**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 in more than 150 countries across the world, providing products renowned for their quality, efficacy and affordability.

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

|  |  |
| --- | --- |
| **Position** | **Regulatory Affairs/Quality Assurance Senior Associate** |
| **Reports To** | **Director, RA/QA** |
| **Responsibilities** | Key responsibilities may include, but are not limited to:   * Prepare and gain high quality Notifiable Changes and Supplemental New Drug Submissions and negotiate timely regulatory approvals for Pharmaceuticals and Biologics * Maintain and track/submit the Level III and IV changes for Pharmaceuticals and Biologics * Assist in compiling complex files for New Drug Submissions and Abbreviated New Drug Submission. * Initiate and lead labeling and quality changes in the change control systems in cooperation with global staff. * Prepare and submit to the Authority the DEL submissions/Annuals submissions * 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 when required * Independent interactions with cross-functional submission and negotiation teams. * Review promotional material and regulatory labeling for Regulatory requirements. * Manage the development or maintenance of procedures and processes to ensure compliance with the Food & Drugs Act, Health Canada Regulations, and other applicable industry standards, in addition to efficiency improvements. * 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. * Responsible for investigations, documentation and follow-up of quality discrepancies including deviations, CAPA, Complaints and etc * Execution of the Quality Assurance activities ensuring compliance with local, corporate and regulatory requirements: quality batch review and release, Periodic Products Reviews, Stability Program Reviews and etc |
| **Qualifications** | * 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 4 years’ progressive experience in Canadian Regulatory Affairs and Quality Assurance. * 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 to [careers@aspenpharma.ca](mailto:careers@aspenpharma.ca) . Specify **RA/QA 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).