Global Manager Regulatory Affairs, Oncology

Full Time, US-Based Remote

Job Summary

The incumbent provides support to the Director, Global Regulatory Affairs and Pharmacovigilance 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 granted and maintained as per applicable Federal Regulations and Guidances in various jurisdictions and throughout the product(s) lifecycle. The strategic and operational scope of this role is well suited to an experienced regulatory professional with expertise first and foremost with US FDA submissions with particular focus in Oncology, for whom the strategic regulatory pathway and operational execution of the filings is well-mastered optimizing the use of existing FDA regulatory approaches to facilitate the development and expedite the review of drugs to treat serious conditions that fill unmet medical needs. The candidate will play a meaningful role to get important new drugs to patients earlier and also support similar filings in other major regulatory jurisdictions within this therapeutic area.

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, EMA, Health Canada and other health authority regulations as applicable
    - Assists with the writing, compilation, review and submission of dossiers to regulatory authorities and ensures documents meet applicable regulatory requirements
    - Assists to support the authoring of submission documents, preclinical, clinical, CMC and /or labelling
    - Provides regulatory guidance regarding the documentation and requirements for regulatory submissions
    - Provides regulatory support and expertise for early phase 1, Phase 2 and 3 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, EMA, Health Canada, and other health authority regulations as applicable
    - Stays informed of regulatory procedures, guidance documents, standards, and changes in the regulatory environment for innovative drugs and assists to revise internal procedures as required.
    - Ensures that regulatory guidance documents and regulations, as well as internal procedures are followed in order to maintain regulatory compliance

- Execution of regulatory reviews and audits
    - Reviews and updates product labels, US Prescribing Information, 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 as applicable
    - Prepares and reviews INDs, NDAs, BLAs, PSURs/PADERs, Annual Reports, and updates to Investigational Brochures to Regulatory agencies
    - Assists with internal and external audits or Health Authority Inspections as per approved schedule/audit plan, and also provides support with supplier audits
    - Reviews reports and other regulatory documentation from Contractual Research Organisations (CROs) and/or consultants

- 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 Partnerships

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

Qualifications Required

- University degree in a scientific field (e.g. B.Sc. in Life Sciences) or equivalent background
- Minimum 8 years of experience in regulatory affairs within the pharmaceutical industry, with innovative pharmaceutical drugs and /or biologics, and in the field of Oncology (mandatory)
- US regulatory experience with the FDA is required
- Very good knowledge and understanding of regulatory pathways in support of the registration and approval of Oncology drugs.
- Direct experience with FDA Project Orbis and/or Project Optimus is an important asset
- Good understanding of, or experience in laboratory research, preclinical and clinical research is an asset
- Prior experience in regulatory inspections is an asset
- Experience managing external partners/CROs is an asset
- Excellent knowledge and comprehension of US Regulations and Guidances; and good knowledge of European and Canadian regulations
- 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 Specific To Position

- Interpersonal leadership and diplomacy
- Ability to set goals, prioritize and meet deadlines
- Excellent planning and organizational skills
- Attention to detail and quality oriented
- Ability to multi-task
- Ability to generate ideas and find solutions
- Ability to work independently
- Able to work well in a team environment and communicate well

- Ability to influence others
- Versatility and flexibility
- Good stress management
- Available for occasional business travel

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 both independently and in a team
- Team spirit and desire to help each other succeed
- Versatility and flexibility

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