

Compliance Associate Quality Assurance (Contract Position)

Description of the role:

The Quality Compliance Associate (QCA), ensures compliance with all relevant Health Canada, Canadian Food Inspection Agency & Corporate regulatory requirements. Using Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) is a critical success factor for commercial product supply to our customers. The QCA will contribute to the maintenance of the Quality Management System (QMS) by ensuring that all external (i.e. GMP, GDP) and internal BI requirements (i.e. Policies, SOPs, OCS, OCP & ACP) are followed. The QCA supports the Senior Quality Compliance Associate and the QA Manager.

Responsibilities:

The Compliance Associate will:

- Support and maintain document management system for local/regional SOPs/working instructions
- Support that applicable Corporate Procedures are transferred into local SOPs/Working instructions
- Participate in regular self-inspection programs to drive continuous improvement and ensure local readiness for corporate or authorities inspections
- Support completion of CAPAs in a timely manner
- Perform GMP/GDP audits at suppliers and external partners
- Ensure product availability by reviewing 3PL documents including inbound product inspections, sampling finished goods, drug products and all packaging components and samples
- Provide support for technical product complaints and deviations.
- Ensure batch disposition (release/reject) for distribution if applicable as per local regulations
- Provide new product launch support
- Assess product quality through review of documentation and ensures that sales/marketing requirements are met
- Provide assistance by requesting certificates to ensure compliance with registration requirements
- Provide assistance with Stability Program, Annual Product Quality Review.
- Maintain a) Master documents for all products, b) annual batch record program, c) Reference Chemical standard Program, d) coordinate sending samples with 3PL to external laboratory, e) retention samples program
- Ensure GMP/GDP & regulatory compliance of products/services which are outsourced to external parties.
- Support the QA Senior Compliance Associate and QA Manager on audits, inspections, complaints, etc. as needed.

Qualifications:

- Strong knowledge in government regulations in order to ensure compliance of external and internal QA requirements.
- Detail oriented and organized to ensure compliance in all areas of QA
- Related experience in QA in the pharmaceutical and animal health industry
- B.Sc in pharmaceutical, or chemistry, or related discipline with focus in GMP regulated environment specialized in QA (> 2 years)
- Knowledge of GMP/quality regulations and compliance regulations with practical experience in QC/QA in the pharmaceutical and animal health vaccine industry
- Experience with GMP audits.
- Knowledge with performing Stability Data Review
- Knowledge with performing Annual Product Quality Review

- Experienced in assessing Returned Goods from the market.
- Strong organizational, analytical and problem solving capabilities
- Strong, proactive communication and negotiation skills to facilitate team-oriented results
- Ability to travel for business, as needed (5%).

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 March 21, 2019 (6 p.m. EST).

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