# Regulatory Affairs Associate – Role ID 198853

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| **JOB TITLE** | **Regulatory Affairs Associate** |
| **REPORTS TO** | Director, Regulatory Affairs |
| **COMPANY** | EMD Inc. |
| **DEPARTMENT** | Regulatory Affairs |

**PURPOSE:**

Support the Regulatory Affairs function to meet Company and departmental objectives.

**MAIN INTERFACES:**

- Interact with various global functions, and in particular, Global Regulatory Affairs and Global Packaging Artwork Development.
- Partner with Quality Operations, Drug Safety, Medical Affairs and Supply Chain.
- Liaise with the Marketing function within the respective Canadian Therapeutic Area Business Units.
- Liaise with Health Canada to support product registration process and ensure regulatory compliance.

**GENERAL/ SPECIFIC RESPONSIBILITIES:**

General:

- Perform Regulatory Affairs activities associated with business continuity initiatives and compliance management for all Therapeutic Areas.
- Represent the Regulatory Affairs function in cross-functional teams and initiatives.
- Responsible for the creation, review, approval and maintenance of product labeling.
- Contribute to relevant Regulatory Intelligence.
- Provide administrative support as necessary.
- All other duties as assigned.





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Specific:

- Plan, compile, and prepare documents for eCTD submissions to Health Canada including responses to Clarification / Information Requests.
- Manage regulatory dossiers under Health Canada review.
- Maintain current authorizations and licenses through annual renewal submissions.
- Participate in the generation and review of agreed elements of the core registration file to ensure compliance with local requirements and compatibility with Corporate and local Canadian business needs.
- Responsible for the creation, review, approval and maintenance of product packaging artwork and Product Monographs to ensure compliance with the Canadian Food and Drugs Act and Regulations and internal standards.
- Interact with Health Canada Regulatory Project Officers and Reviewers, as appropriate.
- Support Pre-submission Meetings with Health Canada.
- Represent Canada Regulatory Affairs on various project teams to provide insights and input in the areas of Nonclinical, Clinical and Chemistry and Manufacturing with respect to Canadian requirements.
- Perform tasks related to Regulatory Intelligence, as necessary.
- Remain up-to-date on applicable Canadian laws, regulations, policies and guidelines.
- Alert Director of issues and potential problems, delays, and or deficiencies, and make recommendations, as appropriate.
- Perform document management for all Regulatory files and correspondence (paper and electronic) including maintaining internal submission tracking and product databases.

  Support and maintain the local Change Control process.

**QUALIFICATIONS:**

- Ideally two to four (2-4) years' experience in Canadian Regulatory Affairs in the biotechnology or pharmaceutical industry or at Health Canada.
- University degree in a Life Science or a relevant scientific discipline.
- Successful completion of a Postgraduate Regulatory Affairs Certificate or a similar resignation such as RAC (CAN) is a definite asset.
- Experience with Biological (BGTD) post-approval CMC submissions is a strong asset.
- Demonstrated knowledge of the Canadian Food and Drugs Act and Regulations and relevant Health Canada policies and guidance documents.
- Solid understanding of product development, including pharmacology, toxicology, pharmacokinetics and clinical studies.
- Strong analytical skills with the ability to assess scientific data.
- Excellent communication skills, including written, verbal, and negotiation.
- Strong organizational and project management skills including the ability to manage multiple projects and priorities effectively.
- Demonstrated interpersonal skills with respect to relationship building and teamwork.

**Interested candidates are asked to apply directly online at:**

https://career5.successfactors.eu/sfcareer/jobreqcareer?jobId=198853&company=merckgroup&username=