Bring your curiosity to life! Join our team! We're seeking bold difference-makers with a great attitude, passion, and a restless need to discover the answers to all kinds of difficult questions. A career at EMD Serono is a personal and professional adventure. Fueled by purpose and rewarded with personal fulfillment, our people are shaping how the world lives, works and plays through next generation advancements in technology and science. For 350 years and across the world, we have passionately pursued our curiosity to find novel and vibrant ways of enhancing the lives of others.

JOB DESCRIPTION

JOB TITLE	**Regulatory Affairs Project Manager**
REPORTS TO	Director, Regulatory Affairs
COMPANY	EMD Serono
DEPARTMENT	Regulatory Affairs

YOUR ROLE:

As a Regulatory Affairs Project Manager, you will be responsible for leading the planning, submission and management of regulatory activities for both new and marketed products. Your skills will enable efficient, timely preparation and submission of regulatory dossiers. This includes the development and implementation of regulatory strategies, leadership of pre-submission interactions and the management of regulatory submission activities to achieve optimal approvals and labeling.

RESPONSIBILITIES:

- Partner with Marketing/Business unit, Quality Operations, Drug Safety, Medical Affairs, Supply Chain.
- Interact with various global functions; in particular, Global Regulatory Affairs and Global Packaging Artwork Development.
- Overall responsibility for the efficient, timely preparation and submission of regulatory dossiers in accordance with the Corporate priorities of projects.
- Contribute as a key therapeutic area cross-functional partner in providing expert strategic regulatory advice for Canadian registrations and functional support
- Lead the Health Canada interactions (pre-submission and submission)
- Evaluate files for new products, claims and line extensions, and develop appropriate regulatory strategies. Maintain registration compliance for approved products to support the ongoing marketing in Canada.
- Responsible for creation, review, approval and maintenance of product labeling.
- Review and approve promotional material and programs
- Provide input into guidelines for Industry during their development.

QUALIFICATIONS:

- Minimum five years experience in Regulatory Affairs in the biotechnology or pharmaceutical industry.
- University degree in a Life Science or a relevant scientific discipline.
- Experience in the Oncology Therapeutic Area is an asset.
- Specific experience with Biological submissions is an asset.
- Demonstrated knowledge of the Canadian Food and Drugs Act and Regulations and relevant Health Canada policies and guidance documents.
- 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=217071&company=merckgroup