Stealth BioTherapeutics, Inc 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, Toxicology

Position Summary:

The Director/Senior Director, Toxicology will be responsible for managing the nonclinical toxicology function, principally focused on the design and oversight of nonclinical safety studies in our virtual biotech environment. The ideal candidate will be a key contributor to the drug development process, representing the toxicology function on program development teams and in meetings with regulatory authorities, as well as leading presentations of strategy, results, and progress-versus- goals to executive management. S/he will author regulatory submissions, negotiate the technical aspects of contracts, and manage the toxicology-specific outsourcing plan and budget.

Responsibilities:

- Develop and direct the toxicology strategy for each drug candidate throughout the stages of development from preclinical to post-marketing.
- Design and direct nonclinical safety studies as the study monitor of studies conducted through CROs.
- Evaluate and interpret results of safety pharmacology and toxicology studies and assess the impact of toxicokinetic/tissue exposure data on those results.
- Serve as the subject matter expert in nonclinical safety pharmacology and toxicology, especially in advising program teams and in authoring/editing GLP study reports and pertinent sections of regulatory filings.
- Contribute to translational pharmacology strategy for pipeline compounds prior to nomination for IND-enabling studies.
- Create and manage toxicology goals including financial and human resource requirements, as well as project timelines. Contribute to development risk assessments as part of a cross-functional effort.

Requirements and Competencies:

- DVM/PhD in Pharmacology, Toxicology, or related discipline with at least 10 years of post-graduate drug development experience.
- An in-depth understanding of safety pharmacology, investigative and regulatory toxicology, and experience designing exploratory and GLP-compliant toxicology

studies.

- Demonstrated ability, in the context of prior experience, to critically evaluate and interpret the results from nonclinical safety studies of small molecule drug candidates, including the likely impact on clinical study design
- Experience in authoring the toxicology sections of investigator brochures and regulatory documents using knowledge of relevant ICH guidance documents and other regulations
- Extensive experience conducting GLP-compliant studies through contract research organizations in a virtual biotech setting
- Skilled in clearly conveying complex concepts and study results in written and verbal form to a range of audiences, such as executive management, regulatory agencies, collaborators, and potential partners.
- Highly motivated self-starter with strong interpersonal skills, including experience in using influence and negotiation to successfully complete projects dependent on collaborators.
- Ability to manage and simultaneously advance multiple tasks and projects and “flex” between strategy and operational execution.