Specialist, Regulatory Affairs - Montreal, QC

Note: The use of the masculine gender includes the feminine and is employed solely to facilitate reading.

Can you imagine a career that touches the lives of people everywhere? Can you imagine yourself working in a fast paced and dynamic workplace where rapid decision making, entrepreneurial initiatives, customer service and community become your new vision? A vision that drives our growth and success…if so, then Paladin is the place for you!

Paladin Labs Inc., headquartered in Montreal, Canada, is a specialty pharmaceutical company with over a hundred products in all therapeutic fields and ranging from new drugs to natural health products or generics and medical devices. Paladin is an operating company of Endo International plc, a global specialty healthcare company focused on improving the lives of patients while creating value.

We are a dynamic and fast growing organization. Paladin is constantly looking for great people to contribute to our growing business. We believe in empowering our employees by giving them the freedom to raise new ideas and encourage decision making in an environment that fosters the growth and development of each individual. Paladin's culture is committed to building our business as well as our community, helping others, encouraging integrity and inspiring people to make a difference.

Position Summary

The Specialist, Regulatory Affairs, assumes responsibilities within the Scientific Affairs team to ensure the timely approval and regulatory maintenance of pharmaceutical products and participates to various regulatory projects with our corporate partners. The ideal candidate is highly organized, has a good regulatory strategic thinking, can adapt to changing priorities and demonstrates good communication and problem solving skills.

Reports to

Director, Regulatory Affairs

Specific Responsibilities

- Assume responsibility for the registration of new pharmaceutical products as well as the maintenance of regulatory compliance for approved products during the post-marketing phase.
- Manage the preparation of excellent regulatory submissions according to predefined timelines. This includes evaluating the data (chemistry/ manufacturing, clinical and pre-clinical), preparation of CTD summaries and project coordination for NDS, Supplemental NDS, Notifiable changes and annual notifications in relation to prescription and OTC drugs, natural health products, biologics and medical devices.
- Participate to the elaboration and implementation of regulatory strategies.
- Participate to the preparation of meetings with Health Canada and is the main contact with the agency during the dossier's revision as well as for any other regulatory enquiry.
- Ensure that scientific data supporting submissions, as well as daily regulatory activities, are in compliance with the Canadian regulations and all relevant guidelines and policies.
- Assembles regulatory files.
- Ensure that the various databases and post-approval activities related to regulatory submissions are kept up-to-date according to departmental procedures.
- Review product labels to ensure compliance with Canadian regulations.
- Effectively liaise with corporate partners.
- Provide regulatory advice to other departments (Quality Services, Operations, Marketing, Government Affairs, etc.)

Characteristics of a Good Candidate

1. **Autonomy / Problem Solving**
   The candidate must work independently, yet interacting with various departments and people as needed. She/he must demonstrate an ability to evaluate and properly adapt the documents supplied by corporate partners for Canadian regulatory requirements. She/he must have the ability to identify important issues and initiate effective related action plans for a timely resolution.

2. **Negotiation skills / Teamwork**
   The candidate must demonstrate ability to negotiate in difficult situations, with groups inside and outside the company and have good interpersonal skills that will allow him/her to effectively function in a fast-paced, people oriented, team environment.

3. **Dealing with Ambiguity**
   The candidate must demonstrate adaptability in situations involving changes as well as the capacity to take action without having all the information. She/he must be able to sorts through complex or incomplete data to gather relevant information.

4. **Analytical and Organizational Skills**
   The candidate must have good analytical skills with high-level attention to detail and commitment to accuracy and depth. She/he will be able to handle multiple projects at a time. The candidate must demonstrate an ability to write and organize submissions in CTD format, based on documents supplied by corporate partners.

5. **Know-how**
   The candidate must demonstrate deep knowledge of Canadian guidelines and regulations for drugs, as well as sound scientific knowledge allowing for a safe and solid interpretation of the above guidelines and regulations.

Candidate Profile

Education & experience (required)

- B.Sc. in life science discipline or equivalent;
- Minimum of 2 years in the regulatory field within the pharmaceutical industry
- Strong knowledge of the Canadian regulations as well as ability to interpret policies and guidelines
- Strong scientific knowledge
- Strong background in CMC (chemistry and manufacture)
- Good project management skills
- Good writing and presentation skills in English
- Good knowledge of Microsoft Office Suite

Asset

- M.Sc. or Ph.D. in drug development/regulatory affairs or healthcare related professional degree
- Good knowledge of drug development process
- Experience in the preparation and submission of electronic submissions
- Bilingualism

**Please note only those selected for an interview will be contacted.*
Thank you for your interest in Paladin.