CMC Lead, Process Sciences & Technology

Who We Are

This is an exciting opportunity to join Opus Genetics, a brand new, clinical-stage ophthalmic biopharmaceutical company dedicated to the development of gene therapies for rare inherited retinal diseases. Our approach is based on validated science from pioneers in the ocular gene therapy space. Opus Genetics employs a unique, sustainable manufacturing approach and a commitment to leveraging our clinical network to reach patients and achieve optimal treatment outcomes.

The Role

The CMC Lead, Process Sciences & Technology will be the technical process owner for their assigned programs with a focus on drug substance and drug product process development and manufacturing to achieve company goals and strategies. This includes working collaboratively with external partners (i.e. CDMOs, suppliers) to develop technical studies, analyze complex data, make data driven decisions, and author, review, and approve technical and regulatory documents. The ideal candidate will have a deep technical understanding of AAV gene therapy drug substance and drug product processes (upstream, downstream, and filling). This role will directly interact with the CDMO partners and be responsible for building and maintaining excellent working relationships. The candidate will be hands on and expected to provide content to all these areas.

Key Deliverables

Work with Opus CDMO partners to develop processes and manufacture phase appropriate material to support pre-clinical studies, clinical trials, and commercial supply. Support, author, and review/approve process development plans and documentation including quality target product profiles (QTPP), design of experiments (DOEs), process descriptions, product specifications, other data reports utilizing QbD best practices. Support, author, and review/approve manufacturing documentation including batch records, campaign summary reports, investigations, etc. Support, author, and review/approve regulatory documentation including pINDs, INDs, agency responses, and BLAs. Lead technology transfer between sites. Perform the role of person in plant as needed at the Opus CDMO partner's sites. Act as the Manufacturing Sciences CMC expert during audits and interactions with regulatory agencies.

Manage work to project plans for multiple gene therapy programs in the preclinical, pre-IND, IND/clinical, and commercial stages. Identify and lead the resolution of operational and functional level challenges, work with program and/or function managers to escalate issues to senior management. Hands on resolution to issues/content generation. Design effective and high-quality presentations and progress reports, as requested.

Skills and Expertise Required

Bachelor's degree from an accredited institution in a science or health-related field with minimum of 7-10 years of experience in the pharmaceutical or biotechnology industry. Ophthalmology experience is preferred.

Additionally, a minimum of 5 years of direct product development and manufacturing (upstream, downstream, and drug product) experience for biopharmaceuticals. Preference will be given for direct AAV gene therapy experience. Previous CDMO experience also preferred.

Experience designing and executing process development experiments/DOEs and associated documentation.

Experience in writing and reviewing regulatory submissions including pINDs, INDs, and BLAs.

Experience with FDA and/or other regulatory agencies.

Strong expertise managing multidisciplinary teams for preclinical and clinical development. Clear understanding of the drug development process with experience in multiple phases.

Demonstrated leadership and ability to influence across all levels of a cross-functional team without direct managerial relationship. Experience in risk assessment, negotiating, and problem solving/mitigation.

Outstanding interpersonal skills, ability to communicate effectively in both oral and written form, and time management skills needed to manage multiple ongoing projects simultaneously.

Demonstrated advanced computer software proficiency (Word, Excel, Smartsheets, PowerPoint, etc.).

The role is located in Raleigh-Durham, NC area. Local candidates preferred.