Analytical Validation Manager

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: We are seeking an Analytical Validation Manager to assist with the qualification and validation of analytical methods to support the manufacture and release of Nightstar's AAV gene therapy products at all stages of clinical development.

About the role:

- The position will involve the development, validation and life cycle management of assays including, in process control testing, lot release, product stability and product characterization
- Experience of a range of analytical methods is required
- Technical input into assay development and design to support later validation activities
- Input into vendor selection and monitoring of vendor performance and delivery according to objectives, timelines and budget.
- Conduct gap analyses of analytical methods to ensure assays are fit for purpose prior to validation
- Preparation of analytical protocols, testing records and standard operating procedures
- Design, preparation and review of assay qualification and validation protocols / reports to ensure all assays are qualified and / or validated as appropriate for the stage of clinical development and in accordance with ICH guidelines
- Oversight of equipment, software and data integrity validation
- Data analysis, troubleshooting and reporting
- Setting system suitability and assay acceptance criteria
- Defining critical reagents and key assay controls and ensuring appropriate control of these
- Life cycle management and data trending of assays to monitor performance
- Management of outsourced analytical activities at CDMOs and CROs
- Technical transfer of assays into or between CRO/CDMOs
- Lead investigations into out of specification results
- Act as SME for analytical validation to support regulatory filings, audits and meetings
- Assist in quality audits as an analytical technical expert

Critical Competencies:

- Previously worked within a QC testing environment in a late phase / commercial biologics testing facility
- Strong knowledge of a range of biological analytical techniques
- Experience of analytical method development
- Expert technical capabilities and awareness of regulatory requirements for assay validation for biologics
- Understanding of the requirements for equipment and software validation and requirements for ensuring data integrity
- Ability to effectively manage and co-ordinate activities at CROs and CDMOs
- Ability to investigate out of specification / out of trend data
- Previous experience in AAV gene therapy and commercial manufacture of a biologic is preferred
- Experience in technology transfer and bridging studies for analytics

Behavioural and Interpersonal:

- Ability to manage complex projects, deliver to timelines and work in a demanding environment
- Strong team player
- Excellent written skills
- Clear communicator of data, progress and risks both written and orally
- Comfortable working with minimal supervision

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