

Regulatory Affairs Project Manager, Oncology/Infection

About AstraZeneca:

As one of the world's leading pharmaceutical companies, our business is focused on providing innovative, effective medicines that make a real difference in important areas of healthcare.

Responsibilities:

Pay Grade: 7

This is a regular full time position

The Regulatory Affairs Project Manager is responsible and accountable for the achievement of all objectives pertaining to their role within the Oncology and the Infection Therapeutic Areas

Accountability

1. Provide regulatory input and direction to Canadian Cross Functional Team and Global regulatory teams in order to deliver regulatory strategies, optimal Health Canada approvals (time and quality), maintain compliance and maximize a product's potential and lifecycle in the Canadian marketplace.
2. Actively support the RA department to maximize efficiency, performance and productivity.
3. Ensure main role responsibilities are delivered in compliance with AZ Corporate responsibility policies.

Responsibilities

- Lead the development and implementation of regulatory strategic plans including Regulatory Strategy Documents
- Preparation, submission and negotiation of approvals of NDSs, SNDSs and NCs
- Maintenance of regulatory compliance of approved products
- Planning and conducting Health Canada meetings
- Development and finalization of Health Professional and Public Communications
- Review and approval of promotional materials and press releases
- Compile responses to ATI requests
- Initiate, review and approve artwork
- Provide strategic and decisive regulatory/business expertise across the organization as required
- Influence the global development of products, representing Canadian regulatory environment and market, to mitigate regulatory risks in the development plans
- Lead or participate in cross-functional and external initiatives
- Ensure regulatory submissions and documents are compliant with both HPFB and AZ requirements and standards (e.g., Electronic submission processes)
- Provide comments on emerging Canadian regulations/policies/guidelines/initiatives/surveys
- Provide guidance and support to junior staff members (associates, students and assistants)

Qualifications

- B.Sc. or equivalent in a related (health science) discipline; advanced degree (M.Sc. or Ph.D.) considered an asset
- Strong knowledge of the Canadian regulatory environment and Health Canada regulations, policies and guidelines
- Minimum 3-5 years regulatory experience in the brand name pharmaceutical or biotechnology industries; prior experience with Oncology & Infection an asset.
- Negotiation skills
- Excellent project management, time management and organizational skills (ability to manage multiple projects and priorities effectively)
- Excellent written and verbal communication skills
- Business acumen, such as writing business proposals and project plans
- Risk identification and management
- Interpersonal and relationship building skills
- Ability to participate in collaborative teamwork
- Detail oriented
- Problem solving ability and innovative strategic thinking
- Proficient in the use of MS Office
- Customer-focused

Interviews:

Only candidates who meet the minimum requirements as outlined above, will be interviewed. Internal candidates who are interested in this position must inform their manager before they apply.

We invite you to join our Canadian operations to discover more about the powerful effect that team can have on your career. If you feel you meet the minimum qualifications specified above, please apply online at: www.astrazeneca.ca under Join Us and Apply to AstraZeneca.

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