

Senior Specialist or Manager, Regulatory Operations and Information 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 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.

Visterra's exciting pipeline includes VIS649, a monoclonal antibody in development as a treatment for Immunoglobulin A nephropathy, with a second indication projected, a mutein nearing the IND stage and two other recombinant proteins projected for clinical trials in the next two years. Therapeutic areas are primarily kidney diseases, but studies in rheumatology and immunology are expected for early stage candidates. Additional pipeline products include VIS410, a human monoclonal antibody designed to offer truly broad-spectrum treatment of influenza A that has completed Phase 2 testing and VIS513, a monoclonal antibody to treat all four serotypes of dengue virus. VIS513 is currently out licensed.

Summary

The Regulatory department at Visterra is focused on all regulatory aspects of clinical, non-clinical, and CMC activities for investigational products, driving them to approval.

Our research team develops and nominates novel monoclonal antibodies and protein conjugates to strategically treat numerous indications. New products are projected annually resulting in regular IND planning and cross functional engagement.

We seek a regulatory professional with a broad skillset and flexible approach who can lead the company in regulatory submissions for investigational products and regulatory information management. Reporting to the Global Head of Regulatory for Visterra, the Senior Specialist or Manager will assist in managing all aspects of regulatory operations and regulatory information management with opportunities to contribute to content as well. The incumbent will act collaboratively to support global, cross-functional teams and work independently to help teams navigate and solve problems related to electronic submissions. Opportunities for writing and

leading content production for Health Authority Briefing Books and Orphan Drug Applications will also be included.

In summary, this role will flex to fit the needs of the department with opportunities to:

- employ skills in the matrix management of an Otsuka affiliate for regulatory submissions;
- plan and execute electronic submissions for original INDs;
- support IND life cycle management;
- initiate and manage regulatory submission projects to lead teams to produce high-quality regulatory submissions;
- write and contribute content for regulatory submissions; and
- build systems and processes to facilitate future regulatory submissions.

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

Responsibilities

- Manage relationships across affiliates to ensure regulatory submissions are planned, prepared and submitted in a timely fashion.
- Work on complex regulatory submissions to ensure electronic submission requirements are met.
- Serve as Visterra's lead expert on partner-managed document management system.
- Lead clinical trial transparency initiatives including initiating and maintaining current clinical trial registry information for the US and EU.
- Perform project management functions with respect to initial IND submissions, CSR submissions and Health Authority interactions.
- Lead the development of SOPs, and a process for creating and optimizing electronic regulatory submissions and archiving.
- schedule and coordinate all regulatory submissions publishing deliverables in clinical, nonclinical, CMC, and labeling.
- Maintain high quality standards for regulatory submissions and lead others to achieve those standards.
- Pre-publish and publish documents for regulatory submission in collaboration with the affiliate company.
- Prepare templates for authors and manage submission processes; train other functions in using regulatory templates and regulatory submission writing.
- Work with authors to ensure submissions are complete and all relevant reference documents and copyrights have been secured.
- 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.

Requirements

- Bachelor's degree required, advanced degree preferable (Pharm.D., MSc, MBA).
- A minimum of 4 years of experience in regulatory affairs/operations within the biotechnology industry; preferably with biologics.
- Strong communication skills, both oral and written, to relate complex information to multiple levels in the organization; Excellent writing and reviewing skills.
- Demonstrated record of independently leading teams to produce routine regulatory submissions meeting eCTD requirements.
- Capability to work independently, 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.
- An advanced skillset in Adobe Acrobat, MS Word, and MS Project; strong knowledge of complementary plug-ins for pre-publishing and publishing of documents.
- Capability to manage complex projects, timelines and teams in a matrix team environment to plan work, create timelines and deliver results.
- A high level of organizational capability, a commitment to efficiency and effectiveness, a possession of determination, and the ability to think strategically and still pay attention to detail.
- Self-motivation, the ability to respond effectively to developing situations, maintain priorities, and manage challenging assignments through collaboration, communication and teamwork.
- An understanding of the development of advanced therapy/innovative biologics products a plus.
- A strong ability to focus, and a great attention to detail.
- Excellent analytical, decision-making, and problem-solving skills.
- The demeanor to enjoy and thrive in a 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.

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