Position Overview

Our rapidly expanding team is seeking a **Senior Regulatory Affairs Associate** to support the regulatory affairs and clinical operations teams located in Guelph, ON. The **Senior Regulatory Affairs Associate** will provide regulatory leadership and support for various domestic and international projects. The main responsibilities of the successful candidate will include the oversight and preparation of various regulatory submissions to support clinical trials and market access while ensuring compliance with applicable global policies, procedures and regulatory guidelines.

Primary Responsibilities

- Prepares of regulatory submissions and related documentation to Health Canada, U.S., and other Regulatory Agencies, including CTA, IND, NDS, NDA, Medical Device applications, etc., according to current Agency requirements
- Interacts with internal and external groups to provide regulatory affairs consultative support for projects
- Initiates and manages regulatory affairs projects to ensure content complies with emerging or new requirements
- Identifies gaps in submission dossier to meet local requirements
- Leads and provides guidance in the development and implementation of global and local regulatory strategies
- Liaises with functional areas to coordinate and compile information required for regulatory documentation
- Ability to communicate and resolve any complex issues and activities related to regulatory submissions
- Interprets and makes decisions relating to regulatory guidelines and policies
- Advises management on changes to regulations, standards and legal stipulations, and SOPs are updated to reflect such changes
- Liaises with Health Canada and other regulatory agencies as needed
- Keeps abreast of domestic and global regulatory trends, laws and movements
- Maintains positive and cooperative communications and collaboration with all internal and external stakeholders
- Other duties as required and as training and experience allow
- Maintains an attitude and philosophy consistent with the Company's standards

Core Competencies:

- Proficient knowledge of new product and process development, current regulatory issues and regulations in Canada and the U.S. for prescription and non-prescription drugs, biologics, and medical devices preferred
- Excellent organizational time management and communication skills
- Excellent interpersonal and public relation skills with ability to work well in a team
- Solid problem-solving skills with an ability to identify solutions to problems under critical deadline constraints
- Strong technical writing skills, and ability to review and critique regulatory documents

- Ability to work independently with efficiency and accuracy and high attention to detail
- Computer literacy with MS Office and Adobe Acrobat

Qualifications

- Bachelor’s degree in a scientific discipline or equivalent qualification
- Regulatory affairs certificate or post-graduate diploma in Regulatory Affairs is preferred
- Minimum 5 years specific experience in regulatory sciences, with dossier writing/submission experience

We thank all candidates for their applications, however, only those candidates selected for an interview will be contacted.

Please apply: swilkinson@nutrasource.ca (HR Manager)