Role Profile

Director, Regulatory Affairs

REPORTS TO: Vice President, Scientific Affairs

WORK LOCATION/TIMES:

1. Head Office or other locations, as defined.
2. Working hours in accordance with Company policy or as required.
3. Travel may be required.

OVERVIEW:

As a senior member of the Scientific Affairs management team, you will be responsible for regulatory compliance, product registration, labeling, and advertising compliance reporting for the company in Canada, USA and internationally.

Specific responsibilities include:

- Formulate and lead regulatory strategy for development projects or marketed products with a focus on creativity and innovation, maximizing the business benefit balanced with regulatory compliance.
- Proactively communicate regulatory strategies, key issues and any other critical topics throughout the life cycle.
- Direct and oversee submission activities (planning, authoring, reviewing, coordination, submission) and make quality regulatory decisions, balancing risks and benefits.
- Facilitate submission approvals through effective communication and negotiation with partners, government agencies, and project team.
- Build positive working relationships with partners and government agency contacts.
- Provide partners with advice in response to their queries, based on regulatory experience and area of expertise.
- Maintain Establishment Registrations, Drug Listings and Licenses both Domestic and International.
- Post market submission maintenance activities (Annual reports, safety reports, etc.).
- Review and approve domestic and international product labeling, promotional materials, product packaging, and advertising copy.
- Conduct regulatory assessments for changes to marketed products.
- Review quality documents (operational procedures, work instructions, validations, etc.) including but not limited to protocols, for appropriate scientific rationale and for adherence to regulatory requirements/guidance, development strategy.

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POSITION PRE-REQUISITES:

- M.S. in Regulatory Science or a related technical field.
- Minimum 10 years knowledge and experience in Regulatory Affairs in the manufacture and distribution of pharmaceutical products, biologics and medical devices.
- Thorough understanding of Canadian and US drug regulations, guidelines and cGMPs; knowledge of EU and ROW requirements is an asset.
- Practical knowledge of pharmaceutical industry regulatory affairs throughout the product lifecycle, with awareness of preclinical, clinical, commercialization, and operations.
- Capability to respond to changes in the regulatory environment and make strategic recommendations to minimize risk to the business.
- Ability to interpret Regulatory Agency policies, guidance and correctly apply them as appropriate in product development.
- Ability to take innovative ideas from proof of concept to promote a successful product regulatory submission and increase probability of regulatory approval.
- Ability to review detailed scientific information and assess whether technical justifications are presented clearly and conclusions are adequately supported by data.
- Ability to assess project risks, and where appropriate, recommend contingency plans and strategies to mitigate regulatory risks.
- Excellent oral/written communication, leadership, organizational and interpersonal skills