Regulatory Affairs Specialist

Our client is one of the fastest growing international pharmaceutical companies dedicated to bringing quality health and wellness products to all Canadians. Their team manufactures and markets a wide variety of pharmaceutical and health products that are distributed in pharmacies, healthcare practices and hospitals across the country.

They invest in their employees and believe in the importance of cultivating performance and outdoing themselves in finding new and better solutions with the aim of responding innovatively and effectively to current needs.

In the context of their present growth, they are seeking to fill a position as Specialist, Regulatory Affairs based in Laval, Quebec.

**KEY RESPONSIBILITIES:**

* Prepare and compile drug submissions in the e-CTD format to Health Canada to obtain marketing authorization and maintain currently marketed products in compliance.
* Plan, manage, and coordinate the preparation, compilation, filing, and approval of high quality regulatory submissions for presentation to Health Canada.
* Maintain and ensure regulatory product compliance through relevant submissions, active regulatory registrations and interactions/negotiations with internal stakeholders and Health Canada.
* Prepare submissions to Health Canada for different dosage forms (NDS, S/NDS, DIN-A)
* Preparation and/or review of responses to Health Canada letters (e.g. Notice of Non-Compliance, Notice of Deficiency, and Clarifaxes)
* Preparation and/or review of Product Monographs, Package Inserts, and Label text
* Coordinate French translations of Product Monographs and Package Inserts (with the support of the Regulatory Affairs Coordinator)
* Coordinate negotiations with Health Canada to ensure prompt regulatory approvals
* Liaise with groups, internally and externally, to collect necessary documents and information
* Review of Change Controls and the determination of filing requirements
* Provide regulatory support to internal/external customers

**QUALIFICATIONS:**

* Education: University Degree, B.Sc. or higher in Health Sciences
* Experience: Minimum 3-5 years of relevant experience in Canadian Pharmaceutical Regulatory Affairs
* Build up dossier from the beginning or from other locations-
* Experience new drug submission/ DIN products.
* Demonstrated strong management skills
* Strong working knowledge of Canadian regulatory guidelines, drug development, manufacturing, and commercialization of pharmaceutical products (drug products and medical devices)
* Ability to prioritize projects, coordinate multiple projects simultaneously and work with tight deadlines
* Entrepreneurship and focus on customer needs. Good business acumen and sense of urgency. Team player and respect of others
* Bilingual (oral and written) -  French and English

**Please reach out to Arpita at** **a.sharma@brunel.net** **to apply!**