Associate Director, Analytical Development

London, UK

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 Associate Director, Analytical Development to take responsibility for the management and implementation of our growing requirements for QC assay development and validation to support the manufacture and release of Nightstar's AAV gene therapy products. The position may also involve the supervision of QC scientists to ensure successful delivery against the CMC divisional goals.

Job Responsibilities:

- The position will involve the development and validation of assays for the following purposes:
  - In Process Control testing in support of clinical manufacture
  - Lot release
  - Biosafety
  - Product Stability – intermediate hold and final product
  - Vector / AAV product characterization
  - Clinical samples
- Experience of a range of analytical methods is required, including some or all of the following:
  - Potency assays (in particular cell based expression and gene function assays)
  - Protein chemistry
  - Molecular biology
  - Cell based bioassays
  - Analytical chemistry
  - Immunoassays
  - Virology / molecular virology
- Technical input into selecting the most appropriate methodology, assay development and design
- Technical transfer of assays from academic laboratories into GMP/QC facilities
- Procurement of materials and reagents
- Management of outsourced activities and CROs
- Management of CRO budget and quarterly accrual reporting
- Defining appropriate system suitability criteria and controls for assays
- Assay design, data analysis and reporting to ensure all assays are validated in accordance with ICH guidelines
- Setting specifications
- Review and sign-off of protocols
- Data review and sign-off of final study reports
- Reporting and presenting of results
- Trouble shooting and investigations into out of specification results
- Input into vendor selection and monitoring of vendor performance and delivery according to content, timelines and budget
- Oversee assay trending and investigation of out of trend results
- Contribute to preparation of responses to support regulatory filings and submissions
- Awareness of developments in novel testing technologies

Critical Competencies:

- Experience of macromolecule quality control, analytical development, validation and testing in support of GMP manufacture of biological (in particular viral) products, spanning development through to routine QC, is essential
- Experience of working with AAV, viral and gene therapy products is preferable
- At Nightstar, we outsource all manufacturing and testing activities. Experience of managing outsourced testing is therefore required

Behavioural and Interpersonal:

- Strong team player
- Ability to manage complex projects and work in a demanding environment
- Clear communicator of progress and risks
- Ability to deliver to timelines and budgets
- Confident and clear presentation of data, verbally and through written reports
- Comfortable working with minimal supervision
- Ability to supervise others

Education Requirements:

- BSc in biochemical engineering, biological or pharmaceutical sciences