JOB DESCRIPTION

Senior Specialist, Regulatory Affairs

Department	Regulatory Affairs, Quality and Compliance
Direct Supervisor	Associate Director, Regulatory Affairs and Pharmacovigilance
Management of Team	Not applicable

Position Summary

The incumbent provides support to the regulatory team with all submissions filed to the health authorities aligned with the global regulatory strategies in support of these filings for new and approved products; assists with information requests for dossiers under active review; and ensures that marketing authorizations for company products are maintained as per applicable Federal Regulations and Guidance in various jurisdictions and throughout the product(s) lifecycle. We are seeking a talented and experienced regulatory affairs subject matter expert who is excited to join a dynamic and growing organization and who is committed to deliver excellence in all projects under their responsibility.

Key Responsibilities

- ***Support all regulatory activities related to company product(s)***
  - Manages regulatory activities to obtain and maintain Marketing Authorizations from FDA, Health Canada, EMA and other health authority regulations as applicable for commercial products.
  - Assists with the compilation, authoring, review and submission of dossiers to regulatory authorities and ensures documents meet applicable regulatory requirements.
  - Provides regulatory input to the development and implementation strategy for new products/projects.
  - Assists to provide regulatory guidance regarding the documentation needed and requirements for regulatory submissions per applicable guidelines.
  - Assists to provide regulatory support and expertise for early phase clinical trials; and pre-IND/clinical development/scientific advice meetings with regulatory Agencies; and the filing of IND/NDA/BLA and related submissions to FDA, EMA, Health Canada and other health authorities as applicable.
  - Assists with/ coordinates the preparation of responses to information requests from health authorities; and subsequent follow-ups with regulatory agencies to maintain and update existing marketing authorizations.
  - Facilitates approval of new product licenses, indications and dosage strengths.
  - Supports regulatory activities relating to product launches; maintains compliance of existing assigned product licenses with applicable health authority regulations.
  - Participates and supports Global RA for applications filed under the EU systems, namely Mutual Recognition and Centralised procedures.
  - Maintains local RA databases and global compliance tracking systems to record license information (new indications, changes in indications, changes in product specifications, changes in licensing, new products and progress with development of new products).

- Provides support to various partners, CROs and US/EU Agents to support registration of Theratechnologies' product(s) and Market Authorizations in other territories/ countries; and liaises with the respective Health Authorities as needed.
- For commercial products, reviews and approves proposed change controls from a regulatory perspective as per FDA, Health Canada and EMA regulations and guidance.
- Assists with the coordination of Product Recall activities and necessary regulatory actions.
- Provides regulatory support and guidance to internal and external customers.
- Analyzes product information, compiles and communicates annual notifications to Health Canada.
- Maintains current knowledge of relevant ICH, FDA, Health Canada, EMA and other health authority regulations as applicable.
- Ensures that regulatory guidance documents and regulations, as well as internal procedures are followed in order to maintain regulatory compliance.
- Fosters good relations with the respective Health Authorities.

- ***Execution of regulatory dossier preparation, reviews and audits***
  - Reviews and updates product labels, product monographs and labelling / packaging artwork.
  - Prepares and reviews INDs, NDAs, BLAs, PSURs/PADERs, Annual Reports, and updates to Investigational Brochures to Regulatory agencies.
  - Assists with the preparation of DEL amendments, Annual Licence Renewals, Notifiable Changes, and PMPRB forms for submission to Health Canada.
  - Assists with the preparation of post-approval variations, extensions and renewal of MAA/ market authorizations with EMA.
  - Assists the team with health authority inspections, internal and external audits according to the approved audit plan/schedule, and with supplier audits as necessary.
  - Reviews reports and other regulatory documentation from Contractual Research Organisations (CROs).

- ***Point of contact for regulatory documentation***
  - Provides support to internal departments to ensure regulatory compliance with regulations in respect of company products.
  - Produces, reviews and submits various documents/reports related to regulatory submission requirements.
  - Assists with the writing of Standard Operating Procedures (SOPs) pertaining to the regulatory function and revisions thereof and ensures their adherence.

- ***Performs any other related tasks as assigned by management***

External Customers

- Health Canada, US FDA, European Medicines Agency (EMA) and other government regulatory agencies
- US, Canada and EU Regulatory Agents and Contractual Research Organisation (CROs)
- External Consultants

Qualifications Required

- B.Sc./ Life Sciences University degree in a scientific field or equivalent, or other scientific background that is deemed appropriate
- Minimum 5 years of experience in regulatory affairs in pharmaceutical drugs and /or biologics in the pharma industry
- Regulatory experience in medical device industry is an asset
- Excellent knowledge and comprehension of Canadian and US Regulations; good knowledge of European regulations is an asset
- Regulatory affairs experience in HIV and Oncology is an asset, or other therapeutic areas
- Good understanding of preclinical and clinical research is an asset
- Prior experience in regulatory audits is an asset
- Experience of managing external partners/CROs is an asset
- Experience with eCTD publishing is an asset
- Good knowledge of Word, Excel, Power Point and Outlook
- Ability to conduct Internet searches in respect of regulatory matters
- Demonstrated skill in managing multiple projects/priorities
- Effective communication and negotiation skills
- Bilingual in French and English, oral and written

Personal Qualities for all Staff

- Ability to set goals and meet deadlines
- Ability to prioritize
- Ability to generate ideas and find solutions
- Ability to work independently
- Able to work well in a team environment and communicate well
- Versatility and flexibility

Personal Qualities Specific to Position

- Interpersonal ability and diplomacy
- Attention to detail and quality
- Good stress management
- Ability to influence others
- Multi-tasking
- Interpersonal leadership
- Planning and organizational skills
- Available for occasional business travel