Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. Our products and services are used to help care for critically and chronically ill patients.

We are committed to putting essential medicines and technologies in the hands of people who help patients and finding the best answers to the challenges they face. We are dedicated to a higher purpose "caring for life" which drives excellence in everything we do.

Fresenius Kabi has a long history in clinical nutrition and is one of the world's leading suppliers of lipid emulsions for parenteral nutrition with an exciting new portfolio.

We are currently seeking a full-time Regulatory Affairs Manager to join our team, at our corporate office in Toronto (165 Galaxy Blvd.).

Responsible for managing submissions portfolios and all decisions relating to the regulatory pathway to obtain approvals. Additionally, contributes to the drug development process by providing Canadian submission requirements to Product Development teams.

Duties include:

- Directs personnel in the preparation of regulatory submissions for Health Canada, including ANDS's, S/NDS's, Notifiable Changes, DIN Submissions, Deficiency Responses, etc.
- Reviews Canadian submissions for quality and completeness
- Reviews provincial formulary submissions
- Prepares and/or reviews product labeling, product monographs, and marketing materials as required
- Liaise with Health Canada personnel, global and regional teams, internal and external organizations such as suppliers
- Controls prioritization of work of RA personnel under their responsibility to ensure prompt submission times
- Manages the RA review of change control documents
- Provides interpretation on complex regulatory guidelines and policies
- Manages outside consultants, including legal counsel, patent agents, and regulatory consultants on any matter required

QUALIFICATIONS

- Minimum Bachelor's degree in Life Sciences is required
- Minimum of 5 years experience in Canadian pharmaceutical regulatory affairs, with at least 2 years of management experience leading teams/people/projects
- Experience with IV generics. Experience with medical devices is an asset
- Detailed knowledge of Canadian regulatory requirements, including ICH policies and guidelines
- Intermediate computer skills required including MS Word, Excel, PowerPoint
- Strong leadership and time management skills
- Strong interpersonal skills (written and verbal) are required

If you are interested and qualified, we invite you to send your resume.

***** PLEASE INCLUDE THE JOB TITLE IN THE SUBJECT LINE WHEN APPLYING – Regulatory Affairs Manager***

Email: hrcanada@fresenius-kabi.com