

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: Medical Device Product Engineer (Injectables)

Position Summary:

In this newly-created position, reporting to the Executive Director, Product Development and Logistics, you will provide support on projects covering a wide range of engineering, compliance, and commercialization challenges related to complex combination products (e.g., drug-device).

Responsibilities: The position will include the following responsibilities:

- Medical device design controls
- Combination product commercialization
- Design verification and validation
- Technology transfer and scale-up
- Data analysis including statistical analysis
- Regulatory submission authorship
- Project management leadership and support
- Technical report authorship, review, and formatting
- Manufacturing investigations
- Quality systems support
- Process and product development

Competencies:

- Highly organized and detail-oriented self-starter with a quality-focused approach to problem-solving
- Strong communication and interpersonal skills; ability to work effectively with remote team members
- Strong process aptitude, with the ability to solicit and effectively utilize subject matter expert input
- Ability to anticipate and proactively resolve issues, applying sound judgement
- Flexibility in making course corrections in response to changes in plans

Requirements:

- Bachelors of Science in Chemical, Biomedical, or Mechanical Engineering from an accredited institution.
- Minimum of 3 years' related experience, including a demonstrated level of combination drug-medical device experience.
- Experience with re-usable pen injectors and nasal spray devices is preferred.