

Caring for Life. Make a difference. Be the difference.

If you are looking to work for a growing, global corporation that is focused on making meaningful improvements in the safety, affordability, and availability of the care medical professionals provide to their patients, then you should consider Fresenius Kabi.

We are an employer that works to build great leaders, teams and businesses. We know our employees are key to everything we accomplish, so we give them the freedom and resources to reach their potential and the opportunity to work with managers who care about their professional development. We value integrity, encourage collaboration, celebrate passion, reward creativity, and demand excellence — because our customers deserve nothing less and our customers are at the heart of every one of our goals.

As a part of Fresenius Kabi, you can enjoy an exciting career, a company culture based on a clear purpose and values, and the knowledge that your work makes a real difference. If you would like to learn more about us, we would love to hear from you.

We are currently seeking a **Regulatory Affairs Manager, Product Life Cycle Management (PLCM)** to join our growing team!

The RA Manager, PLCM, is responsible for leading a team of Regulatory Affairs Professionals as well as the management of all regulatory activities that support regulatory compliance of marketed products.

- **The Impact you will Make:**

- Develop regulatory strategies and implementation plans for the preparation and submission of supplemental applications; SNDS, SANDS, post DIN
- Manage and execute regulatory activities to ensure post-approval regulatory compliance for marketed products
- Review regulatory submission materials to ensure accuracy, comprehensiveness, or compliance with regulatory standards
- Prioritize work of RA personnel to ensure submission timelines are met
- Coach, mentor and develop RA team members
- Communicate regulatory information to multiple departments and ensure that information is interpreted correctly
- Present alternatives strategies for meeting regulatory requirements in order to support business needs
- Maintain current knowledge of relevant regulations, including proposed and finalized rules
- Provide interpretation on complex regulatory guidelines and policies; and deliver training as needed
- Manage outside regulatory consultants on any matter as required
- Work as a member of the management team in order to achieve business objectives
- Perform all work in support of our Corporate Values of Customer Focus, Quality, Integrity, Collaboration and Creativity

- Perform all work in accordance with the established regulatory compliance and safety requirements
- **What You'll Bring**
Experience. You possess a Bachelor of Science (BSc) degree in Chemistry, Pharmacy or Life Sciences; or alternatively possess a Master of Science (MSc). You have at least 7 years of experience working in the Canadian Regulatory Affairs industry including Compliance and have solid experience with therapeutic (pharmaceutical) products.
- *Skilled leader.* You have at least 3 years of experience leading and managing a team. You are comfortable setting and meeting objectives for yourself, your department and your individual team members. You are able to coach, mentor and motivate in order to achieve those objectives.
- *Strong communicator.* You have strong oral and written communication skills and have been proven to be able to influence others.
- *Exceptional organizational and time management skills.* You are highly-detailed, and you can shift focus from one priority to another while maintaining accuracy. You can manage a high volume of work and balance multiple activities, prioritizing requests and projects, for stakeholders of all levels of the organization.
- *The technical experience.* You are proficient in the use of MS Office, Adobe Acrobat and Sharepoint Software. You have detailed knowledge of Canadian regulatory requirements and working knowledge of global (mainly FDA and EMA) requirements.

What We'll Bring

- *Exposure.* The hands-on experience and exposure to a global organization, combined with the mentorship of a dynamic senior management team.
- *Positive Collaborative Environment.* A welcoming, fun and energetic team environment that encourages open communication and collaboration. Our culture encourages our employees to hone current skills and build new capabilities, while discovering their genius.
- *Impact.* You will lead the customer service team through our continued growth and diversification, and will be able to shape and structure the department to meet those challenges.

The company is committed to meeting the accessibility needs of people with disabilities. Fresenius Kabi Canada & Calea Ltd. is dedicated to breaking down barriers to accessibility, preventing new barriers from arising and to meeting the accessibility requirements prescribed by the Accessibility for Ontarians with Disabilities Act (AODA). If you require accommodation at any time please contact us