Visterra

Scientist/Sr. Scientist – Bioanalytical Development

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:

The Scientist – Bioanalytical Development is responsible for supporting activities related to transitioning drug development candidates into early clinical studies with a focus on developing bioanalytical methods for preclinical/clinical programs and transferring them to CROs. The Bioanalytical Development Scientist will be responsible for activities related to drug development candidates. They will oversee the execution of experiments to support IND filings and early clinical development with internal staff and external CROs. Visterra is seeking a flexible candidate with a broad-based knowledge of immunology and biologics drug development. The primary focus is bioanalytical support for programs in preclinical and clinical development balancing long-term strategy with tactical and detailed technical decision-making and project management. This individual is responsible for technical oversight, outsourcing, technology transfer and documentation for bioanalytical methods in support of preclinical/clinical programs and clinical biomarker strategy. The individual will actively participate in program teams, as well as collaborate effectively across functions. The successful candidate shall demonstrate a proven track record in development and have experience with biologics and understanding of FDA/EMA guidelines. This individual will be highly analytical, goal-oriented, and timeline sensitive while maintaining high quality standards.

Responsibilities:

- Oversee method qualification and validation of primarily ELISA/ECL based PK, ADA and biomarker assays to support large molecule drug candidates.
- Oversee external contractors to enable the development of appropriate bioanalytical methods to support preclinical and clinical development programs.
- Oversee GXP testing of preclinical and clinical samples.

- Collaborate in the design, execute and interpretation of experiments to develop bioassays and custom reagents to support late-stage research, and preclinical/clinical development.
- Contribute to biomarker strategy to assess exploratory biomarkers during early phase clinical trials.
- Oversee development of and maintain inventory of critical reagents.
- Present data at cross functional team meetings, summarize data in reports to support IND filings.
- Establish and maintain high-quality systems for outsourcing, managing and reporting data from preclinical and clinical studies that meet both regulatory guidelines and industry best practices.
- Effectively present data to mixed audiences including the executive team if required.
- Prepare and review reports and packages for regulatory submissions.
- Demonstrates a strong ability to effectively communicate.
- Proven ability to meet deliverables and timelines
- Maintains a contemporary knowledge of current industry and regulatory trends, standards and methodologies

Requirements

- A minimum of two years of working experience, including strong track record of hands-on experience in R&D and the biotechnology industry
- Ph.D or M.S. (1-5 years of experience) in Immunology, Biology or related field of study
- Working experiences with biologics is highly desirable
- Knowledge of regulatory requirements, including GLP, GCP, ICH and other applicable guidelines for Bioanalytical development in support of clinical trials
- Experience in outsourcing and managing CROs for regulated (GLP, GCP) studies
- Ability to think critically, synthesize and extract simple principles from complex datasets, communicate effectively across broad spectrum of audience both internal and external, excellent written skills

Management responsibilities: This position does not have supervisory responsibilities

Travel: None

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.