**JOB POSTING**

**Aspen Holdings** - one of the largest pharmaceutical companies in the southern hemisphere. With a 160-year heritage, Aspen is a global specialty and branded multinational pharmaceutical company with a presence in both emerging and developed markets. Have approximately 9 800 employees at 71 established offices in over 50 countries and we improve the health of patients in more than 150 countries through our high quality, affordable products. Please visit www.aspenpharma.com for more information.

**Aspen 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. Please visit www.aspenpharma.ca for more information.

Aspen Canada currently has an opening for the following position:

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| **Position** | **Medical Information, Pharmacovigilance and Regulatory Compliance Associate** |
| **Reports To** | **Director, Regulatory Affairs & Quality Assurance** |
| **Responsibilities** | Key responsibilities may include, but are not limited to: **Medical Information & Pharmacovigilance – 70%:**

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| * Contribute to daily pharmacovigilance and medical Information operations for medicinal products
* Assessment of incoming communication to identify potential adverse event reports and submission of expedited and periodic reports to Health Canada.
* Case management: Triage cases/adverse event reports in Canada: receive, evaluate, process, track and accurate data entry of adverse events within timelines as described in the Global and local Pharmacovigilance SOPs
* Collect and process adverse drug reactions from all sources, when required
* MedDRA coding of all relevant cases, when required
* Submit all reportable cases for assigned products to the regulatory agency according to local legislation, when required
* Initiates and conducts follow-up activities related to local ADR reports
* Conduct literature search for the products
* Screening of regulatory agency databases for identification of Individual Case Safety Reports for assigned products
* Fulfill the adverse event reporting exchange requirements as described in the Pharmacovigilance Agreements
* Reconcile adverse event reports received from stakeholders
* Contributes to Pharmacovigilance inspection readiness, in collaboration with the Quality department (PV audits, CAPA plans).
* Maintain Aspen Canada SOPs pertaining to PV and Medical Information
* Manage Medical Enquiries in a timely manner, including maintenance of standard response documents in collaboration with Global Medical Affairs.
* Adhere to all Corporate and local policies and procedures; maintain the training up to date
* Reconcile medical information records with external and internal stakeholders
* Test inbound channels of local phone line/websites and document the outcome

**Regulatory/Quality Compliance – 30%*** Prepare Annual Reports (DEL, MDEL, DIN renewals, YBPRs) and Administrative Submissions to the regulatory agency
* Responsible for preparing and filing regulatory submissions for product monograph and labelling updates
* Prepare the Annual Notifications and submit to the regulatory agency
* Conduct the Annual Product Reviews (APRs) and the Stability Reviews
* Review labeling for Regulatory requirements
* Independent interactions with cross-functional teams
* Use and update regulatory information systems for planning, preparing, tracking and storing submissions to regulatory agency
* Initiate or contribute to routine local process improvements, which have an impact on the working of the Regulatory Affairs function
* Conduct thorough review and investigations, documentation, and follow up regarding any quality and compliance non-conformances in quality, regulatory and pharmacovigilance activities to ensure comply with local, corporate, and regulatory requirements
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| **Authority** | The authority and resources required to fulfil the responsibilities of the Pharmacovigilance, Medical Information and Regulatory Compliance Assocte will be provided by management. This includes:* Support Aspen Canada Call Centre in the handling of Adverse Events (AE) and Medical Information enquiries
* Act as the local expert in all matters pertaining to PV within the post-marketing space and Medical Information and communicate on behalf of Aspen Canada with relevant global functions
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| **Qualifications** | * Post-secondary Degree in a scientific or medically related field
* Strong knowledge of Health Canada guidelines for post-marketing drugs safety surveillance
* Knowledge of regulatory guidelines and legislations in Canada in pharmacovigilance
* 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.
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| **Career Experience** | * Must demonstrate working knowledge of Health Canada regulations and guidelines relating to Pharmacovigilance processes (e.g. post-marketing surveillance activities/ training).
* Experience with safety databases (ARGUS) and systems
* Experience with safety case processing;
* Able to effectively coordinate safety related activities
* Knowledge of ICH, CIOMS, Canadian legislation and Good Pharmacovigilance Practices (GVP)
* Understanding of medical terminology (MedDRA coding) is an assest
* Bilingualism (English/French) is an asset.
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| **Required Core Competencies/Skills** | * Self-starter
* Problem solving skills
* Accuracy and attention to detail
* Effective organization and planning skills and ability to prioritize
* Ability to work under pressure and to tight deadlines
* Ability to work in a fast-paced international environment
* Ability to manage projects in a matrix team environment and with both internal and external partners
* Willing to travel
* Strong team player

Demonstrates Aspen Competencies: Performance driven – deciding & initiating action; achieving personal work goals & objectives; creates the future – creating & innovating; formulating strategies & concepts; makes good decisions – analyzing, deciding & initiating action; fosters consumer & customer commitment – applying expertise & technology, entrepreneurial & commercial thinking; accountability & ownership – delivering results &meeting customer expectations; deciding & initiating action; develops talent, teamwork &diversity – working with people, relating & networking; deals with ambiguity, embrace change –adapting & responding to change; coping with pressure & setbacks; communicates effectively –relating & networking; persuading & influencing; presenting & communicating information; leads and influences others – leading & supervising; persuading & influencing; continuously grows & develop – achieving personal work goals; learning & researching; Demonstrates a passion for Aspen; contributes special expertise; takes action with integrity |

If you are interested in this position, please send your cover letter and resume to careers@aspenpharma.ca . Specify **Medical Information, Pharmacovigilance and Regulatory Compliance 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).