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: Manager/Senior Manager, GMP Quality Assurance

Position Summary:

The Manager/Senior Manager, GMP Quality Assurance position will be responsible for driving Quality initiatives to completion in collaboration with cross-functional team members as well as external vendors. This newly-created position will also be responsible for support of GMP clinical and commercial batch manufacturing and associated Quality Systems.

Responsibilities:

- In collaboration with cross-functional teams, conduct quality reviews of both internal and external documents in compliance with US and EU regulations, including, but not limited to master and executed batch records, process and analytical method validations and quality agreements.
- Author/revise corporate Quality Systems policies and Standard Operating Procedures (SOPs) and support the continued development of the Quality Systems.
- Maintain Quality oversight of external Contract Manufacturing Organizations (CMOs) by representing QA during recurring meetings and communicating back to Quality Senior Management.
- Perform review of routine drug substance and drug product stability documentation, including raw laboratory data, certificates of analysis, and trending reports.
- Perform QA reviews of change controls, deviations, investigations and CAPAs.
- Perform QA reviews of deviations, investigations for manufacturing processes assessing impact on drug substance and/or drug product and resulting CAPAs.
- Perform disposition activities for drug substance and drug product.
- Support Pre-Approval Inspection (PAI) readiness activities, both internally and with CMOs.
- Assist with audits of GMP vendors, document management, training and other QA functions as necessary to maintain quality oversight of ongoing activities in a rapidly paced environment.

Competencies:

- Resourceful, self-starter and team player with a strong results orientation.
- Excellent written and oral communication skills, with the ability to communicate complex information in a virtual environment.
- Ability to analyze and interpret analytical data.
- Strong organizational skills with the ability to effectively multi-task and prioritize.
- Strong attention to detail and problem-solving skills.

- Ability to flexibly adapt to changing business needs and meet timelines.

Requirements:

- Bachelor's degree in a scientific discipline or biotechnology field.
- 3+ years relevant GMP QA experience in pharma/biotech company, working within Quality Systems and regulated GMP environments.
- Manufacturing knowledge of small-molecule drug substance and aseptic processing of drug product, as well as Combination Device experience preferred.
- Strong understanding of GMPs, FDA, EU and ICH regulatory standards/guidance documents.
- Proficiency with computer systems such as Microsoft Word, Excel, Adobe Acrobat and electronic quality management systems.
- Previous experience working with pharmaceutical vendors / collaborators (CMOs) highly preferred.
- Travel requirement expected to be 10- 20%.