Visterra
275 Second Avenue, 4th Floor · Waltham, MA 02451
Tel: 617-498-1070
www.visterrainc.com

Manager of Regulatory Affairs

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 is glad to be a member of the Otsuka family of companies. As an independent company within Otsuka, Visterra works as a dynamic, creative, small environment with the benefits of being part of a large, globally successful company. Visterra has approximately 70 employees and is in Waltham, Massachusetts.

Summary

The regulatory department at Visterra is focused on clinical development of monoclonal antibodies for a variety of indications. Visterra currently has a phase 2 product for Immunoglobulin A Nephropathy (IgAN) and a phase 3 product for influenza. New products are projected annually. Visterra values flexibility and seeks a regulatory manager with serious skills and a broad mind who can learn new things, be effective in all aspects of regulatory for investigational products and lead internal projects. There will be opportunities to employ skills in regulatory strategy, planning Health Authority meetings, global team leadership, regulatory submissions, and vendor management. We focus on early and mid-stage development for all regulatory aspects of clinical, non-clinical and CMC activities.

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Reporting to the Global Head of Regulatory for Visterra, the Manager/Sr. Manager will assist in the development and execution of regulatory strategies for monoclonal antibodies including Health Authority meetings and taking leadership for critical and routine regulatory submissions to advance biologics from initial IND/CTA though clinical development. The Manager will act collaboratively to support global, cross-functional teams and work independently to help teams navigate and solve problems in critical disciplines of clinical, non-clinical and CMC and secure appropriate regulatory designations such as Orphan Drug, Fast Track, Breakthrough Therapy and Prime.

Responsibilities

- Lead the planning, preparation and submission of regulatory documents and interactions with Health Authorities. Provide guidance on document contents, perform expert regulatory review of SME authored documents and work with vendors to prepare high-quality electronic submissions.
- Develop global regulatory strategy documents for one or more investigational products. Collaborate with multi-disciplinary colleagues to execute the global regulatory strategy.
- Perform regulatory assessment of nonclinical, clinical and CMC matters and provide phase-appropriate guidance for global clinical development.
- Review technical documentation including nonclinical, clinical, CMC and labeling for submissions and responses to questions to assure conformance with regulations; and regulatory guidelines.
- Serve as the US Regulatory Strategy Lead for phase 2 product in orphan indication. Work with the Head of Regulatory to develop the regulatory strategy leading to phase 3 and BLA submission. Will also serve as lead for additional pipeline products.
- Lead teams to produce routine and complex submissions by determining content, creating timelines, tracking, reviewing and completing regulatory submissions for clinical trials including CTAs, IMPDs, nonclinical reports and other related regulatory submissions (Orphan drug designation (ODD), breakthrough designation (BTD) and IND annual report, pediatric study plans (PSP), SUSARs, DSUR, labeling documents, and more).
- Participate on the Global Product Development Team, Global Regulatory Team and clinical trial teams. Provide US regional input and ensure regional alignment with regulatory strategies for global programs and products. Lead submission teams and internal project teams.
- Participate and lead teams for Health Authority interactions as appropriate.
- Incorporate regulatory environment trends to ensure the projects/products reflect up-to-date regulatory strategies.

- Manage activities of the publishing and regulatory vendors in preparation of high-quality submission packages and their timely delivery to health agencies.
- Manage the Global Submission Planner and organize Health Authority correspondence and regulatory information.
- Perform other duties as required.

Requirements

- Bachelor's degree required, advanced degree preferable (Pharm.D., MSc, PhD, MBA).
- A minimum of 4 years of experience in regulatory affairs/operations within the biotechnology industry; preferably with biologics (recombinant proteins).
- Demonstrated record of independently leading teams to produce routine regulatory submissions meeting eCTD requirements.
- Collaborative, with a positive attitude and constructive mind-set.
- Experience with regulatory submission procedures and regulations, preparation and writing regulatory documentation for regulatory maintenance activities and to support agency interactions.
- Experience in orphan drugs preferred.
- Knowledgeable in major market and ICH guidelines relevant to clinical product development.
- Strong communication skills, both oral and written to relate complex information to multiple levels in the organization.
- Capable of managing complex projects, timelines and teams in a matrix team environment to plan work, create timelines and deliver results.
- Excellent collaboration, influencing and negotiation skills, and be able to establish and maintain collaborative working relationships with department heads, parent company and external third-party personnel.
- Must be highly organized, committed to efficiency and effectiveness, possessing determination, the ability to think strategically and still pay attention to detail.
- Ability to work independently, to analyze requirements, company objectives and propose solutions. Self-motivated, able to respond effectively to developing situations, maintain priorities, and manage challenging assignments through collaboration, communication and teamwork.
- Understanding of the development of advanced therapy/innovative biologics products a plus.
- Experience in directing interactions with regulatory authorities desirable.
- Excellent writing and reviewing skills.

- An ability to think critically, communicate effectively across broad spectrum of audience both internal and external, and clearly articulate complex subject matter.
- Analytically strong with great attention to detail
- Excellent organizational skills, with proven ability to work independently, prioritize work effectively and meet deadlines.
- An ability to effectively collaborate cross-functionally across all levels of the organization.
- Enjoys and thrives in a multi-tasked and hands-on environment.
- Proficient in MSOffice products, including Word, PowerPoint and Project.

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.