Associate Director / Director, Regulatory CMC

Location: Waltham, 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: Reporting directly to the Head of Regulatory Affairs and Quality Assurance, the Associate Director / Director of Regulatory CMC will be responsible for the development of regulatory CMC submissions for gene therapy programs globally. In this position, you will be responsible for driving the development of innovative CMC regulatory strategies and the preparation and submission of high-quality CMC sections of INDs, IMPDs, CTAs, and original marketing applications (BLAs/MAAs), in close collaboration with our in-house CMC and Quality teams, contract manufacturing organizations, external experts, collaborators, strategic partners, and global health authorities.

About the role:

- Provide regulatory CMC strategic leadership to support development of multiple innovative gene therapy products
- Write CMC technical reports as source documents and eCTD sections for INDs, IMPDs, BLAs, MAAs ,etc.
- Develop CMC response strategies and submissions to regulators
- Manage completion of CMC submission documents and other assigned tasks within established timelines and with high quality – in terms of scientific content, organization, clarity, accuracy, format, consistency and adherence to regulatory guidelines, styles and processes
- Develop CMC briefing packages for meetings with global health authorities
- Lead the preparation for and conduct of CMC meetings with global health authorities
- Lead negotiations with regulatory agencies to resolve CMC issues and shepherd proactive interactions with regulators globally; prepare and submit responses to CMC questions; support interactions with regulatory agencies during GMP and pre-approval inspections
- Provide critical review of all CMC documentation supporting regulatory applications
- Assess proposed manufacturing process changes and provide strategic regulatory guidance to enable global implementation
- Identify and assess CMC regulatory risks
- Prepare and deliver effective presentations for internal and external audiences

Critical Competencies:

- Bachelor of Science in a scientific discipline, advanced degree highly preferred.
- Prior pharmaceutical industry experience and a minimum of 8 years in CMC Regulatory Affairs.
- Extensive experience in biologics submissions required; previous ATMP experience is a strong plus.
- Evidence of successful submissions to FDA, EMA, and national Competent Authorities (e.g., BLAs, INDs, IMPDs, MAAs, CTAs, briefing documents) and demonstrated evidence of writing of regulatory documents.
- At a minimum, established working knowledge of US & EU guidelines and regulations. Expansion to other global regions is a strong plus.
- Established working knowledge of US & EU guidelines and regulations.
- Strong knowledge of eCTD elements and structure and regulatory technical writing skills.
- Regulatory experience supporting both development projects and commercial products.

- Experience working with all levels of management and consulting with key business stakeholders. An ability to influence for greater outcomes is a plus.
- Strong knowledge of current Good Manufacturing Practices (GMP), drug and biologics development regulations and guidelines including ICH, FDA and EMA guidelines
- Proficient in use of EDMS required, experience with Veeva Vault is preferred.
- Proficient in Microsoft Office suite and applications.

Behavioral and Interpersonal:

- Demonstrated ability to work well with other accomplished professionals within and across functions/teams.
- Strong communication skills both written and oral.
- Ability to multi-task and shift priorities rapidly to meet tight deadlines.
- Detail oriented and well organized.
- Independently motivated and solution oriented

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