| Aspen Pharmacare Canada Inc. | | | | |
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| Department | ***Regulatory Affairs & Quality Assurance*** | | **ACQS-003_Att-05** | Version 02 |
| Title | Regulatory Affairs & Quality Assurance Senior Associate | | Effective from: March 25, 2021 | |
| Author (Department Head) | Director, Regulatory Affairs & Quality Assurance | Inga Machula | Signature | April 26, 2021 |
| Checked/approved | General Manager Canada | Mike Egli | Signature | April 26, 2021 |

**Job description**

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| **Job description:** | Regulatory Affairs & Quality Assurance, Senior Associate |
| **Objective:** | Plan, coordinate, compile, submit, obtain approval and maintain drug product registrations for Canada.<br>Support Quality Assurance operations at Aspen Canada.<br>Assist in maintenance the interface between Aspen Global RA teams, Aspen Canada and local Regulatory authorities. |
| **Department:** | Regulatory Affairs & Quality Assurance |
| **Manager:** | Director, Regulatory Affairs & Quality Assurance |
| **Reports to:** | Director, Regulatory Affairs & Quality Assurance |
| **Substitution:** | Director, Regulatory Affairs & Quality Assurance or Quality Assurance Associate |
| **Responsibilities:** | Key responsibilities may include, but are not limited to:<br><br>***Regulatory Affairs – 80 %:***<br><br>Post-MAA product life-cycle management:<br>• Lead the planning and preparation of regulatory submissions and label development, with the support of Director RA/QA, for post MAA approval products (NC, SNDS, ANDS, L3s and etc.)<br>• Manage annual submissions/renewals to regulatory agency (DEL, MDEL, DIN renewals, YBPRs), when assigned by manager<br>• Perform labelling review to ensure in compliance with current legislation<br>• Maintain regulatory documentation and records<br>• Lead the change control management system; provide regulatory assessment of the changes made to the products<br>• Build, develop and maintain interactions with regulatory agency and other external stakeholders through effective collaboration and communication.<br>• Independent interactions with local and corporate cross-functional teams when negotiating for the submissions and/or other projects/assignments<br>• Perform promotional reviews for marketing material<br>• Use and update regulatory information systems for planning, preparing, tracking and storing submissions to regulatory agency<br>• Initiate or contribute to routine local process improvements, which have an impact on the working of the Regulatory Affairs function.<br>• Manage the development or maintenance of local regulatory procedures to ensure compliance with the Food & Drugs Act, Health Canada |

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| | Regulations, and other applicable industry standards, in addition to efficiency improvements.<br>• Perform other Regulatory Affairs duties as required<br>• Comply with Corporate and Aspen Canada policies and procedures; adhere to the local legislation, regulation, policy or guidance elated to regulatory and quality compliance<br><br><u>Products in development:</u><br>• Assist in preparation of regulatory submissions and label development, with the support of the Director RA/QA, for products in development<br>• Participate in preparation to pre-submission meetings with regulatory agency during the drug development<br><br>***<u>Quality Management (QM) and Quality Assurance (QA) – 20%</u>:***<br><br>• Assist in Quality Assurance Function activities ensuring company compliance with local and corporate requirements: quality batch review and release, periodic products reviews (PQRs), Stability Program Reviews and etc<br>• Responsible for investigations, documentation and follow-up on quality/regulatory non-conformances including deviations, CAPA, complaints and etc. |
| **Authority:** | The authority and resources required to fulfil the responsibilities of the Sr Associate RA/QA will be provided by management. This includes:<br><br>• Communication with Regulatory Authorities on behalf of Aspen Canada for the purpose of registering and maintaining registrations with the Regulatory Authorities |
| **Required qualifications:** | • BSc (required) or MSc (preferred) in Pharmacy, Pharmacology, Chemistry, Biological Sciences, or equivalent.<br>• Postgraduate Certificate in Pharmaceutical Regulatory Affairs and Quality Assurance is an asset<br>• Must have knowledge of the Food & Drugs Act and Food and Drug Regulations.<br>• Strong analytical skills with the ability to assess scientific data.<br>• Proficient computer skills, including all MS Office applications.<br>• Exceptional oral and written communication skills.<br>• Ability to build and maintain strong and collaborative working relationships with internal and external business partners. |

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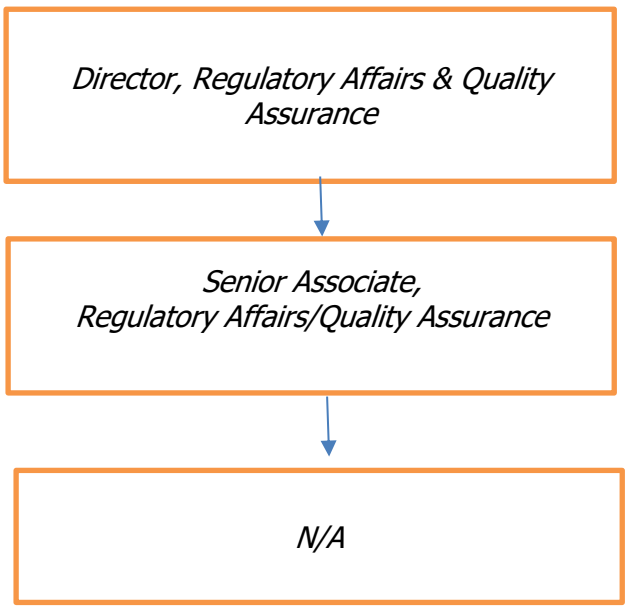
| | • Strong time management and organizational skills.<br>• Demonstrated solid judgement and negotiation skills.<br>• Ability to work well independently and under pressure.<br>• Embodies a "can-do attitude" with a "roll-up-your-sleeves" approach<br>• Must have demonstrated success in a regulatory environment (e.g. experience leading a Regulatory submissions), and knowledge of drug development (clinical studies, chemistry and manufacturing etc.) in the healthcare industry. |
| **Required career experience:** | • Minimum 4 years' progressive experience in Canadian Regulatory Affairs and Quality Assurance. |
| **Required core competencies/skills:** | 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 |

**Organizational context:**



**Aspen Pharmacare Canada Inc.**

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| Title | Regulatory Affairs & Quality Assurance Senior Associate | Effective from: March 25, 2021 | |

**Start date with Aspen:**
**Supersedes job description dated:**

| | **Jobholder** | **Line Manager** | **Executive Management** |
|---|---|---|---|
| **Date** | | | |
| **Name** | | | |
| **Signature** | | | |

*The signature of the employee confirms the assumption of the position described herein and all associated responsibilities. The employee is clear about all of the responsibilities and explicitly understands them.*