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 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 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 and determine effect on Stealth practices;
- Assist, as needed, in disposition activities for clinical trial drug substance and drug product.

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;
- 5+ years relevant GCP experience in pharma/biotech company, working within quality systems and regulated GCP environments both US and ex-US;
- Clinical site monitoring experience is a plus;
- Strong understanding of GCPs, FDA, EU and ICH regulatory standards/guidance documents;
- Must be able to travel to Clinical sites (as required); Travel Requirement expected to be 25%.