Manager, International Regulatory Affairs

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 focused on acquiring or in-licensing innovative pharmaceutical products for the Canadian market. Paladin has a focused marketing and sales organization that has helped it evolve into one of Canada's leading specialty pharmaceutical companies. 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 *Manager, International Regulatory Affairs* assumes responsibilities within the Scientific Affairs team to ensure, in cooperation with corporate partners, the timely approvals of new pharmaceutical products and the maintenance of International marketed products. 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.

This is a Montreal-based position.

Reports to

Director, Regulatory Affairs

Specific Responsibilities

1. Assumes responsibility for maintaining the regulatory compliance status of internationally marketed pharmaceutical products, in accordance with requirements set by local government bodies, including requirements for the submission of annual reports.

    1.1 Ensures that labelling and local information documents for pharmaceutical products are accurate and comply with the international regulations in force.

1.2 Assesses changes to chemical, manufacturing, non-clinical and/or clinical data concerning a pharmaceutical product, and coordinates updates to the relevant regulatory records for trading partners and/or foreign regulatory agencies, in accordance with the local requirements in force.

2. Assesses the regulatory documentation available for a product for the purpose of compiling a global regulatory record for new markets.

3. Acts as a liaison with trading partners and consultants involved in the foreign marketing process for pharmaceutical products.

4. Works with trading partners to ensure that international regulatory records are prepared in accordance with the policies and guidelines in effect in the target markets (including legalization, if necessary) and are submitted to the regulatory agencies within set time frames.

5. Works with Paladin Labs' Operations, Quality Assurance and Pharmacovigilance Group to ensure efficient internal communication.

6. Is responsible for preparing specific Canadian regulatory records, as determined by the Director of Regulatory Affairs. This task includes the steps involved in the assessment of scientific (chemical, manufacturing, non-clinical and/or clinical) data, the development of regulatory strategies and the preparation of Common Technical Document (CTD) summaries within set time frames.

Characteristics of a Good Candidate

1. **Analytical, Research 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.

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. **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.

4. **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.

Experience, Training and Education

Education & experience

Required

- Bachelor in Life Sciences or similar.
- Minimum of 3 - 5 years in the regulatory field within the pharmaceutical industry.
- Strong knowledge of the International regulations as well as ability to interpret policies and guidelines.
- Strong scientific knowledge.
- Good writing and presentation skills in English
- Bilingualism

Asset

- M.Sc. or Ph.D. in drug development/regulatory affairs or healthcare related professional degree
- Strong background in CMC (chemistry and manufacture)
- Good knowledge of drug development process

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