

JOB POSTING

Aspen Pharmacare Canada, a branch of Aspen Holdings, was founded in 2014 to offer the Aspen Group's expanding portfolio of pharmaceutical and consumer healthcare products to Canadians. Aspen Holdings is a South African-based supplier of branded and generic pharmaceuticals to more than 150 countries, providing products renowned for their quality, efficacy and affordability. In Canada, Aspen is committed to continuing this legacy by providing high quality, branded medicines at prices that are competitive and represent fair value to our customers and patients.

At Aspen you'll find an engaging fast-paced environment, challenging projects and the opportunity to design your career. Seize the ability to think differently and collaborate with innovative minds to influence some of the most critical issues facing healthcare in Canada.

Aspen Pharmacare Canada currently has an opening for the following position:

Position	Regulatory Affairs Senior Associate
Reports To	Director RA/QA
Responsibilities	<p>Key responsibilities may include, but are not limited to:</p> <ul style="list-style-type: none"> • Prepare, negotiate and gain high quality and timely regulatory approvals, Notifiable Changes and Supplemental New Drug Submissions. • Assist in preparing, negotiating and gaining high quality and timely regulatory approvals for New Drug Submissions and Abbreviated New Drug Submission. • Provide input to Global and local RA strategies. Assess potential risks and provide input for product development plans. • Initiate and lead labeling and quality changes in the change control systems. Assess proposed product, process and manufacturing site changes and execute necessary actions for implementation in cooperation with global staff. • Build, develop and maintain interactions with Canadian Health Authorities and other external stakeholders through effective collaboration and communication. • Request and assist in conducting Health Authority meetings as needed during the drug development and filing processes. • Independent interactions with cross-functional submission and negotiation teams. • In collaboration with Marketing and Medical Affairs review and approve promotional material and regulatory labeling for regulatory compliance. • Manage the development or maintenance of procedures and processes to ensure compliance with the Health Canada Food & Drugs Act and Regulations, and other applicable industry standards, in addition to efficiency improvements.

	<ul style="list-style-type: none"> • Perform other Regulatory Affairs duties as required, potentially across specific Therapeutic Areas. • Maintain Canadian Regulatory compliance to relevant SOPs or Health Canada legislation, regulation, policy or guidance related documentation. • Prepare and submit the DEL submissions/Annuals and Level III submissions.
Qualifications	<ul style="list-style-type: none"> • BSc (required) or MSc (preferred) in Pharmacy, Pharmacology, Chemistry, Biological Sciences, or equivalent. • Postgraduate Certificate in Pharmaceutical Regulatory Affairs and Quality Assurance is an asset • Minimum 5 years' progressive experience in Regulatory Affairs . • Must have knowledge of the Food & Drugs Act and Food and Drug Regulations. • Strong analytical skills with the ability to assess scientific data. • Proficient computer skills, including all MS Office applications. • Exceptional oral and written communication skills. • Ability to build and maintain strong and collaborative working relationships with internal and external business partners. • Strong time management and organizational skills. • Demonstrated solid judgement and negotiation skills. • Ability to work well independently and under pressure. • Embodies a “can-do attitude” with a “roll-up-your-sleeves” approach • Must have demonstrated success in a regulatory environment (e.g. experience leading a Regulatory submission team), and knowledge of drug development (clinical studies, chemistry and manufacturing etc.) in the healthcare industry. • Demonstrating Aspen’s core business competencies, the ideal candidate will be performance driven, create the future, make sound decisions, foster consumer and customer commitment and take accountability and ownership. In addition, the candidate will be comfortable dealing with ambiguity, have excellent professional communication skills, have the ability to influence others, demonstrate a passion for their company, continuously grow and develop and take action with integrity

If you are interested in this position, please send your cover letter and resume with salary expectations to can.careers@ca.aspenpharma.ca . Specify RA Sr.Associate in the subject line of your email and your cover letter.

We thank you for your interest in employment with Aspen Pharmacare Canada however, only those candidates selected for an interview will be contacted.

We are committed to providing persons with disabilities equal opportunities regarding all employment activities, including access to jobs and accommodations during employment as required, in accordance with the Ontario Human Rights Code (OHRC) and the Accessibility for Ontarians with Disabilities Act (AODA).