**Who we are:**

***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.

**Fresenius Kabi Canada is seeking a Senior Regulatory Affairs Associate (Medical Devices) to join the growing and dynamic team that supports our medical devices product portfolio!**

**The Impact You will Make:**

The Regulatory Affairs Senior Associate is responsible for:
•Compilation of documentation and prepare medical device regulatory applications for submission to Health Canada
•Management of communications with regulatory agencies and external partners managing regulatory submissions on behalf of the organization
•Providing regulatory review of product design, product changes and quality management system documentation (including policies, procedures, documents and records)
•Maintenance and update device listings, device licenses, and establishment registrations
•Monitoring markets for regulatory changes to applicable regulations and requirements and communicate changes across the organization
•Providing regular reports to management on the status of regulatory submissions, licenses/clearances and registrations
•Supporting quality management system and compliance activities as needed (e.g. change control, audits)
•Participating in opportunities to develop regulatory and medical device business knowledge
•Review of marketing material to determine alignment with regulated product claims
This position communicates regularly with internal customers (marketing, supply chain and vigilance functions) and externally with manufacturing facilities and prepares high-quality summaries for medical device application based on documentation 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. Completion of a college regulatory affairs program is an asset. You have a minimum of 3 years of pharmaceutical experience in a

Canadian regulatory affairs capacity specializing in Medical Devices, adhering to the latest regulatory requirements.

- *Communication & Presentation.* You are a skilled communicator both written and verbally cross-functionally, and in collaboration with all levels both inside and outside the organization including Health Canada.
- *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.
- *Computer Skills*. You are proficient in Microsoft® Office.

**What We'll Bring**

- *Exposure*. The hands-on experience and exposure to a global organization.
- *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 integal 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.