Stealth BIOTHERAPEUTICS | Leading Mitochondrial Medicine

Position Title: Quality Assurance Systems Specialist/Senior Specialist

Position Summary:
The QA Systems Specialist/Sr. Specialist position will be responsible for assisting with the day-to-day maintenance of QA systems, processing of documents, authoring Quality SOP's, supporting, and enhancing Document Management Systems and Quality Management Systems and coordinating and assisting with Training Program.

Responsibilities:
Assist with day-to-day maintenance of the following QA Systems:

- Document Management
- Training
- Change Control
- CAPA
- Deviations
- Label control
- Complaints
- Audits
- Regulatory Inspection Readiness Support
- Material Review Board (MRB) meetings

Manage day to day processing of documents through the various systems, including:

- Assign document numbers and maintain tracking mechanisms
- Manage documents through approval and issuance processes
- Follow up on overdue items
- Report metrics

Additional responsibilities:

- Author Quality SOPs
- Support and enhance electronic Quality Management Systems (QMS) as needed
- Experience working in Validated Electronic Quality Systems

Competencies:

- Excellent verbal, written communication and interpersonal skills
- Ability to collaboratively work cross-functionally with a wide variety of clinical, scientific, and operational team members, at all levels
- Strong organizational and multitasking abilities, problem solving skills, and attention to detail
- Organized, ability to prioritize work and meet timelines in fast-paced environment

- Self-starter and team player who can effectively communicate with colleagues in a remote work environment
- Sound judgement with the ability to flexibly adapt to changing timelines

Minimum Requirements:

- Bachelor's degree with 3+ years of Quality Systems experience in Pharmaceutical, Biotech or Medical Devices
- Demonstrated proficiency in use of QA Systems, as well as the Microsoft office suite, including Word, Power Point, Outlook and Excel