Associate Director of GCP Quality Assurance

Location: London, UK

About Us: At Nightstar, our mission is to maintain and restore sight in patients with inherited retinal diseases. We are a clinical-stage company focused on developing and commercializing a pipeline of novel and potentially curative, one-time retinal gene therapies for patients suffering from rare inherited retinal diseases that would otherwise progress to blindness, and, for which, there are no currently approved treatments.

Job Purpose:, We are seeking an Associate Director of GCP Quality Assurance based in our London office. Reporting to the Head of Regulatory Affairs and Quality Assurance, this is a hands-on role and an excellent opportunity for someone with strong organizational skills and the ability to work on a variety of programs simultaneously. In addition, the successful candidate must have good judgment, work well under pressure, and be detailed oriented.

Job Responsibilities:

- Work with functional leaders to develop and implement the GCP quality management system, including the following elements, with a goal of assuring internal and external (clinical sites/vendors/CROs) adherence to GCP and applicable regulations:
    - Prepare and maintain GCP audit plan
    - Facilitate the clinical vendor qualification process, including vendor qualification and requalification activities
    - Assess clinical laboratories' adherence to GCP and applicable regulations in concert with GLP QA experts, as necessary
    - Conduct and oversee contractors who conduct clinical vendor, subcontractor, computerized system, internal, and clinical site in-process and for-cause audits
    - Work with functional leaders to facilitate development of SOPs for the GCP compliance program and quality documentation such as quality agreements
    - Provide consultative support to clinical study teams, including review of study protocols, ICFs, monitoring plans, clinical study reports, etc.
    - Manage deviations and CAPAs internally and through CROs
    - Drive the development and tracking of quality metrics
    - Evaluate and investigate clinical study non-compliance, quality events, incidents, queries, and complaints
    - Communicate and present escalated Quality issues to Quality Council and Nightstar Management Team
    - Contribute to continuous improvement processes within the Quality Team
    - Lead continuous improvement across clinical development

Critical Competencies:

- Bachelor's degree
- Minimum of 8 years of experience in biotech/pharma industry in GCP QA role
- Experience conducting GCP compliance audits of vendors/CROs, clinical sites, computerized systems, and internal (process) systems

- Exceptional attention to detail and excellent organizational skills.
- Excellent oral and written communication skills.
- Ability to thrive in a dynamic and fast-paced environment.
- Ability to prioritize duties and manage multiple matters from start to finish with minimal supervision with a demonstrated ability to lead change and make independent decisions.
- Ability to work effectively and positively with executive-level management.
- Ability to handle highly confidential and sensitive materials and information with complete discretion and having good judgment in working with clients, and occasionally under ambiguous or challenging circumstances.
- A dynamic self-starter with a positive attitude and strong influencing skills.

Contact: Katherine Danyluk, Recruiting Coordinator
careers@nightstartx.com
+1 (617) 481-1709