Job Title: Senior Manager, Regulatory Affairs
Job Type : Full Time (Permanent)
Reports to : Sr Director, Global RA & Pharmacovigilance

Department: Regulatory Affairs
Location: Mississauga, Ontario

Miravo Healthcare
6733 Mississauga Road
Suite 800
Mississauga, ON
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POSITION SUMMARY:

The Sr. Manager, Regulatory Affairs provides regulatory expertise and support for company's new and marketed products. The position interacts with internal and external stakeholders including commercial, medical, supply chain and Health Canada.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

• Manage and support the submission process for new drug submissions, supplements, amendments, and updates in support of business objectives
• Manage the review of documents generated by external consultants and project team members to assess the likelihood that the content will meet pre-specified objectives, and provide input
• Develop draft responses to Health Canada, and/or review responses and documents intended for submission to Health Canada to ensure compliance with regulatory standards
• Support the maintenance of approved Natural Health Products (NHPs) and medical devices which includes annual renewals and amendments
• Serve as a focal point with Health Canada and develop effective working relationship with Health Canada
• Plan and conduct Health Canada meetings.
• Review promotional and advertising materials to ensure compliance with the Pharmaceutical Advertising Advisory Board (PAAB) Code of Advertising Acceptance.
• Support the Regulatory function in accordance with corporate goals, policies and procedures.
• Maintain awareness of the Canadian regulatory environment and assess impact of pertinent changes that may affect the company.
• Responsible for reporting adverse events associated with company's products.
• Other duties as assigned.

REQUIRED EDUCATION AND EXPERIENCE:

• Bachelor degree in a science-related discipline
• Master's Degree or higher is an asset
• Minimum of 5-7 years of progressive regulatory experience in the Canadian brand name pharmaceutical industry
• Experience with document management and CTD/e-CTD
• Comprehensive knowledge and experience in the Canadian regulatory environment and Health Canada regulations, polices and guidelines
• Proven success of submitted NDS, SNDS, and CTAs
• Experience in dealing with multiple therapeutic areas and a number of Divisions at Health Canada is an asset
• Experience in NHPs and medical devices
• Experience in pharmacovigilance is an asset
• Start-up experience in pharmaceutical importer/distributer is an asset

ADDITIONAL SKILLS, KNOWLEDGE AND/OR ABILITIES:
• Knowledge of Canadian regulations (Food and Drugs Act and Regulations), Good Manufacturing Practices, Drug Establishment Licensing
• Ability to liaise with Health Canada
• Demonstrates problem solving ability and generates alternative solutions prior to elevation of issues to senior management
• Able to interpret and assess impact of new regulatory requirements
• Able to deal with issues of critical importance such as potential recall scenarios and provide advice
• Strong interpersonal, analytical and organization skills

Disclaimer: The above statements are intended to describe the general nature and level of work performed by employees assigned to this job. They are not intended to be an exhaustive list of all duties, responsibilities, and qualifications. Management reserves the right to change or modify such duties as required.

How to Apply:

Please visit the company website by following the below link and submit your resume -

https://www.miravohealthcare.com/opportunities/senior-manager-regulatory-affairs/