Associate Director/Director of Medical Writing

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 a Medical Writer 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 detailed oriented.

Job Responsibilities:

- Plan, prepare, write, edit, format, and finalize clinical and regulatory documents; including, INDs, study reports, modules, BLAs, CSRs, etc.
- Assist in developing strategy for organizing and preparing documents for regulatory health authority submissions
- Coordinate the internal review of documents
- Represent Medical Writing on project teams and, as such, advise teams on content and format requirements for various documents, as well as coordinate writing activities for document development (eg, timelines and review/revision responsibilities) with the project teams
- Assist in the development of templates, style guidelines, and SOPs for clinical documentation
- Ensure final document adheres to standard operating procedures (SOP) and good clinical practice (GCP)
- Perform quality control review of medical writing documents
- Effectively collaborate with multiple departments including R&D and Regulatory Affairs
- Oversee Medical Writing contractors and external Medical Writing vendors

Critical Competencies:

- A minimum of 5 years of experience in biotech/pharma industry
- Experience with regulatory documents; including, INDs, study reports, modules, BLAs, and CSRs
- Experience working with regulatory department on submissions
- Leadership experience
- Ability to manage through various stakeholders to resolve issues and challenges

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.