



Associate Director/Director of GCP Quality Assurance

Lexington, MA

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/Director of Quality Assurance for the Company's Lexington, MA office. This is an excellent opportunity for someone with strong organizational skills and the ability to work on a variety of tasks and projects simultaneously. In addition, the successful candidate must have good judgment, work well under pressure, and be detail oriented.

Job Responsibilities:

- Oversee and participate as needed in internal and external report/document, data, clinical site, vendor/CRO, and internal process audits
- Oversee clinical vendor/subcontractor/site qualification audits
- Assess clinical laboratories adherence to GCP and applicable regulations
- Ensure internal and external (clinical sites/vendors/CROs) adherence to GCP and applicable regulations
- Assist in the writing and/or reviewing of SOPs for the GCP compliance program, quality documentation such as quality agreements and review various clinical study documentation such as study protocols, ICFs, monitoring plans, clinical study reports, etc.
- Drive the development and tracking of quality metrics
- Evaluate and investigate clinical study non-compliance, quality events, incidents, queries, and complaints

Critical Competencies:

- A minimum of 5 years of experience in biotech/pharma industry
- Experience with a combination of GCP and GMP, preferably GCP
- Experience conducting audits
- Experience with compliance and SOPs
- Management experience

Behavioral and Interpersonal:

- Exceptional attention to detail and excellent organizational skills with a desire to roll up one's sleeves
- 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 effectively and positively work 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

Education Requirements:

- Bachelor's degree, Master's degree, or Ph.D.