# *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.

## Position Summary

The Manager, 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, while managing a team of 1 to 3 people. The candidate should have a very solid scientific background as well as an excellent understanding of the pharmaceutical industry and must master in detail the various applicable regulations (pharmaceuticals, NHP, medical devices, biologics). The candidate must be able to handle multiple priorities and projects; must be highly organized. The candidate must adapt to changing priorities, must have the capacity to take action without having all the information.

This is a Montreal-based position.

## Reports to

Associate Director

## Specific Responsibilities

- Supervise 1 to 3 employees; provide support with coaching, mentoring and review of submissions prepared by junior employees.
- Mentor new hires as requested by management
- 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.
- Prepare submissions (NDS, SNDS, ANDS, annual notifications...) for prescription and OTC drugs, biologics, natural health products, as well as medical devices. This includes critical evaluation of scientific data (chemistry/ manufacturing, clinical and pre-clinical).
- Ensure that scientific data supporting submissions (including chemistry/manufacturing and clinical), as well as daily regulatory activities, are in compliance with the Canadian regulations and all relevant guidelines and policies.

- Provide regulatory support for site transfers.
- Participate to the elaboration and implementation of regulatory strategies.
- Prepare 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.
- Perform due diligence activities.
- Effectively liaise with corporate partners.
- Provide regulatory advice to other departments (Quality Services, Operations, Marketing, Government Affairs, etc.).
- Assembles, compiles regulatory files in eCTD format and upload files in eCTD software.

## Characteristics of a Good Candidate

- ✓ Autonomy and leadership.
- ✓ Ability to negotiate, and persuade effectively.
- ✓ Ability to work on multiple projects at the same time while managing people.
- ✓ Ability to keep tight deadlines and work under pressure.
- ✓ Flexibility and ability to adapt to change.
- ✓ Sound judgment in applying regulatory requirements.
- ✓ Diplomacy in establishing and maintaining interpersonal relationships.
- ✓ Excellent critical thinking and communication
- ✓ Analytical and synthesis skills.
- ✓ Scientific rigor.
- ✓ Attention to detail.
- ✓ Organizational skills and structured work habits.

## Candidate Profile

*Experience, Training and Education*

**Required**

- M.Sc. in life science discipline or equivalent
- **Minimum 5 years** in the regulatory field within the pharmaceutical industry
- Very strong scientific knowledge
- Excellent writing and presentation skills in English
- Good project management skills
- Excellent knowledge of the Canadian regulations as well as ability to interpret policies and guidelines.
- People management skills (min. of 2 years' experience managing direct reports)
- Responsibility for preparation of submission such as NDS and SNDS
- Bilingualism (written and spoken)
- Good knowledge of Microsoft Office Suite

**Asset**

- Excellent knowledge of drug development process
- Strong background in CMC and clinical
- eCTD knowledge and experience

*To apply, please send your resume: hr@paladinlabs.com*
*Only selected candidates will be contacted.*