



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 [full-time Senior Regulatory Affairs Associate](#) to join our dynamic and engaged team!

The Impact You Will Make:

The Senior Regulatory Affairs Associate is responsible for managing regulatory projects, preparation and on time filing of high quality regulatory drug submissions including Abbreviated New Drug Submissions (ANDS), New Drug Submissions (NDSs), Drug Identification Numbers and Supplements, that comply with all local regulatory and global requirements as assigned. Using the necessary resources and working closely with their manager and colleagues, the Senior Regulatory Affairs Associate prepares and files drug submissions; and prepares responses to inquiries from the various regulatory agencies to support the approval of a drug. The Senior Associate is also responsible for product life cycle maintenance, assesses and responds to change controls, as required.

What You'll Bring:

- ✓ ***Knowledge & Experience.*** You possess a Bachelor of Science degree in Chemistry, Microbiology, Biology, Pharmacology or another life science. Completion of a college regulatory affairs program and a Regulatory Affairs Certification (RAC) is an asset. You also have five or more years of pharmaceutical experience in a regulatory affairs capacity.
- ✓ ***Attitude & Passion.*** You are self-motivated 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. Your organizational and problem-solving skills are strong while identifying areas for continuous improvement. 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, as well as Document Management System and eCTD. Your critical thinking and decision-making skills are

above average and you demonstrate excellent analytical skills and high level of accuracy. You can effectively analyze data, possess strong investigative skills, and have strong interpretation and manipulation skills.

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.
- ✓ **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 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.

APPLY NOW!!

https://workforcenow.adp.com/mascsr/default/mdf/recruitment/recruitment.html?cid=5ca0ff89-702c-4742-979b-a4834ca4bd99&cclid=19000101_000001&jobId=372345&source=CC2&lang=en_CA