Associate Director, Regulatory Affairs

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: Nightstar is currently expanding its Regulatory team to support clinical phase assets and is searching for an Associate Director, Regulatory Affairs. This individual will operate in a high visibility role and will be responsible for representing Regulatory Affairs in cross-disciplinary project teams, developing regulatory strategies for assigned program(s), and manage high-quality submissions to regulatory agencies through external consultants. As Nightstar develops clinical assets there could be additional duties and responsibilities to this role, including the expansion and management of additional team members. This position reports to the Senior Vice President, Regulatory Affairs and Quality Assurance.

Job Responsibilities:

- Propose and design well-informed regulatory strategies for the US and EU
- Represent Regulatory Affairs on and provide regulatory guidance to program teams and subteams, especially Clinical and Nonclinical
- Assist in the preparation for regulatory agency meetings
- Lead the preparation of regulatory submissions including INDs, CTAs, annual reports, briefing packages
- Write regulatory documents to support regulatory submissions
- Coordinate with external publishing resources for on-time delivery of high-quality regulatory submissions to regulatory agencies
- Establish and maintain ClinicalTrials.gov postings for supported studies
- Establish relevant processes and procedures to support the Regulatory Affairs function activities
- Participate in regulatory intelligence gathering activities and maintain knowledge of US and EU regulatory requirements
- Ensure compliance with regulatory requirements

Critical Competencies:

- Minimum of 5 years pharmaceutical industry experience with a minimum of 3 years in Regulatory Affairs
- Evidence of successful submissions to FDA (e.g., INDs, briefing packages)
- Demonstrated evidence of writing of regulatory documents (Module 1, Module 2, briefing packages, orphan drug designation applications, pediatric plans)
- Knowledge of FDA and ICH regulations and guidelines a must
- Knowledge of EU and Health Canada regulations and guidelines desirable
- Knowledge of drug development
- Excellent written and oral communication skills

- Excellent interpersonal skills
- Strong project management skills and drive for excellence

Education Requirements:

- Bachelor's degree in life sciences required; advanced degree preferred