Janssen Inc., member of the *Janssen Pharmaceutical Companies of Johnson & Johnson*, is currently hiring a **Regulatory Affairs Manager** for a **1-year contractual position** located in **Toronto, Ontario**.

Apply Here: https://bit.ly/2nftjUC

At *Janssen*, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, metabolic and chronic diseases and women's health. Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world. *Janssen Inc.* is a member of the *Janssen Pharmaceutical Companies of Johnson & Johnson.* Please visit www.janssen.com/canada for more information.

The **Regulatory Affairs Manager** will lead the regulatory activities to obtain and maintain product registration status in compliance with Canadian laws and regulations, as well as corporate policies and procedures. The **Regulatory Affairs Manager** will lead and support product registration and serve as the subject matter expert for Regulatory Affairs and provide guidance to local and global business partners. The **Regulatory Affairs Manager** will develop and implement regulatory strategies to meet project deliverables.

In this role, you will:

- Lead the preparation and compilation of regulatory submissions including New Drug Submissions (NDSs), Supplemental New Drug Submissions (SNDSs), Notifiable Changes (NCs), and ad hoc reports to Health Canada and maintain the life cycle of currently marketed products
- Focus only on therapeutic/labeling submissions.
- Lead the preparation and review of responses to Health Canada queries in relation to clinical efficacy and safety, clinical pharmacology, biopharmaceutics and preclinical subject matter (e.g. Clarifax, Notice of Non-Compliance [NON], and Notice of Deficiency [NOD]) in a timely manner.
- Lead interactions with Health Canada throughout the submission review cycle to ensure prompt regulatory approval, optimal labeling and implementation of local regulatory strategies.
- Collaborate with global regulatory teams and the Global Regulatory Affairs (GRA) function/teams to facilitate regulatory activities.
- Collaborate with internal stakeholders to ensure alignment of regulatory affairs strategy with business priorities, and to meet strategic business objectives and stretch goals/deadlines set out by the leadership team.
- Develop effective working relationships with experts to support regulatory strategies as needed.
- Manage emerging issues (e.g. new safety or quality finding) and associated risk communications to stakeholders.
- Provide regulatory guidance and input to internal stakeholders on messaging, promotional material review, and PAAB responses.
- Monitor the regulatory environment, interpret changes, analyze gaps and conduct impact assessment, and participate/lead implementation into systems/processes.
- Actively contribute to improving critical departmental processes and to initiatives to enhance the internal work environment.

Qualifications

- A minimum Bachelor's in Biological or related sciences is required. Bachelor's in Molecular/Cell biology an asset. Advanced degree preferred.
- A minimum of 3 years of Regulatory Affairs pharmaceutical or related experience is required.
- Experienced with preparation and compilation of New Drug Submissions (NDSs), Supplemental New Drug Submissions (SNDSs), Notifiable Changes (NCs) for Health Canada is required.
- Experience in the oncology therapeutic area is highly desirable.
- Experience preparing therapeutic/labeling submissions is highly desirable.
- Strong working knowledge of the drug development process is required.
- Strong knowledge of Canadian drug laws, regulations, guidelines and policies, and the Health Authority organizational structure and processes for the review and approval of drug submissions is required.
- Understanding of the application of laws, regulations, guidances and policies to specific projects is preferred.
- Ability to interpret and understand Regulations in the context of the scientific and commercial environment is preferred.
- Strong scientific writing skills are required.
- Ability to interpret and summarize clinical data is required.
- Ability to interpret basic biostatistics highly desirable.
- This one-year contractual position will be located in Toronto, Ontario and will require up to 10% travel.

Diversity and inclusion are central elements of the shared culture across the Johnson & Johnson Family of Companies. Attracting, developing and retaining a workforce that reflects the diversity of our customers and communities is essential to our success. We are committed to providing a respectful, inclusive and accessible work environment where all employees have the opportunity to achieve their potential.