



Manufacturing Manager

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 Purpose: The Manufacturing Manager will be responsible for the management and implementation of process development and outsourced contract manufacture of Nightstar's AAV gene therapy product(s) and critical raw materials (plasmids)

About the role:

- Technical input into selecting the most appropriate manufacturing method, process development and experimental design
- Input into vendor selection, monitoring of vendor performance and delivery according to content, timelines and budget
- Technical transfer of manufacturing processes between CMOs
- Management of outsourced activities, particularly plasmid manufacturing and quality control testing activities
- Technical input into process validation (in particular Plasmid manufacturing and quality control testing)
- Review and sign-off of protocols, manufacturing documentation and study reports
- Reporting of results internally within Nightstar to project teams and senior management
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Critical Competencies:

- BSc degree required
- Minimum of 10 years industry experience
- Experience within bioprocessing, including:
 - A detailed understanding of plasmid manufacturing and purification
 - A detailed understanding of formulation of plasmid DNA
 - A detailed awareness of plasmid DNA analytical and stability testing methods
 - An understanding of mammalian cell transfection methods utilising plasmid DNA
 - A good understanding of Sterile Filtration and Fill / Finish of biological process intermediates
 - Experience and/or knowledge of molecular biological techniques such as DNA sequencing, synthesis and cloning techniques would be advantageous

Behavioural and Interpersonal:

- Manage complex multi-disciplinary projects
- Confidently and clearly present data, progress, issues and risks, both verbally and through written reports
- Be self-starting and comfortable working with minimal supervision
- Deliver to tight timelines and budgets

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