

## Associate Director, Preclinical 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.

Visterra's exciting pipeline includes VIS410, a human monoclonal antibody designed to offer truly broad-spectrum treatment of influenza A that is currently in clinical trials; VIS513, a monoclonal antibody to treat all four serotypes of dengue virus; VIS649, a monoclonal antibody in development as a treatment for Immunoglobulin A nephropathy, and several other early stage candidates targeting infectious diseases, cancers and kidney disease.

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 70 employees and is located in Waltham, Massachusetts.

### Summary

The Associate Director, Preclinical Development is responsible for overseeing activities related to transitioning drug development candidates into early clinical studies with a focus on preclinical studies to support IND submissions. This includes nonclinical safety strategy and implementation as well as ensuring bioanalytical methods are appropriate to support these preclinical studies. The Associate Director, Preclinical Development will be responsible for 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 preclinical studies to support IND filings 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 in vivo studies and supporting bioanalytical methods. The individual will actively participate in program teams, as well as collaborate effectively across functions. The successful candidate will demonstrate a proven track record in development and

have experience with biologics and FDA/EMA guidelines. This individual will be highly analytical, goal-oriented, and timeline sensitive while maintaining high quality standards.

### Responsibilities

- Develops preclinical testing strategies for drug development candidates.
- Selects and overseeing CROs responsible for preclinical safety/PK/PD/Biomarker assessments.
- Oversee external contractors to enable the development of appropriate bioanalytical methods to support preclinical development programs.
- Authors reports summarizing ongoing nonclinical work to support regulatory interactions.
- Responsible for the scientific oversight and review of preclinical data.
- Presents data at cross functional team meetings, summarizes data in reports to support IND filings.
- Provides scientific strategic input and oversees development of preclinical study protocols.
- Contributes to the authoring and revision of regulatory submissions.
- Works closely with internal teams to accumulate scientific knowledge necessary to support drug development goals.
- Prepares and presents scientific material for conference presentations or publications
- Able to support programs at different stages of development.
- Responsibilities span from CRO selection, contract oversight, vendor management and data analysis.
- Oversees completion of key program goals and deliverables related to preclinical development.
- Demonstrates a strong ability to effectively communicate.
- Proven ability to meet deliverables and timelines.
- Performs other duties as required.

### Requirements

- Ph.D. with 5-10 years of industry experience, or BS/MS with 10+ years of experience in biopharmaceutical development, with an emphasis on preclinical safety and supporting bioanalytical methods.

- Experience in outsourcing, vendor management, and interfacing with internal groups, establishing and managing consultants and CROs driving timely delivery of clear, accurate, and well-written nonclinical study data.
- Strong knowledge of FDA, EMA, and ICH guidance documents including GLP regulations
- Required experience in authoring INDs, preparing / presenting science-based responses to regulatory questions.
- Deep understanding of QA, regulatory, and clinical functions to guide key nonclinical safety assessment activities, setting up drug candidates for success at all stages of development.
- Ability to synthesize and interpret diverse, multidisciplinary data sets.
- 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.
- Strong verbal communication skills accompanied by scientific writing skills.
- Enjoys and thrives in a fast-paced, multi-tasked, and hands-on environment.

*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.*