Position: Manager, Regulatory Affairs

Location: Ottawa

BWXT ITG Canada, Inc. provides its customers, who conduct life-saving medical procedures for patients around the world, the benefit of decades of experience in the development, manufacturing, packaging and delivery of medical isotopes and radiopharmaceuticals. Headquartered in Kanata, Ontario, BWXT ITG Canada, Inc. employs over 150 highly-skilled people in Kanata and Vancouver, British Columbia. BWXT ITG Canada, Inc. is part of the BWXT nuclear power segment (NPG) of BWX Technologies, Inc.

Accountable to the Vice President and General Manager, this is a leadership position responsible for the development and implementation of regulatory strategy and successful timely registration of drug products, active pharmaceutical ingredients and medical devices for global markets.

Supporting the strategic objectives of the company, leads the development and execution of the regulatory strategy to ensure registration and ongoing compliance with regulatory requirements for products developed and manufactured by the company, or in support of contract manufacturing requirements.

- Establishes the regulatory filing strategy and requirements for products developed and/or manufactured by the company. Is able to establish credible regulatory timelines and ensure the leadership team and resources are available to support meeting the timeline.
- Represents the regulatory group on product development teams and the core project team communicating regulatory requirements for product development.
- Works collaboratively with the product development team lead and functional area representatives to provide strategic regulatory input to key development documents and study reports, as required, and ensures that key deliverables supporting regulatory strategy are provided in alignment with program timelines and management expectations.
- Coordinates, oversees and prepares submissions to be filed with the Regulatory Authorities in multiple jurisdictions for radiopharmaceuticals, active pharmaceutical ingredients (APIs) and devices, both proprietary and in support of customer filings.
- Ensures that new regulatory information is appropriately reviewed by subject matter experts, performs regulatory risk assessments as required, and communicates proposed program modifications and impact to the defined regulatory strategy to leadership. Ensures adequate training is prepared and delivered to the organization as a result of existing or new regulatory requirements to maintain organizational compliance.
- Maintains direct liaison with government authorities on scientific issues during the review process as well as on any matter relating to the manufacture of products.
- Seeks opportunities to participate in regulation development and implementation.
- Maintains consistent oversight of deliverables and ensures issues are escalated when needed and encourages resolution at the appropriate level. Plays a key role in development and implementation of appropriate systems, processes and standards.
- Ensures records are maintained, ensures all new and renewal applications are filed as required.
- Manages pharmacovigilance activities for the organization.
- Is the primary host for audits carried out by regulatory agencies and may be the host or assist the host with customer audits.

- Demonstrated ability to manage a regulatory recall, including concise and rapid decision making, managing implementation of the process and managing communication with regulatory authorities, and overseeing communication with customers.
- Provides oversight for any planned advertising/marketing of regulated products ensuring compliance with all regulatory requirements.
- Performs other duties as appropriate.

KNOWLEDGE & EXPERIENCE

EDUCATION AND EXPERIENCE

- Normally an advanced University Degree in life sciences or a health care related discipline plus 10 to 12 years working experience. Several years' experience in Regulatory Affairs or equivalent background.
- Experience with radiopharmaceutical, active pharmaceutical ingredients or medical devices in quality assurance, quality control or manufacturing is an asset.
- Experience working directly with the FDA and/or Health Canada on regulatory filings/strategy is required.

KNOWLEDGE AND ABILITIES

- Experience with designing and executing development strategies for drugs and devices.
- Ability to influence the leadership team and the rest of the organization.
- Ability to understand and evaluate complex scientific data and communicate regulatory risks with clarity, honesty and integrity.
- Owns the results within their responsibility, able to achieve buy-in and understanding across different functional areas within the company
- Experience with electronic submissions/the electronic submission process
- Effective communication skills, superior written communication
- Experience managing pharmacovigilance
- Knowledge of how regulatory agencies operate, structure and process
- Negotiation skills

RECOMMENDATIONS AND DECISIONS

- Must implement strategy for submissions for the business to ensure acceptability and expedient approval.
- Must work cross functionally with internal and external stakeholders to ensure that required regulatory filing and licenses are obtained and maintained.

If you are interested in exploring this opportunity, please reach out to us for a confidential conversation.

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