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.

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 75 employees and is located in Waltham, Massachusetts.

Summary

Visterra is currently seeking a talented, 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 pre-clinical, clinical, CMC, and regulatory. This position will report to the Director of Program and Alliance management and be responsible for the planning, scheduling, execution, 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.

This is a full-time position located at Visterra’s facility in Waltham, MA.

Responsibilities

- Work collaboratively on a project-based team developing therapeutic biologic molecules from conception through to pre-clinical in vivo studies. Supervise at least one junior researcher.
- Serve as Program Manager, including all logistical and operational activities for 1-2 research/IND enabling/IND assembly/development programs including internal and external project team oversight as appropriate. As Program Manager, this role will
  - Leverage input from all critical functions to create integrated strategic development plans that define goals, milestones, decision points, critical path, timelines, assumptions, and alternative scenarios.
  - Prepare and manage detailed Gantt charts in MS Project, and create visuals in
OnePager Pro.

- Perform all aspects of meeting management, including scheduling, agendas, minutes, actions, follow-up; manage budgets and timelines.
- Planning and execute product development plans.
- Execute detailed project planning, tracking and reporting of progress to project team and management.
- Ensure risk analysis and mitigation strategies are in place and followed for each project.
- Own responsibility for project performance, risk management, budget management, and issue resolution for each program team.

- Manage IND enabling activities, including the facilitation of and partnership with preclinical safety assessment/toxicology, DMPK/bioanalysis, CMC, QC/QA, Regulatory, and clinical working groups.
- Manage IND assembly, including supporting Regulatory Affairs, managing the strategy, timelines, and implementation of IND assembly plan of eCTD, and filing of IND.
- Foster strong relationships and collaborate with team members and functional line managers and serve as a key point person for program team members on project-related communication, issue identification, and management.
- Facilitate oversight and alliance management of vendors, partners, CROs, consultants and contractors in all aspects of study execution.
- Facilitate, manage, and effectively communicate between functional areas, project teams, and sr. management.
  - Prepare and present program updates in MS PowerPoint.

Requirements

- BS/BA in life sciences or related area; MBA/PhD preferred.
- 8+ years of relevant biotech and/or pharmaceutical industry experience.
- Program management experience in drug development including a extensive experience as program manager in pre-IND and/or IND enabling development space, and a demonstrated ability to lead cross functional development teams as Program Manager.
- Overall understanding of the biologics/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, and the knowledge and ability to apply best practices.
- Ability to contribute expertise to the development and implementation of program management best practices to help further the needs of the business efficiently.
- Strong interpersonal and communication skills.
• Ability to work effectively and congenially in a team setting.
• Proficiency in MS Office suite, including PowerPoint, Project, Excel; OnePager Pro.

Other Relevant Experience

• Regulatory; CMC; Clinical Operations; Alliance Management
• Biologics development strongly preferred.
• Excellent interpersonal, verbal and written communications skills with stakeholders, including leadership team, project teams, and external teams, and the ability to clearly articulate complex subject matter.
• Excellent time management and organizational skills; demonstrating an ability to work independently, meet deadlines and prioritize work effectively.
• Demonstrated ability to manage and prioritize a team and meet deadlines.
• Flexible towards work assignments and new learnings, and a creative, collaborative approach to problem solving.

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.

For consideration, please submit a cover letter and resume to careers@visterrainc.com.