Visterra
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Regulatory Writer / Senior Regulatory Writer, Regulatory Affairs

Company

Visterra is a clinical stage biotechnology company committed to developing innovative biologic therapies (monoclonal antibodies and therapeutic muteins) for the treatment of kidney diseases, with an immuno-nephrology focus in drug development. Our proprietary technology platform enables the design and engineering of precision antibody or protein-based drug candidates to modulate key disease targets. 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 subsidiary of Otsuka Pharmaceutical Co., Ltd. of Japan. Visterra has approximately 90 employees, and is located in Waltham, Massachusetts.

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 Writer with a solid writing skillset, knowledge of electronic submissions and flexibility to lead the company in preparing regulatory submissions for investigational products. Reporting to the Head of Regulatory for Visterra, the Regulatory Writer will write regulatory submissions including CTD Modules 1, 2 and 3 documents, Health Authority Meeting Requests/Briefing Books, Fast Track/Breakthrough Therapy Designation requests, Orphan Drug Designation applications and other global regulatory submissions. The specialist will act collaboratively to support global, cross-functional teams and work independently to manage the production of regulatory submissions. The specialist will also work with another company within the Otsuka organization to facilitate making electronic submissions.

In summary, this role will contribute to the needs of the department by:

- Employing skills in the matrix management of a partner company for producing regulatory submissions;
- Writing critical regulatory submissions such as Module 2 documents;
- Planning and executing electronic submissions for original INDs;
- Supporting IND life cycle management;

- Initiating and managing regulatory submission projects to lead teams to produce high-quality regulatory submissions;
- Writing and contributing content for regulatory submissions; and
- Building systems and processes to facilitate future regulatory submissions.

Responsibilities

- Write critical regulatory submissions for global Health Authorities, including Module 2 documents, requests for meetings, requests for expedited programs, and more.
- Work with teams on complex regulatory submissions to contribute to strategy, messaging, document flow, logic and consistency. Manage review processes to resolve issues and ensure documents are complete.
- Serve as Visterra's lead expert on a partner-managed document management system. Manage relationship with the partner company to ensure regulatory submissions are planned, prepared and submitted in a timely fashion.
- 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.
- Prepare templates for authors and manage submission processes; train other functions in using regulatory templates and regulatory submission writing.
- Collaborate with authors to ensure submissions are complete and all relevant reference documents and copyrights have been secured.
- Manage the Global Submission Planner and organize Health Authority correspondence and regulatory information.
- Lead a company-wide adoption of a document management system.

Requirements

- Bachelor's degree required, advanced degree preferable (Ph.D., Pharm.D., MSc).
- A minimum of 1 years of experience (Ph.D. +1 year, M.S. +2, B.S. +3) in regulatory/medical writing, preferably within the biotechnology industry. Demonstrated strong writing skills in authoring and managing the production of scientific documents.
- Strong communication skills.
- Ability to work independently, with a positive attitude and constructive mind-set.

- Demonstrated ability to set and manage timelines.
- Experience with eCTD regulatory submissions highly desired.
- Highly skilled with Adobe Acrobat, MS Word, and MS Project; Strong knowledge of complementary plug-ins for pre-publishing and publishing of documents.
- Highly organized, committed to efficiency and effectiveness, possessing determination, the ability to think strategically and still pay attention to detail.
- Self-motivated, able to respond effectively to developing situations, maintain priorities, and manage challenging assignments through collaboration, communication and teamwork.
- Enjoys and thrives 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 cover letter and resume to careers@visterrainc.com.