepare and present internal and external documentation relating to regulatory documents (e.g. IND, CTA, Protocols and IBs).
- Initiate and facilitate collaboration with DMPK, modeling/simulation, and clinical pharmacology consultants as necessary.

**Competencies:**

- Ability to communicate clearly and effectively with project teams, management and CROs.
- Ability to work effectively in a team environment, meet deadlines, and prioritize and balance responsibilities.
- Independently motivated, detail oriented, and strong problem-solving skills.
- Ability to maintain broad knowledge of state-of-the art principles and theories.

**Requirements:**

- PhD in Pharmacokinetics, Drug Metabolism or related field, with at least 5 years industry experience evaluating small molecule therapeutics; excellent understanding of early stage drug discovery and development processes. An understanding of mitochondrial dysfunction and therapeutics is a plus.
- Demonstrated knowledge of global regulatory requirements and expectations for nonclinical DMPK packages to support first-in-human and clinical development studies.
- Extensive experience in the outsourcing and external oversight of nonclinical DMPK studies conducted by qualified suppliers.