



## JOB POSTING

**POSITION:** Manager, National Regulatory Affairs  
**STATUS:** Full Time  
**LOCATION:** Kohl & Frisch Limited (Keele)  
**REPORTS TO:** V.P. Supply Chain

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### Primary Role of this Position

The National Regulatory Affairs Manager is responsible for managing all narcotic, pharmaceutical medical device and OTC related federal licensing activities to ensure on-going compliance. The position is also the main company contact and liaison with Health Canada.

The National Regulatory Affairs Manager shall ensure operations are compliant to applicable GMP standards as defined by GUI-0001 "Good Manufacturing Practices" and GUI-0069 "Guidelines for Temperature Control of Drugs Products during Storage and Transportation".

### Major Responsibilities

1. Regulatory:
  - a. Ensure appropriate licensing is obtained and maintained as required from Health Canada for all Kohl & Frisch operations across Canada
  - b. Single point of contact for all Health Canada inquiries and inspections
  - c. Oversight and/or preparation of all responses to all Health Canada inspection reports including any action plans required for compliance
  - d. Maintain working knowledge of all current regulatory changes within the industry and ensure processes are adjusted as necessary
  - e. Support the DCs on all scheduled and random Health Canada inspections
  - f. Collaborate, as may be required, with all relevant internal functions to ensure compliance with Health Canada regulations
  - g. Proactively identify potential contravention of Health Canada Regulations, taking measures to apply corrective action; escalate unresolved issues for consideration by Executive Team as appropriate
2. Training:
  - a. Oversee the development of all necessary training material for applicable K&F staff (i.e. DCM, Transportation, QPICs, AQPICs, ARPICs, etc) on licensing, GMP and other regulatory areas
  - b. Assist, as required, with the delivery of any regulatory training
3. Procedural:
  - a. Ensure all Standard Operating Procedures remain up-to-date and are reviewed on an annual basis (or more frequently if required)
  - b. Suggest and assist in implementing relevant continuous improvement opportunities to SOP's and WI's in an effort to apply a standard approach across the DC and transportation network
  - c. Recommend, develop and implement an internal audit protocol to ensure compliance with SOP's and Health Canada regulations
  - d. Provide guidance to all K&F staff on any regulatory compliance issues
  - e. Provide input into processes related to QPICs, AQPICs & ARPICs to ensure consistency and compliance with Health Canada regulations
  - f. Develop, implement and maintain effective and efficient temperature control policies for product storage, handling and transportation
4. Communication:
  - a. Report all pertinent regulatory metrics to senior management (i.e. Inspection results, outstanding NAFs, etc.); provide interpretations and recommendations for continuous improvement
  - b. Provide an annual update (at a minimum) to the Executive Team on Health Canada Regulatory Affairs initiatives and any current or anticipated Health Canada policy or regulatory changes that could have an impact on K&F operations, making recommendations for proactive measures in meeting these requirements
5. Security
  - a. Nationally analyze internal operations and procedures to identify weaknesses in security related to regulatory requirements

### **Key Stakeholders / Relationships**

- DC Management – DC Managers, Operations Managers & Supervisors
- QPICs, AQPICs & ARPICs
- Transportation Management
- Inventory Management
- Manufacturer Relations
- Key Accounts & Sales

### **Education and Experience**

- Bachelors of Science Degree or in a related field
- 8-10 years of experience in a similar position

### **Qualifications**

- Knowledge of Health Canada's GMP Regulations applied to wholesalers and distributors
- Knowledge of Narcotic Control Regulations, Precursor Control Regulations, Medical Device and Natural Health Product Regulations
- Strong knowledge of the pharmaceutical industry and cold chain shipping requirements
- Strong organizational skills, presentation skills and negotiation skills
- Proactive and a strong team player

### **How to Apply**

Interested applicants should forward their **Resume and Cover Letter** to Mary Slaczka at [msslaczka@kohlandfrisch.com](mailto:msslaczka@kohlandfrisch.com) as soon as possible.

*Kohl and Frisch would like to thank all applicants for their interest. Only those candidates who are selected for an interview will be contacted.*