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: Assistant General Counsel

Position Summary: In this newly created position reporting to our Chief Legal Counsel, the Assistant General Counsel will provide a broad array of key support to the organization as it evolves into an innovative commercial-stage company, with continued strong investments in research and development. The position will be responsible for handling a variety of legal, regulatory and compliance issues governing on-market and pipeline products with a focus on related regulations. Additionally, the Assistant General Counsel will develop, manage, and maintain a comprehensive compliance program across domestic and global markets. The attorney will have frequent interactions with internal clients across multiple R&D programs and functional groups.

Key Responsibilities:

- Support the commercial function with the review and assessment of advertising and promotional materials through participation in various review committees
  - Assess disease state and medical materials
  - Provide healthcare compliance guidance for various therapeutic areas
  - Advise company executives on healthcare compliance policies procedures and laws
  - Collaborate with Medical and Regulatory Affairs to conduct a detailed review and evaluation of the adequacy of promotional claims and tactics to ensure consistency with FDA approved labeling.
- Draft and negotiate contracts (e.g., commercial, clinical trial, KOL, CRO, manufacturing,) and/or other agreements.
- Develop and implement policies and appropriate employee training programs regarding Stealth's compliance program and other legal and ethical responsibilities.
- Conduct compliance audits and investigations, as needed. Ensure that Stealth is AUDIT READY, across all functions.
- Ensure implementation of transparency and disclosure requirements.
- Proactively support and monitor a compliance culture where every employee is aware of, and anticipates risks, and is committed to doing the right thing.
- Drive common vision, objectives, and strategy within the framework of compliance from Stealth's executive team to its management, employees, customers, distributors, vendors, and shareholders.
- Provide legal support for global clinical development matters; supply chain transactions; and special projects

- Frequently interact with and provide substantive advice to Marketing, Medical Affairs and Regulatory Affairs departments concerning a broad range of legal, regulatory and compliance issues, including FDA regulations, False Claims Act, Anti-Kickback Statute, OIG guidance, the PhRMA Code, the Sunshine Act, Foreign Corrupt Practices Act and competition law in connection with product labeling, promotional and non-promotional activities.
- Help select and direct the work of outside counsel, define project objectives, manage project and budget.
- Serve as the legal representative on promotional materials review committee, and provide legal review of sales training materials, corporate communications, etc.
- Provide advice on market access initiatives and patient assistance programs.
- Advance and further refine the Company's existing compliance programs to ensure compliance with all applicable rules and regulations, including but not limited to the anti-bribery regulations and the Foreign Corrupt Practices Act, the U.S. Anti-Kickback Statutes, the Stark Laws, the False Claims Act, HIPAA, the Sunshine Act/Transparency reporting regulations, and Export Control regulations.
- As required, conduct internal investigations into allegations of violations of law or Company policy.
- Advise members of the business regarding how to implement initiatives in a manner that is consistent with compliance policies and best practices.
- Maintain knowledge of related legislative, regulatory and judicial developments and trends that may impact areas of responsibility and remain current with related global laws and regulations applicable to biotech and medical device manufacturers.
- Support review of contracts and propose revisions to enhance compliance objectives, as needed, in collaboration with broader legal team responsible for contracts process.

Competencies:

- Excellent communication (verbal, written) and interpersonal skills
- Ability to collaboratively work cross-functionally with a wide variety of technical, scientific, medical and operational team members to resolve complex issues
- Demonstrated ability to work on multiple projects simultaneously and effectively prioritize
- Self-starter and team player with sound judgement and a strong results orientation.
- Ability to flexibly adapt to changing business needs; comfortable with ambiguity
- Strong problem solving, risk analysis, and project management skills
- Organized, able to meet timelines in fast-paced environment with strong attention to detail

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Requirements:

- 5+ years of related experience specifically in a Pharmaceutical, Life Science, or Biotechnology company. Prior law firm experience preferred but not required.
- Experience working in a public company is required
- SEC filing experience required
- BA/BS in Life Sciences; Juris Doctorate degree
- Demonstrated knowledge of regulations and regulatory guidance specific to advertising and promotion of pharmaceutical/biological products. Must have knowledge and experience to act upon compliance issues related to sales marketing and medical affairs activities