JOB DESCRIPTION

Specialist, Regulatory Affairs

Service	Regulatory Affairs, Quality and Compliance
Direct Supervisor	Manager, 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 (e.g. FDA, Health Canada, European Medicines Agency) aligned with the regulatory strategies in support of these filings; assists with information requests for dossiers under active review; and ensures that marketing authorizations are maintained as per applicable Federal Regulations and Guidance in various jurisdictions and throughout the product(s) lifecycle.

Key Responsibilities

- Support all regulatory activities related to company product(s)
  - ✓ Manages regulatory activities to obtain and maintain Marketing Authorizations for commercial products for FDA, Health Canada, EMA and other health authority regulations as applicable
  - ✓ Assists with the compilation, writing, review and submission of dossiers to regulatory authorities and ensures documents meet applicable regulatory requirements
  - ✓ Assists in providing regulatory guidance regarding the documentation and requirements for regulatory submissions
  - ✓ Assists in providing regulatory support and expertise for early phase clinical trials; pre-IND and clinical development 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
  - ✓ 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.
  - ✓ Assists with the coordination of Product Recall activities and necessary regulatory actions
  - ✓ Provides regulatory support and guidance to internal and external customers
  - ✓ Assists with/ coordinates the preparation of responses to questions and inquiries from health authorities; and subsequent follow-ups with regulatory agencies to maintain and update existing marketing authorizations
  - ✓ 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
  - ✓ Assists the team with internal audits as per approved schedule, and with supplier audits

- Execution of regulatory reviews and audits
  - ✓ Reviews and updates product labels, product monographs and labelling / packaging artwork
  - ✓ Assists with the preparation of DEL amendments, Annual Licence Renewals, Notifiable Changes, and PMPRB forms for submission to Health Canada
  - ✓ Prepares and reviews INDs, NDAs, BLAs, PSURs/PADERs, Annual Reports, and updates to Investigational Brochures to Regulatory agencies
  - ✓ Assists with internal and external audits according to the approved audit plan
  - ✓ 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) 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

- University degree in a scientific field (e.g. B.Sc. in Life Sciences) or other scientific background that is deemed appropriate
- 3-5 years experience in the pharmaceutical industry, specifically in regulatory affairs in pharmaceutical drugs and /or biologics
- Regulatory affairs experience in Oncology is an asset and/or other therapeutic areas
- Good understanding of, or experience in laboratory research, preclinical and clinical research is an asset
- Prior experience in regulatory audits is an asset
- Experience of managing external partners/CROs is an asset
- Excellent knowledge and comprehension of Canadian and US Regulations; good knowledge of European regulations is an asset
- Good knowledge of Word, Excel, Power Point and Outlook
- Ability to conduct Internet searches in respect of regulatory matters
- 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

Validated by: _____ Date: _____

Signature of direct supervisor: _____