

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, Supplier Quality Assurance

Position Summary:

In this newly created position, the Sr. Manager, Supplier Quality Assurance will be responsible for driving Quality initiatives to completion in conjunction with Stealth's internal departments and external suppliers. Reporting to our Head of Quality, this position will focus on Quality supplier management, integrating activities within Stealth's electronic Quality Management System (eQMS). Additional responsibilities include management of additional Quality systems such as change control, deviation, CAPA, complaints, training and document management.

Responsibilities:

- Manage the Quality supplier program including an annual audit schedule (including internal), sourcing contract auditor, negotiating audit dates and the input of documentation into Stealth's eQMS (audit agenda, audit report, observation table/responses and audit certificates)
- Perform supplier audits and determine suitability
- Provide input to the Quality management review process including the collection and presentation of supplier performance data and relative risk ranking
- Provide input to the annual product review for commercialized products
- Maintain audit readiness through evaluation of Quality systems status, both internally and with contract manufacturing organizations (CMOs)
- Assist in managing additional Quality systems such as change control, deviation, CAPA, complaints, training and document management

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
- Previous experience working with pharmaceutical suppliers / collaborators (e.g. CMOs)
- Pharmaceutical supplier auditing experience a must
- 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
- Ability to travel domestically up to 10%, as needed