Validation Manager

Location: Lexington, 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 Responsibilities:

Validation

Manage validation activities and resources for the relevant GMP manufacturing campaigns of Nightstar's products to ensure smooth and effective transition from early phase clinical proof of concept to pivotal trials and commercial launch.

Responsible for sponsor oversight of GMP supply chain contractor's implementation, delivery and continuous improvement of adequate programmes for:

- process characterization, design space definition, qualification and validation
- facility, equipment and utility qualification and validation
- cleaning validation
- computer system validation and
- shipping and storage validation.

Ensure that systems and controls for qualification and validation activities meet standards and applicable regulatory requirements for late stage clinical and commercial AAV (and starting raw materials) manufacture.

Prepare Validation Master Plans.

Review and approve validation protocols and reports for completeness, GMP compliance and quality of data.

Project manage external validation programmes to include; agreeing and communicating scope and timescales, setting budget, identifying required resources (internal and external).

Support, as required, concurrent analytical and bioanalytical validation activities.

Liaise with Quality Control, Quality Assurance and Regulatory functions to ensure that scope, execution and reporting of validation meets required expectations.

Participate as required in PAI and other regulatory inspections as client representative

Contracts

Manage the development, negotiation, execution and administration of contracts for validation and commercial supply services.

Liaise with internal stakeholders and establish contractual agreements with key suppliers and providers.

Collaborate with the legal advisors to implement diligent contract administration and oversight procedures

Identify, assess and manage contractual risk and risk registers

Support cross functional training in these contract management practices

Supply Chain

Work with external stakeholders to implement and manage a secure supply chain for sourcing key GMP materials to support late phase clinical and commercial manufacture. Interface with internal stakeholders (technical leads, clinical project management and regulatory) to ensure and oversee uninterrupted late stage clinical and commercial IMP and drug supply

Implement and standardise best sourcing and security of supply practices

Manage RFI and RFP activities

Help with implementing systems for supply chain risk mitigation and supplier performance monitoring

Participate in initiatives to identify cost savings opportunities and optimise cost of goods manufactured (COGM)

Manage implementation, qualification and validation of new processes developed as required into the commercial supply chain

Collaborate with QA on supplier qualification and supplier initiated change controls

Critical Competencies:

- 10+ years industrial experience in biotechnology GMP manufacturing environment
- Demonstrated outsourcing management experience

- Demonstrated late stage product validation experience
- Supply chain management experience
- Experience with viral or gene therapy products and production
- Orphan drug development experience (desirable)
- Expertise in GMP manufacture of viral (gene therapy) and microbial (DNA) products
- Thorough understanding of cGMPs and life cycle approach to process qualification and validation
- Detailed knowledge of the practical and theoretical requirements of validation projects, including facilities, process equipment, utilities, cleaning and computer systems.
- Understanding and experience with facility design, commissioning and validation.
- Previous successful interactions with regulatory agencies.

Behavioral and Interpersonal:

- Strong ability in problem solving
- Attention to detail with documentation and coordination/oversight practices
- Excellent interpersonal and communication skills
- Ability to prioritize multiple tasks and act decisively
- Team approach to programme management
- Able to work both independently and collaboratively in a team
- Able to influence others and lead complex projects
- Demonstrated ability to multi-task and manage competing priorities.

Education Requirements:

- BSc in biochemical engineering, biological or pharmaceutical sciences with relevant post graduate qualification (or equivalent professional qualification or accreditation)