Manager, Regulatory Operations

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 to the Head of Regulatory Affairs and Quality Assurance, the Regulatory Operations Manager is responsible for formatting electronic documents, building of regulatory submission deliverables ensuring submissions are of highest quality and delivered on-time, managing the Regulatory Electronic Document Management System (EDMS; Veeva Vault) and coordinating with external publishing/submission vendors. The position will also archive and track regulatory correspondences, documents and submissions.

About the role:

- Supports daily submission activity in coordination between Regulatory Strategy and external publishing vendor(s). Manages submission timelines.
- Electronically format, and builds Regulatory submission deliverables and ensures quality, accuracy, and submission-readiness per Regulatory agency guidance and specifications, and internal procedures.
- Review and format documents according to Nightstar Style Guide and standards. Troubleshoot and resolve complex document issues.
- QC Regulatory Documents and Submissions
- Gather regulatory intelligence information on publishing standards in support of regulatory submissions.
- Maintain and fix Regulatory System and Database issues (e.g., SharePoint, Veeva).
- Archive Health Authority communications received from global health authorities.
- Develops and maintains Regulatory document processing and Regulatory submission publishing standards and procedures in accordance with all applicable regulatory regulations, guidance, and specifications.
- Assists with developing standards and procedures related to authoring, review, transmittal, and archiving of electronic regulatory documents and submissions.
- Creates and maintains regulatory tracking database by program, country, and study.
- Maintains Document Authoring Template Library (StartingPoint) and Template development.
- Supports QA document management and EDMS.
- Train internal staff on document management system including document templates

Critical Competencies:

- BS preferred + 5-7 years of related experience.
- Detailed knowledge of applicable FDA, EU and ICH guidelines related to regulatory submissions, clinical trials and marketing applications.
- Working knowledge of eCTD publishing systems, EDMS technology (Veeva Vault preferred), and authoring tools and templates (Accenture StartingPoint preferred).

- Clear understanding of regulatory submission content and format requirements.

Behavioral and Interpersonal:

- Independent, ability to multitask, self-motivated, well organized, detail oriented, able to prioritize, works effectively under pressure, and has excellent written and verbal communication skills.
- Ability to multi-task and work under pressure
- Highly collaborative and proven ability to work effectively across all levels of the organization

Contact: Katherine Danyluk, Recruiting Coordinator
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