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, GCP Quality Assurance

Position Summary:

The Senior Manager, GCP Quality Assurance will be responsible for driving Clinical Quality initiatives to completion in conjunction with Stealth's Clinical/Regulatory departments and external vendors. This position will also be responsible for support of administration and processing of GCP/GMP documentation and associated tasks. This position reports to the Stealth Head of Quality.

Key Responsibilities:

- In conjunction with QA Management and staff, assist in creating, implementing and maintaining an efficient, phase-appropriate and compliant GCP systems;
- Partner with stakeholders to develop GCP SOPs, policies and procedures consistent with corporate objectives;
- Provide QA Support for CRO oversight:
  - Represent Stealth QA on Sponsor/CRO/Site project calls and provide updates to QA Management;
  - Provide QA support for critical quality issues, protocol deviations and investigations;
- Provide QA/QC review of protocols, CSRs, and other Clinical and Regulatory documentation as needed;
- Assist in the development and implementation of GCP training programs and conduct training sessions as required;
- Assist in the coordination and oversight of internal and external GCP audits;
- Proactively identify potential quality issues/discrepancies and work with QA Management to effectively resolve in a compliant and timely manner;
- Research changes and updates to ICH, GCP regulations;
- Assist in the preparation and coordination of Material View Board (MRB) meetings, as needed;
- Perform disposition activities for clinical trial drug substance and drug product, as needed.

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 analyze & interpret analytical data;
- Strong attention to detail and good problem-solving skills;
- Resourceful, self-starter and team player with a strong results orientation.

Stealth BIOTHERAPEUTICS | Leading Mitochondrial Medicine

Requirements

- A Bachelor's degree in a scientific discipline or biotechnology field;
- 7+ years relevant GCP experience in pharma/biotech company, working within quality systems and regulated GCP/ICH environments;
- Clinical site monitoring experience is a plus;
- Strong understanding of GCPs/GMPs, FDA, EU and ICH regulatory standards/guidance documents;
- Must be able to travel to Clinical sites; Travel Requirement expected to be 25%.