
Innovative medicines for people and animals have for more than 130 years been what the research-driven pharmaceutical company Boehringer Ingelheim stands for. Boehringer Ingelheim is one of the pharmaceutical industry's top 20 companies and to this day remains family-owned. Day by day, our employees create value through innovation for the three business areas human pharmaceuticals, animal health and biopharmaceutical contract manufacturing.

# *Associate, Established Products and Regulatory Operations (2 year contract)*

Burlington, Ontario

In collaboration with the Manager, to plan, manage and coordinate the filing and approval of high quality regulatory submissions of established products to Health Canada and ensure product compliance through relevant regulatory registrations and interactions/negotiations with internal stakeholders and Health Canada.
Responsible for independently managing and performing the activities and interactions with the Central Service Unit (CSU)related to the compilation and archiving of high quality regulatory submissions (both hard and electronic format) in a timely manner for all BI HP products.

**Project management:**

- Independently maintain submission publishing process standards, execute and monitor/track progress of submission plans to effectively meet submission deadlines, by interacting with relevant stakeholders, and liaising with CSU (third party) to track progress against these plans.
- Review compilation and publishing plans to ensure compliance with applicable Health Canada regulations and guidelines, as well as BI Regulatory Operations work practices and guidelines.
- Provide business support for the workflow of regulatory submission documents through the document management system, including archiving (hard copy and electronic copy).
- Under close supervision of the Manager, develop project/action plans and implement all activities as directed, to achieve the timely and efficient registration of high quality submissions of Established HP Products (post-market variations) within timelines specified by Corporate Office or local Management.

**Continuous Improvement:**

- Foster operational excellence by keeping the department and Global Regulatory Operations team(s) informed on Health Canada eCTD/non-eCTD updates and ongoing Health Canada Pilot projects as well as its potential business impact.
- Lead/user for many RA systems (BIRDS, IDEA, SLCI (AMT/RSPP)), identifying business/user requirements, testing and participating in the completion of appropriate systems documentation.
- Participate in the development and implementation of standards, and procedures related to the publishing, review, transmittal, and archiving of electronic regulatory documentation and conduct associated trainings; recommend and help implement associated process improvements.

**Technical Expertise:**

- Provide expertise in electronic information management and submission tools and strategies to assist other members of Regulatory Affairs and third party (CSU) during submission preparation and delivery.
- Utilizes systems, tools and key technologies for electronic document capture, generation, manipulation, scanning, and QC.

**Quality:**

- Maintain and administer in a timely manner the global regulatory information and documentation databases/systems to ensure all KPIs are met (CPD3, RSPP).
- As directed, responsible for the review and timely response for the Access to Information Requests received by Health Canada (E2B reports).

## Qualifications

- Bachelor's degree in life science and/or computer science or equivalent work experience in drug regulatory affairs in the pharmaceutical industry/health authority (2-5 years) is required.
- Certificate in Canadian Drug Regulatory Affairs from recognized institution is an asset.
- Sound knowledge of the Canadian Food and Drugs Act and Regulations, and Health Canada policies and guidelines.
- Thorough knowledge of eCTD/NeeS experience/understanding (experience with word processing and publishing tools).
- Advanced knowledge of electronic filing and archiving systems in document management system as well as other business office software applications (e.g Microsoft Word, Outlook).
- Strong attention to detail and excellent project management skills, planning, organizational and time management skills.
- Strong communication and negotiation skills.
- Ability to work independently or in a team environment and complete work within strict deadlines.

For more information please visit www.boehringer-ingelheim.ca

**Applications for this position will be accepted until October 15, 2019**