Project Manager, 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 Labs is an operating company of Endo International plc, a highly focused generics and specialty branded pharmaceutical company.

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.

Summary position

The Project Manager, Regulatory Affairs, works within the Scientific Affairs team to ensure the timely approval and regulatory maintenance of pharmaceutical products and participate to various regulatory projects with our corporate partners. The ideal candidate is highly organized, has a good scientific base and 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

Associate Director, Regulatory Affairs

Specific Responsibilities

1. Manage the preparation and filing of solid 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.
2. Participate to the elaboration and implementation of regulatory strategies.
3. Ensure that scientific data supporting submissions (e.g., NDS, SNDS, NC), as well as daily regulatory activities (e.g., assess change controls) are in compliance with the Canadian regulations and all relevant guidelines and policies.
4. Assembles, compiles regulatory files in eCTD format and upload files in eCTD software.
5. Ensure that the various database and post-approval activities related to regulatory submissions are kept up to-date according to departmental procedures.
6. Create, review and/or re-design of labels to ensure compliance with Canadian regulations.
7. Effectively liaise with corporate partners.

Characteristics of a Good Candidate

- ✓ Autonomy and leadership.
- ✓ Ability to work on multiple projects at the same time.
- ✓ Ability to keep tight deadlines and work under pressure.
- ✓ Flexibility and ability to adapt to change.
- ✓ Sound judgment in applying regulatory requirements.
- ✓ Strategic thinking
- ✓ Very good analytical and synthesis skills.
- ✓ Scientific rigor.
- ✓ Attention to detail.
- ✓ Organizational skills and structured work habits.

Candidate Profile

Experience, Training and Education

Required

- B.Sc. in life science discipline or equivalent.
- Minimum 3 years in the regulatory field within the pharmaceutical industry.
- Strong scientific knowledge.
- Good writing and presentation skills in English.
- Project management skills.
- Good knowledge of the Canadian regulations as well as ability to interpret policies and guidelines.
- Excellent communications skills, written and oral in both French and 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.
- People management skills.
- Assume responsibility for preparation of submissions such as NDS, SNDS…
- Background in CMC and clinical.
- eCTD knowledge and experience.

To apply, please send your resume: hr@paladinlabs.com

Only selected candidates will be contacted.