Bioanalytical Scientist

Location: 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 Responsibilities:

The position will involve the following to support gene therapy product development (preclinical/clinical):

- Oversight and review of outsourced development and validation of cellular and humoral immunogenicity assays
- Oversight and review of outsourced development and validation of qPCR assays for biodistribution/vector shedding
- Input into clinical trial design with respect to immunogenicity and vector shedding sampling
- Liaison with central laboratories in the design and supply of clinical sample collection kits
- Preparation of training materials and delivery of training to clinical sites in sample collection procedures
- Liaison between clinical sites, central laboratories and bioanalytical CROs for scheduling of sample shipments and sample analysis
- Review of preclinical/clinical immunogenicity and biodistribution/vector shedding
- Input into vendor selection and monitoring of vendor performance and delivery according to content, timelines and budget
- Technical input into selecting the most appropriate methodology, assay design and qualification/validation strategy (removed CRO as is above)
- Procurement of materials and reagents
- Management of outsourced activities
- Responsibility for review and sign-off of protocols
- Data review and sign-off of final study reports
- Internal collation and reporting of results
- Assay trouble shooting and investigations
- Awareness of developments in regulatory and industry consensus opinion on gene therapy immunogenicity and biodistribution/vector shedding sampling and analysis requirements
- Contribute to preparation of regulatory submissions and responses to regulatory questions relating to immunogenicity testing

Critical Competencies:

An immunology background and experience of the following analytical methods is required:

- ELISA
- ELISPOT
- Cell based neutralizing antibody assays

- Experience of other ligand binding assay platforms (e.g. ECL (MSD), Gryros, etc…), molecular biology techniques (e.g digital drop PCR, qPCR) and flow cytometry desirable but not essential

Behavioral and Interpersonal:

- In additional to strong technical knowledge, the candidate must be able to manage complex projects, and be a 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

Education Requirements:

- BSc in biochemical engineering, biological or pharmaceutical sciences