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: Regulatory Submissions Contractor (Manager level)

Position Summary: We are seeking a results-oriented, self-starter with excellent communication skills to play a key contract role on our growing regulatory team. Primary responsibilities include planning, preparing, and coordinating regulatory submissions, providing regulatory guidance to cross-functional stakeholders, and collaborating with external stakeholders to align timelines and advance program progress .

Contract Term: 6 months **Hours**: 40 hours per week

Responsibilities: responsibilities include, but are not limited to, the following:

- Plan, prepare, and review submissions to regulatory authorities including FDA, EMA, and other authorities to support the conduct of clinical trials and approval of marketing applications (NDA, IND, CTA, and MAA)
- Ensure that regulatory documents are accurate, complete, verifiable, and are in compliance with regulatory requirements
- Facilitate alignment with internal cross-functional stakeholders, as well as external consultants and vendors to ensure timely completion of regulatory filings
- Coordinate with eCTD publishing vendor to align regulatory submission schedule
- Coordinate and prepare responses to requests for information from regulatory authorities
- Plan and track milestones of regulatory lifecycle and status of informational documents
- QC submission documents for eCTD compliance
- Perform ad hoc Regulatory intelligence searches and projects
- In partnership with cross-functional program teams, identify critical path activities and risk mitigation strategies to optimize chances for successful outcomes
- Maintain required documentation in document management systems
- Support the development of processes to ensure compliance and update SOPs as necessary.

Qualifications and Competencies:

- Requires a BS degree and 3+ years regulatory experience in US Regulatory Affairs
- Strong understanding of regulatory submission requirements, document formatting and submission building (eCTD)
- Strong knowledge of global (US, EU, ROW, ICH, etc.) regulatory requirements
- Strong written and verbal communication; ability to effectively collaborate with internal and external stakeholders
- Detail-oriented self-starter with strong project management skills

- Ability to multi-task in a fast-paced environment with changing priorities
- Ability to connect strategy with operational execution