**Overview:**

<table>
<thead>
<tr>
<th>Job title:</th>
<th>Senior Manager, Global Regulatory Affairs, Canada</th>
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<tbody>
<tr>
<td>Employment Type:</td>
<td>Permanent</td>
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<tr>
<td>Department:</td>
<td>Medicine Development Center (MDC), Global Regulatory Affairs Core Functional Unit</td>
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<tr>
<td>Report to position:</td>
<td>Director, Medical &amp; Regulatory Affairs</td>
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<tr>
<td>Location:</td>
<td>Eisai Limited (Canada), Mississauga, ON</td>
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Based on MDC policy, accomplish product creation tasks for the fulfillment of patient reality. Assess present status of RA-CMC information and propose enhancements that bring a reduction of medicines development periods. The Senior Manager will cooperate with all stakeholders for the advancement of assigned projects and for the maintenance of regulatory quality of Eisai products.

1. Develop and implement the regional regulatory strategies for Canada within the Global Regulatory Affairs organization
2. Lead the preparation of submission documents and provide response to questions from health authorities in a timely manner
3. Have accountability for the quality of submissions

**Responsibilities (include, but not limited to):**

- Acts as the main contact point for all regulatory activities (Clinical and CMC regulatory) for all Eisai marketed products and products in development in Canada
- Provides regional support for all components of regulatory submissions (CTA, NDS, amendments, variations, scientific advice briefing documents, agency communications etc.) to ensure that high quality documents are prepared in compliance with the applicable regulatory requirements and in line with project timelines
- Develops Clinical and CMC strategies for Canada submissions, and provides additional guidance to CMC product sub-teams
- Provides regional input on Global Change Controls outlining Canada requirements for proposed changes
- Leads responses to Health Authority questions by working closely with International Project Teams
- Provides regional regulatory strategy and manages timelines to meet key project milestones and goals
- Maintains strong relationships, interacts with, and influences a network key external stakeholders
- Acts as company’s representative on industry association committees with the objective to shape local environment based on global guidance
- Engages with patients’ reality socialization human health care (HHC) activity

**Required Qualifications/Experience:**

- College or University degree in an associated functional discipline (Life Sciences, Chemistry or Pharmacy)
- Extensive (10 years +) regulatory experience plus additional related experience (i.e., in Research and Development or Manufacturing, clinical marketed products, etc.), preferably including some broader industry experience
- A strong working knowledge of the application of the principles of chemistry to drug synthesis
- Extensive experience leading Health Canada regulatory interactions, including successful negotiations of a broad range of submission, leading successful Health Canada meetings
- Experience leading all aspects related to Clinical Trial Applications, including facilitating clinical supply
- Experience working in local cross-functional teams, acting as the Regulatory Affairs representative

**Required Skills:**

- Excellent communications skills and ability to work with people in other locations and time zones
- Ability to express a scientific opinion clearly and concisely and to defend regulatory decisions under pressure
- High organisational skills and time management
- Confidence in dealing with Regulatory Authorities
- Ability to manage multiple projects, tasks, and work in a matrix environment

Applicants please contact Ben Lamarche: blamarche@locksearchgroup.com