Stealth BioTherapeutics, Inc. is an innovative biopharmaceutical company committed to bringing patients mitochondria targeted therapies to treat both common and rare diseases. Driven by a desire to help patients with unmet medical needs, our team collaborates with well-recognized institutions, physicians, and scientists to develop the next generation of therapies focusing on mitochondria dysfunction in many diseases.

Position Title: Senior Medical Director

Position Summary: Reporting to the Chief Clinical Officer, this newly created Senior Medical Director role will lead the continued development and execution of the Medical Affairs strategy to support product launch and lifecycle management. This individual will serve as a key scientific leader and cross-functional partner, driving the integrated rare disease medical plan, including evidence generation, publication planning, scientific communications, and MLR review, while ensuring alignment with Clinical, Commercial, Regulatory, and Market Access priorities. The ideal candidate will be comfortable operating at both the strategic and tactical levels, with a willingness to manage and advance key initiatives as the team continues to scale.

Responsibilities:

Medical Strategy & Launch Readiness

- Develop and execute the Integrated Medical Affairs Plan for rare disease: Translate the broader clinical strategy into a tactical 12–18-month medical plan.
- Scientific Platform & Messaging: Build the core scientific narrative and ensure it is consistently used across all approved materials.
- Launch Coordination: Lead the medical team to ensure all educational materials and field tools are sufficient to support the field medical team.

Medical, Legal, & Regulatory Review

- Primary Medical Reviewer: Serve as the lead medical authority on the MRC committee, ensuring all non-promotional content is medically accurate and supportable.
- Content Direction: Provide clinical guidance to creative and medical education agencies to ensure complex data is visualized accurately for clinicians.
- Compliance Bridge: Partner with Legal to ensure field activities and medical materials remain within the bounds of FDA regulations and company policy.

External Expert Engagement & Advisory Boards

- Medical Advisory Boards: Own the end-to-end strategy for Advisory Boards, from identifying the appropriate advisors to distilling insights for the internal clinical and commercial teams.

- High Impact External Expert Relationship Management: Cultivate deep relationships with influential academic researchers and clinicians in the mitochondrial disease space.

Evidence Generation & Data Dissemination

- Post Marketing Studies: Evaluate investigator sponsored research proposals as needed.
- Publication Management: Direct the publication process, ensuring high quality data is submitted to major congresses and peer-reviewed journals.
- Data Acquisition (DUA/SRA): Identify specific knowledge gaps and scout academic datasets or research organizations to fill those gaps via Data Use or Strategic Research Agreements.

Field Medical & Training Support

- Subject Matter Expert (SME): Serve as the internal expert for the Field MSL team, providing advanced training and ensuring they are prepared to answer complex medical inquiries.
- Internal Partner: Act as the medical consultant for the Market Access and Commercial teams to ensure payer value propositions are scientifically sound.

Pipeline, Safety, & Expanded Access

- Pipeline Feedback: Funnel field insights back to R&D to help refine study protocols or identify potential new indications.
- Expanded Access (EAP): Contribute to the medical evaluation and case-by-case review of compassionate use requests.
- Safety Governance: Contribute medical expertise to safety documents (DSURs/PSURs/PADERs) and participate in product-level Safety Review Teams.

Medical Information & Call Center Oversight

- **Scientific Content Ownership: Oversee the development and maintenance of** the Medical Information Standard Response Letters and Frequently Asked Questions to ensure all external communications are accurate, current, and balanced.
- Quality & Compliance Monitoring: Provide medical oversight for the call center to ensure the vendor or internal team is accurately interpreting data and escalating complex medical inquiries or potential Adverse Events and Product Complaints properly.
- Escalation Point: Serve as the senior medical resource for Level 2 inquiries that represent complex or technical questions that require a deeper clinical understanding than the standard response provides.

- Insight Generation: Analyze call center trends and inquiry data to identify knowledge gaps in the medical community, using these insights to inform future Advisory Board topics or educational materials.
- Vendor Management: Lead the medical onboarding and ongoing scientific training for call center staff to ensure they are proficient in the product's clinical profile and the disease state landscape.

Competencies:

- Proven capability to translate clinical data and scientific insights into a clear Medical Affairs strategy and drive successful execution, including product launch readiness.
- Deep expertise in clinical research and data interpretation, with sound judgment to guide medical and business decisions.
- Demonstrated effectiveness in collaborating across Medical, Clinical, Commercial, Regulatory, and Market Access functions and influencing decisions in a matrixed environment.
- Strong track record of building credibility with KOLs and external stakeholders.
- Comfortable operating in a lean, fast-paced environment, with a hands-on approach to execution and the ability to prioritize and adapt to evolving business needs.
- Experience scaling Medical Affairs infrastructure, processes, and ways of working, with a high level of ownership and accountability.

Requirements:

- MD, DO, or PharmD with minimum of 10 years in Medical Affairs within the pharmaceutical or biotech industry, with significant medical experience and at least 3 years in a Senior Medical Director role.
- Proven track record in **rare disease**
- Experience as a primary medical reviewer in a busy MLR environment.
- Demonstrated ability to lead Advisory Boards that directly influence clinical or commercial strategy.