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: Vice President, Regulatory Affairs

Position Summary: The Vice President, Regulatory Affairs will be a key member of the Clinical leadership team, responsible for defining and driving global regulatory strategy as the company prepares for its first commercial product launch. Reporting to our Chief Clinical Development Officer, this seasoned professional will lead all aspects of regulatory affairs, including late-stage development, marketing application submissions, health authority engagement, post-approval lifecycle management, and commercial.

The ideal candidate will bring deep experience in biotech drug development and global registration processes (IND, NDA, MAA, etc.), along with a track record of successful regulatory submissions and product launches. They will play a critical role in shaping global regulatory pathways, ensuring inspection readiness, and supporting the commercial organization.

Responsibilities:

Regulatory Strategy & Global Launch Readiness

- Develop and execute global regulatory strategies to support late-stage development and successful registration of the company's lead product(s)
- Lead the preparation, submission, and approval process for NDA, MAA, and other global marketing applications
- Serve as the primary interface with regulatory authorities (e.g., FDA, EMA, Health Canada) and lead critical interactions such as pre-NDA/MAA meetings and advisory committees
- Anticipate regulatory challenges related to launch, including labeling, packaging, post-marketing commitments, and manufacturing compliance
- Align regulatory plans with global launch strategy, including country-specific registration timelines and requirements

Regulatory Operations & Compliance

- Oversee the development of high-quality regulatory submissions, ensuring alignment with regulatory expectations and company objectives
- Ensure regulatory documents and dossiers meet content, format, and quality standards (e.g., eCTD, global CTD)
- Lead and support the implementation of regulatory systems, tools, and infrastructure to enable global operations and launch readiness
- Partner with internal teams (Clinical, CMC, Quality, Commercial, Medical Affairs) to ensure integrated regulatory planning and execution

- Maintain awareness of evolving global regulatory frameworks (FDA, EMA, ICH, etc.) and communicate potential impact to stakeholders

Leadership & Cross-Functional Collaboration

- Lead and further build the high-performing Regulatory Affairs team to support both near-term and future pipeline goals
- Manage and coordinate external regulatory consultants, CROs, and global affiliates involved in submission preparation and country-level filings
- Collaborate with Quality and Supply Chain to ensure manufacturing and CMC readiness for launch
- Partner with Commercial and Market Access teams to support launch activities such as promotional review, labeling strategy, and payer interactions
- Act as a strategic regulatory advisor to executive leadership and participate in corporate decision-making processes

Post-Approval & Lifecycle Management

- Support global post-marketing activities including label updates, pharmacovigilance commitments, and regulatory maintenance
- Lead post-approval variations, change management filings, and regulatory compliance reporting
- Develop regulatory strategies for potential line extensions, new indications, and lifecycle innovation

Commercial Regulatory Affairs

- Ensure that all promotional, marketing, and communication materials for a company's products comply with FDA (and other agency) regulations while aligning with the approved Prescribing Information (PI)
- Serve as the regulatory reviewer on the company's Medical-Legal-Regulatory (MLR)
- Interpret labeling, clinical data, and FDA regulations to guide commercial strategy early in campaign planning
- Interface with FDA's Office of Prescription Drug Promotion (OPDP)
- Cross-Functional Collaboration
- Partner closely with Medical Affairs to manage the boundary between promotion and scientific exchange (e.g., SIUU responses)
- Manage submissions to OPDP

Key Competencies:

- Strategic thinker with the ability to translate complex regulatory landscapes into actionable plans
- Skilled communicator with strong regulatory writing and negotiation abilities
- Strong leadership and people development skills; experience building regulatory functions in growing organizations

- Highly collaborative in cross-functional, matrixed environments
- Operates with urgency and accountability in a fast-paced, pre-commercial environment
- Solutions-oriented with a commitment to scientific and regulatory excellence

Qualifications:

Required:

- Bachelor's degree in a scientific discipline (life sciences, pharmacy, or related field)
- 12+ years of Regulatory Affairs experience in the biotech or biopharmaceutical industry
- 7+ years of leadership experience, including managing teams and external partners
- Proven success leading late-stage regulatory strategy and global marketing application submissions (e.g., NDA, MAA)
- Strong understanding of global regulatory requirements and pathways (US, EU, ICH, RoW)
- Experience interacting with FDA, EMA, and other global agencies at a senior level
- Demonstrated experience supporting first product launch from a regulatory perspective

Preferred:

- Advanced degree (PharmD, PhD, MS, JD,)
- RAC or other regulatory certifications
- Experience in rare disease or ophthalmology preferred
- Familiarity with combination products, biologics, or accelerated approval pathways a plus

Other Requirements:

- Ability to travel domestically and internationally as needed to support regulatory and launch activities
- Comfortable working remotely in a dynamic, evolving biotech environment where adaptability and innovation are critical