Fresenius Kabi Canada is seeking a
Senior Regulatory Affairs Associate
to join the growing and dynamic team that supports our specialty drugs and medical device product portfolios!

Who we are:

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.

The Impact You Will Make:

The Sr. Regulatory Affairs Associate is responsible for the preparation and on time filing of high-quality regulatory drug submissions including New Drug Submissions (NDS), Drug Identification Numbers, post approval submissions, medical device applications, and preparing responses to agency questions for our Specialty products, both drugs and biologics.

In addition, the incumbent assesses international drug products dossiers, identifies gaps to meet local requirements, and prepares gap analysis reports listing all supporting documentation needed to prepare our NDSs.

This position communicates regularly with internal customers and externally with manufacturing facilities, and prepares high-quality Chemistry and Manufacturing summaries for NDS, based on CTD dossiers prepared for the US or Europe.

What You'll Bring:

- *Knowledge & Experience.* You possess a Bachelor of Science degree in either chemistry, microbiology, pharmacology or life sciences (Master's degree or completion of a college regulatory affairs program is an asset). You have a minimum of 5 years of pharmaceutical experience in a Canadian regulatory affairs capacity, with at least two years in a medical device related field, adhering to the latest regulatory requirements.
- *Communication & Presentation.* You are a skilled leader and able to effectively communicate both written and verbally, cross-functionally, and in collaboration with all levels both inside and outside the organization.
- *Problem-solving.* Your critical thinking and decision-making skills are above average, and you demonstrate excellent analytical skills and high level of accuracy. You identify and assess issues/ problems and present solutions with a process-improvement mindset.
- *Attitude & Passion*. You are self-motivated, possess initiative, and able to work productively with minimal supervision. You have proven your ability to adhere to standards and procedures and maintain continuous confidentiality.

- *Exceptional organizational and time management skills*. You maintain strong attention to detail with the ability to multitask and handle fluctuating workloads simultaneously. You have excellent project management and follow up skills and are deadline oriented with a strong ability to prioritize tasks.
- *Technical experience*. You are proficient in Microsoft® Office, PowerPoint and Excel.

What We'll Bring

- *Exposure*. The hands-on experience and exposure to a global organization, combined with the mentorship of a dynamic and knowledgeable Regulatory Affairs team. The opportunity to work on a specialty drugs and medical devices portfolio.
- *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 be an integral part of the projects and initiatives that will contribute to the strategic planning and growth of the organization. The opportunity to broaden your scope or current skillset with a business that combines product and service.

If you are interested and qualified, we invite you to apply on our Career Centre:

https://workforcenow.adp.com/mascsr/default/mdf/recruitment/recruitment.html?cid=5ca0ff89-702c-4742-979b-a4834ca4bd99&ccId=19000101_000001&jobId=302860&lang=en_CA&source=CC4

If you require accommodations, please contact Human Resources to ensure your equal participation in the recruitment process.