



JOB DESCRIPTION
Director, Head of Regulatory Affairs Canada (207269)

JOB TITLE	Director, Head of Regulatory Affairs Canada	
REPORTS TO	Head of GRA EU & SICA, dotted line to Managing Director, EMD Inc.	
COMPANY	EMD Inc.	
DEPARTMENT	Global Regulatory Affairs	
NO. OF REPORTS	Direct Report(s) 3	Total Department 4

PURPOSE:

- The Director of Regulatory Affairs, Canada will report locally to the Managing Director and globally to the Global Head of Regulatory Affairs and will be responsible for all regulatory activity within the Canadian organization. This includes the overall direction and management of Regulatory Affairs. In addition, this role will be the primary liaison between EMD Inc. the Merck-Serono Global Head Offices (Darmstadt and Aubonne), the US Corporate Head Office (Rockland), as well as with the Canadian Health Products and Foods Branch (HPFB) for these key areas.

MAIN INTERFACES:

INTERNAL: Leadership Team members; Business Unit; Supply Chain; Market Access & Government Relations; Business Development; General Council & Compliance; Regulatory Affairs; Drug Safety; Medical ; Quality Operations;

GLOBAL: Global Product Development Teams; Global RA; Global DS; Global QA/ QC; Manufacturing sites

- **EXTERNAL:** Government of Canada (HPFB)

GENERAL RESPONSIBILITIES:

- Provide overall leadership and direction to the Regulatory Affairs team and supports development and training of staff and operational planning to optimize efficiency and quality
- Develop functional plans and budgets for managing Regulatory Affairs activities
- Participate and contribute to Global Regulatory Teams
- Collaborates with the Medical Department, Business Units' Marketing and Sales teams, , Drug Safety, Quality Operations and Supply Chain to enhance life cycle management and continued market availability of products and devices across all therapeutic areas
- Member of the Canadian Leadership Team, Canadian and Global New Product Development Teams, and additional ad hoc Canadian and Global teams as required
- Oversees regulatory affairs activities for all investigational and marketed products and devices for in Canada
- Maintains consistent communication with the Merck-Serono Corporate office on all Regulatory Affairs activities
- Directs the activities of the Regulatory team to ensure:



- High quality submissions and efficient and impactful negotiations with the HPFB that result in favourable terms for the HC approval and subsequent life-cycle management.
- All practices and product-related activities undertaken by EMD Inc., Canada both prior to and following approval, comply with the regulations set by the federal, provincial governments and industry guidelines of Canada, ensuring promotional materials and products on the market comply with approved dossier and product monograph.
- Appropriate compliance with all current Merck-Serono Corporate standards and guidelines.

SPECIFIC RESPONSIBILITIES:

- Respect and adhere to ethical/legal/regulatory/company guidelines
- All other duties as assigned

QUALIFICATIONS:

EDUCATION & LANGUAGES

- MSc in biological sciences or equivalent, PhD/PharmD strongly preferred, MBA an asset
- Bilingualism (English and French) preferred

PROFESSIONAL SKILLS & EXPERIENCE

- Minimum 15 years' experience in the proprietary pharmaceutical industry/government in the areas of research and development, operational management/project management, product safety and pharmacovigilance, regulatory affairs and quality operations
- Minimum 8 years in people management or team leadership role
- Comprehensive understanding of the Canadian Food and Drug Regulations and some exposure to European and US drug law Demonstrated strategic thinking and ability to create department strategy;
- Demonstrated team leadership skills
- Demonstrated proficiency in project management, notably managing multiple projects simultaneously;
- Demonstrated ability to build strong relationships with Key Opinion Leaders;
- Demonstrated ability to manage budgets;
- Demonstrated ability to understand and effectively communicate scientific information;
- Effective oral communication, written communication, presentation and teaching skills;
- Demonstrated ability to manage department resources;
- Solid MS Office, MS Project skills and Internet proficiency;
- Strong interpersonal skills and willingness to travel

COMPETENCIES

- Collaborative
- Purposeful
- Results-Driven
- Empowering
- Future-Oriented
- Innovative



Interested candidates are asked to apply directly online at:

<https://career5.successfactors.eu/sfcareer/jobreqcareer?jobId=207269&company=merckgroup>