

**Regulatory Affairs Associate
(Animal Health Division)
1 Year Contract**

Description of the role:

For projects assigned by the Head of Veterinary Affairs, the Regulatory Affairs Associate independently prepares, reviews and files high quality regulatory animal health product pre- and post-approval submissions and ensures product compliance through proactive interactions with Canadian/international BI personnel as well as the Canadian Authorities. Consults with management, business units and other functional areas with respect to Canadian licensing options and timelines. Supports the QA Department on regulatory assessment of QA-related issues.

Responsibilities:

The Regulatory Affairs Associate

- Proactively develops action plans and implements all activities, to achieve the timely and efficient registration of high quality submissions (market authorizations and post-market variations) for all assigned BI veterinary products within timelines prioritized and specified by the Canadian Animal Health Management Team and Veterinary Affairs Manager. Leads interactions between Canadian/international BI personnel and the Canadian Animal Health Authorities (CFIA & VDD).
- Ensures entry and quality of product documentation for Canadian AH products in corporate systems such as CPD-3, WWPPS and BIRDS.
- Supports the QA Department in ensuring compliance of all permits and registrations required for the importation and distribution of BI animal health products in Canada.
- Supports QA Department and in preparing and leading BICL AH participation in quality inspections from regulatory agencies and from Corporate and supporting the CAPA plans developed and implemented following observations.
- Supports global manufacturing and Canadian QA group in the assessment of proposed Change Controls.
- Adheres to all comprehensive BICL and Global, Animal health compliance requirements.
- Has regular interaction with the Business Units to ensure understanding of their needs and provide required information on the registration status of the products.

Qualifications:

- Minimum Education/Degree Requirements: Bachelor's Degree (Biochemistry, Biology, Biopharmaceuticals, Chemistry, Medicine, Pharmacology, Veterinary Medicine)
- A minimum of 3 years' experience in a Regulatory position within the pharmaceutical industry

Required Capabilities:

- Excellent Project Management skills, i.e. superior organizational, written and oral communication skills, the ability to work independently as well as to collaborate effectively with team members locally and internationally to meet strict deadlines.
- Thorough knowledge and understanding of Canadian regulations/guidelines concerning development, manufacturing and distribution of pharmaceutical, veterinary health products and biological products (GMPs, Food and Drug Regulations & CFIA regulations).
- Good working knowledge of business office software applications including Microsoft Office Word, Excel, PowerPoint and capacity to be trained to use specialized databases.
- Fluent in English, knowledge of French is an asset.
- Basic knowledge of medical terminology.

About Boehringer Ingelheim (Canada) Ltd.

Improving the health and quality of life of patients is the goal of Boehringer Ingelheim, a research-driven pharmaceutical company. In doing so, the focus is on diseases for which no satisfactory treatment option exists to date. The company therefore concentrates on developing innovative therapies that can extend patients' lives. In animal health, Boehringer Ingelheim stands for advanced prevention.

Family-owned since it was established in 1885, Boehringer Ingelheim is one of the top 20 companies in the pharmaceutical industry. Some 50,000 employees create value through innovation daily for the three business areas human pharmaceuticals, animal health and biopharmaceuticals. In 2017, Boehringer Ingelheim achieved net sales of nearly 18.1 billion euros. Research and development expenditure, exceeding three billion euros, corresponded to 17.0 per cent of net sales.

As a family-owned company, Boehringer Ingelheim plans in generations and focuses on long-term success. The company therefore aims at organic growth from its own resources with simultaneous openness to partnerships and strategic alliances in research. In everything it does, Boehringer Ingelheim naturally adopts responsibility towards mankind and the environment.

The Canadian headquarters of Boehringer Ingelheim was established in 1972 in Montreal, Quebec and is now located in Burlington, Ontario. Boehringer Ingelheim employs approximately 600 people across Canada.

More information about Boehringer Ingelheim can be found at <http://www.boehringer-ingelheim.ca/> or in our annual report: <http://annualreport.boehringer-ingelheim.com>

For complete details about this career opportunity and to apply, visit:

<https://careers.boehringer-ingelheim.com/>

(Enter "Canada" in the Location field to narrow your search)

Create an Account as a New User to apply on-line, create job alerts, and more.

Applications for this position will be accepted until January 5, 2019.

We thank all applicants for your interest in this opportunity, however only those candidates selected for an interview will be contacted.