Associate Director, Program and Alliance Management

Company:

Visterra is a clinical stage biotechnology company committed to developing innovative antibody-based therapies for the treatment of patients with kidney diseases and other hard-to-treat diseases. Our proprietary technology platform enables the design and engineering of precision antibody-based product candidates that specifically bind to, and modulate, key disease targets. Applying this technology to disease targets that are not adequately addressed by traditional therapeutic approaches, we are developing a robust pipeline of novel therapies for patients with unmet needs. Our most advanced program is in Phase 2 clinical development.

Visterra is a wholly-owned subsidiary of Otsuka America, Inc., which is a U.S. holding company and a wholly owned subsidiary of Otsuka Pharmaceutical Co., Ltd. of Japan. Visterra has approximately 50 employees and is located in Waltham, Massachusetts.

Summary:

Visterra is currently seeking a highly motivated and qualified individual for the position of Associate Director, Program and Alliance Management. This is an opportunity for an individual to serve as an integral member of development teams and play an instrumental role in the strategic planning and execution of critical development programs. This cross-functional position requires broad knowledge across all facets of drug development, including: non-clinical, clinical, CMC, and regulatory. This position will report to the Director of Program and Alliance management to support the planning, scheduling, monitoring, reporting, and other operational/tactical aspects of the drug development programs. This role will be responsible for integration of all Functional Area plans into comprehensive Program Plans and communication of those plans to key stakeholders and executive management.

Key duties and responsibilities:

- Manage all logistical and operational activities for 1-2 research/IND enabling/development programs including internal and external project team oversight as appropriate.
    - Prepare and manage detailed Gantt charts in MS Project.
    - Meeting management – scheduling, agendas, minutes, actions, follow-up, budgets.
    - Detailed project planning/tracking and reporting of project progress. Issues regular updates to management.
    - Responsible for ensuring risk analysis and mitigation strategies for project.
- Manage IND enabling activities – familiar with preclinical safety assessment/toxicology, DMPK/bioanalysis, CMC, QC/QA, Regulatory, and clinical working groups.
- IND assembly:
    - Responsible for strategy, timelines, and implementation of IND assembly plan of eCTD.
    - Experience in managing document drafting/review/approval for eCTD Modules 1-5.
- Facilitates oversight and alliance management of vendors, partners, CROs, consultants and contractors in all aspects of study execution.
- Facilitate and manage communication between functional areas, project teams, and senior management.
    - Prepare and present program updates in MS PowerPoint.

Visterra

Minimum Qualifications

- BS/BA in life sciences or related area; MBA/PhD preferred
- 7+ years of relevant biotech and/or pharmaceutical industry experience
- PM experience in drug development including extensive experience as project manager in pre-IND and/or IND enabling development space
    - Demonstrated ability to lead cross functional development teams as PM
- Overall understanding of the pharmaceutical research and development process and the regulatory process by which drug products are filed and approved
- Ability to manage multiple programs as required
- Ability to anticipate and resolve issues to mitigate risk and achieve objectives
- Excellent program/project management skills
- Proficiency in MS Project, PowerPoint

Preferred Skills and Experience:

- OnePager Pro, Office Timeline
- Regulatory; CMC; Clinical Operations; Alliance Management
- Biologics development

Personal Skills:

- Excellent interpersonal, verbal and written communications skills with stakeholders (leadership team, project teams, external teams)
- Extremely well organized
- Flexible towards work assignments and new learnings

Supervisory Responsibilities: N/A

Travel: as needed (estimated 5%)

Visterra provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.