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/Sr. Director Regulatory Affairs

Position Summary: Reporting to the VP, Regulatory Affairs/Quality Assurance, the Sr. Director, Regulatory Affairs will develop and implement global regulatory strategies in support of business objectives, and will ensure regulatory compliance with pre-and-post approval filing and reporting requirements.

Responsibilities:

- Working in partnership with the Vice President, Regulatory Affairs/Quality Assurance:
  - Develop and implement global regulatory strategies in support of business objectives
  - Ensure regulatory compliance with pre- and post-approval filing and reporting requirements
  - Represent company RA at external meetings with FDA and other global health authorities
  - Provide regulatory expertise and support for pre-clinical, CMC, and clinical areas for investigational products
  - Provide global strategic regulatory leadership and guidance to project teams
  - Ensure clinical, non-clinical, and CMC programs are designed and implemented to meet regulatory requirements
  - Define regulatory expectations for program teams
  - Develop strategies and drafts and/or reviews responses and other documents intended for submission to FDA and other global health authorities
- Perform as the back-up to VP-RA as primary liaison with FDA, and other global regulatory authorities. Serve as the back-up/delegate to VP-RA, as needed, in other matters.
- Review and interpret regulatory rules and guidance as they relate to company products and procedures
- Ensure, through management and/or delegation, that content of regulatory dossiers meet format and content requirements applicable to specific health authority regulatory requirements
- Manage, or delegate the management of, the completion of documents and other assigned tasks within established timelines and with high quality - in terms of scientific content, organization, clarity, accuracy, format, consistency, and adherence to regulatory guidelines, styles, and processes
- Lead the regulatory dossier submission process for Clinical Trial Applications (US, EU, Canada, etc.) and registration submission. Oversee the management of timelines, as needed, in conjunction with internal and/or external project management
- Provide overall leadership for the development of global regulatory submission documents

- Manage, review, and/or edit and ensure the quality of regulatory documents or sections of regulatory documents prepared by other writers (internal or external), ensuring adherence to standards
- Serve as primary author for key regulatory documents or sections of regulatory documents (primarily briefing documents, meeting requests, and specialty submission documents)
- Take initiative to suggest modifications to existing programs/plans and offer new ideas for the organization
- Recruit, train, coach, and supervise staff and provide oversight for regulatory consultants and contractors
- Support or lead non-project activities, as needed (ie, SOP/standards development, organizational initiatives)

Competencies:

- Excellent verbal and written communication skills; ability to collaboratively influence across multiple functions within a matrix environment
- Strong negotiation and facilitation skills; ability to communicate sound regulatory advice based on regulations, as well as the business needs
- Demonstrated ability to apply knowledge strategically and operationally across projects
- Self-motivated and detail oriented with sound judgement and problem solving skills
- Ability to multi-task in a fast-paced environment with changing priorities
- Ability to work independently as well as part of a team

Requirements:

- Bachelor of Science degree, and 10+ years' regulatory affairs experience within the biotech or pharmaceutical industry
- A minimum of 7 years regulatory experience within the drug development and approval process in IND/CTAs /marketing applications
- Knowledge of global (US, EU, ROW, ICH, etc.) regulatory requirements
- Experience working on ophthalmology programs, as well as recent successful NDA submission experience strongly preferred