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 Project Manager will provide support for the assigned function to provide effective cost and timeline management for product development projects to achieve company goals and strategies. This includes developing and executing internal and external cross-functional project plans, monitoring completion of deliverables, leading issue resolution, maintaining projects on budget, and designing and optimizing communication workflows to ensure seamless decision making and processes. The ideal candidate will also have a deep technical understanding of drug substance processes, drug product processes, analytics, quality, regulatory, and supply chain. The candidate will be hands on and expected to provide content to all these areas.

Key Deliverables

Develop project plans for multiple gene therapy programs in the preclinical, pre-IND, IND/clinical, and commercialization stages. Assign team members to key tasks and establish a system for accountability and performance. Identify and track milestone performance. Facilitate effective meetings, setting focused agendas and providing post-meeting documentation (minutes and action items). Manage and track action items. Ensure timely regulatory submissions and ultimately commercialization. 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 regulatory experience in the pharmaceutical or biotechnology industry.

PMP or similar certifications preferred or previously demonstrated successful project management leadership from initiation to completion.

Experience in regulatory submissions including IND and BLA/NDAs. Ophthalmology and/or gene therapy expertise is preferred but not required.

Deep working knowledge and demonstrated experience with CMC section development. Knowledge of nonclinical and clinical aspects of FDA regulatory submissions and experience with FDA agency interactions.

Strong expertise managing multidisciplinary teams for preclinical and clinical development. Clear understanding of the drug development process with experience in multiple phases. Strong technical background/aptitude is preferred.

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.).

Relocation to the Raleigh-Durham, NC area is preferred.