Associate Director/Director of GMP 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 GMP Quality Assurance for the Company's Lexington, MA office. The Associate Director/Director, GMP Quality Assurance manages and coordinates GMP regulated QA activities from early stage development through commercial product.

Job Responsibilities:

- Effectively interact with external contract manufacturers as well as an internal multidisciplinary team to ensure compliance and timeliness in all aspects of GMP manufacturing activities. Partner with CMC colleagues to design value-added, fit-for-purpose quality into the development process.
- Manage third party vendors contracted to perform any QA functions in support of the cGMP manufacture of clinical supplies and commercial product
- Plan and conduct cGMP audits of manufacturing activities to assess compliance with all pertinent regulations as well as with company SOPs
- Identify outstanding Sponsor oversight procedural and process gaps, and oversee implementation of necessary corrective actions and continuous improvement activities. Partner with cross-functional stakeholders for continuous improvement activities, create/revise SOPs and provide training as an SME on quality systems and procedures.
- Author/revise, review and approve controlled GMP documents
- Conduct/oversee cGMP training
- Run the day-to-day operations of the auditing, monitoring, supplier management and cGMP material supply chain activities
- Be able to prioritize activities associated with timelines and risk management from a quality perspective
- Contribute to the development of the overall quality system
- Develop necessary procedures (e.g., vendor qualification, vendor oversight, disposition, technical transfer, CAPA)

Critical Competencies:

- A minimum of 5 years of experience in biotech/pharma industry
- Thorough knowledge of cGMPs (CFR/ICH/EU) and applicable international regulations and guidelines as they apply to drug manufacturing and aseptic processing
- Experience interfacing with CMOs
- Experience with a combination of GCP and GMP, preferably GMP
- Exposure and experience with inspections by regulatory authorities, particularly FDA and EMA

- 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.
- Background in life sciences preferred