



Contact CJ Prestia
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Senior Manager, International Regulatory Affairs

Location: Cambridge, MA

Reports to: Director, Regulatory Affairs

Description: The Sr. Manager, International Regulatory Affairs is responsible for the leadership and support in all activities relating registration requirements and line extension indications in all countries except for the US. Responsibilities include innovative international regulatory strategies for product development and approval (biologics); preparation or facilitate preparation of international regulatory documents and various submissions for product registration, as well as any compliance matters; if needed, represent the company with international regulatory authorities, contractors and corporate partners; provide regulatory support for various departments, projects, and teams/committees.

Job Responsibilities:

The Senior Manager of International Regulatory Affairs will facilitate the overall regulatory strategy to support product development and approval efforts for all pre- and post-marketing projects in non-US countries (e.g., primarily in the EU and Canada with intent to expand out to include Latin America, Asia/Pacific). This individual will help oversee contractor support to ensure timely and high quality regulatory submissions to these Boards of Health.

- Contributor in a multi-functional team environment; help implement the international regulatory strategy for all pre- and post-marketing projects.
- Help in the development of the international component of the Regulatory Development Plan for programs in development.
- Evaluate new and revised regulations/guidance for impact on product development plans in order to propose and implement appropriate changes.
- Provide guidance regarding evolving practices and requirements to facilitate effective product development and approval efforts in International markets.

- **Work closely with functional areas throughout the company. Advise functional areas regarding content requirements for international regulatory submissions; review documents from functional contributors for consistency and completeness.**
- **Help select and manage contractors to support timely and high quality regulatory filings to international Boards of Health.**
- **In liaison with US regulatory peer(s), help develop core labeling for products in development as data become available.**
- **Assure ongoing efforts towards fulfillment of international product approval conditions for marketed products.**
- **Foster a proactive, collaborative and goal-driven organization.**

Experience and Background

- **Candidate will need a minimum of 5-10 years of directly related regulatory international bio/pharmaceutical experience (particularly EU but other geographical areas a plus). Looking for a preferred advanced degree (MS/PharmD/PhD).**
- **Extensive knowledge of EU and Canadian regulations, policies, procedures, drug development guidelines and compliance; other non-US experience outside of EU would be desirable.**
- **Experience of direct contact with EMA and/or other international health authorities. Previous coagulation product development and/or regulatory experience.**
- **Experience working with managing contract support.**
- **Ability to help formulate global regulatory strategies based on understanding of the product and hands-on experience in regulatory procedures to achieve competitive and speedy product approvals.**
- **Experience and judgment to plan and accomplish goals and objectives.**
- **Good working understanding of projects in assigned area of responsibility allowing for creative and innovative solutions to address potential hurdles in development.**
- **Excellent negotiation and communication skills and the ability to work independently and function well in a team-orientated environment are essential.**
- **Needs knowledge of eCTD and computer literacy.**
- **More than 5 years in industry.**