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: Senior Manager, Quality Assurance

Position Summary:

The Sr. Manager, QA will be primarily responsible for the management of the Stealth electronic Quality Management System (eQMS). This position reports to the Head of Quality. This includes the management of Quality Systems such as Change Control, Deviation, CAPA, Complaints, Audits, Training and Document Management.

Responsibilities:

- System Administration of the eQMS including managing software updates;
- Manage the Audit program including scheduling and resourcing;
- 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) through the qualification of Suppliers;
- Manage the annual Management Review process including the collection and presentation of Supplier performance data and relative Risk ranking;
- Manage the Annual Product Review for commercialized product;
- Maintain Audit Readiness through evaluation of Quality Systems status, both internally and with CMOs.

Competencies:

- Excellent written and oral communication skills, with the ability to communicate complex information in a virtual environment;
- Strong organizational skills with the ability to effectively multi-task and prioritize;
- Ability to flexibly adapt to changing business needs and meet timelines;
- Ability to prioritize and drive open items to completion;
- Strong attention to detail and good problem-solving skills;
- Resourceful, self-starter and team player with a strong results orientation.

Requirements:

- Bachelor's degree in a scientific discipline or biotechnology field;
- 5+ years relevant GxP QA experience in the Pharmaceutical/Biotechnology industries, managing an eQMS;

- Proficiency with computer systems such as Microsoft Word, Excel, Adobe Acrobat and eQMSs;
- Strong understanding of GxPs, FDA, EU and ICH regulatory standards/guidance documents;
- Previous experience working with pharmaceutical vendors / collaborators (CMOs);
- Auditing experience a plus;
- Travel Requirement expected to be 5- 10%.