



Create the difference and join the Pharmascience team!

*Regulatory Affairs Associate - International
Montreal, Canada*

Founded in 1983, Pharmascience is now one of the most dynamic companies in the Canadian pharmaceutical industry. Pharmascience was the first Canadian pharmaceutical company to simultaneously integrate research, development, production and marketing of generic, innovative and consumer products. The integration of these fields has positioned us right at the center of one of the most promising economic sectors. Thanks to its wide range of prescription and OTC products, Pharmascience now finds itself among the leaders of the Canadian generic industry.

Pharmascience offers you stimulating challenges, interesting promotion and development possibilities, in short, an unparalleled opportunity to enlarge your field of expertise. Your work will challenge your sense of innovation, initiative, entrepreneurship and leadership — not only are we looking for these qualities, we encourage and reward them.

DESCRIPTION:

The **Regulatory Affairs Associate** is responsible for the preparation, review, submission and life cycle management of Pharmascience products in international markets. Ensure regulatory submissions are accurate, scientifically sound and are in compliance with foreign government guidelines. Ensure that our International partners, clients and co-development partners are notified on any change brought to their file and ensure regulatory compliance throughout the lifecycle of the product. The Regulatory Affairs Associate is responsible for maintaining up-to-date knowledge and expertise on regulations and guidelines for assigned markets, ensuring regulatory compliance for marketed products. Coordinate with functional teams (R&D, Global Operations, QA/QC, Legal, Biopharmaceutics and Project Management) in the preparation/compilation of regulatory documents and execution of additional tests as required in the scope of submission. Answer additional information requests from assigned foreign Ministries of Health and coordinate internal efforts to ensure that a proper and complete answer is given in a timely fashion. Handle the legalization of documentation as per the requirements of the individual countries. This position reports directly to the Supervisor, Regulatory Affairs – International.

EXPERIENCE & REQUIREMENTS:

- ◆ Bachelors or Masters Degree in Chemistry, Biochemistry, Pharmacology or other relevant disciplines.
- ◆ Regulatory Affairs Certification (RAC) would be an asset.
- ◆ Two (2) to four (4) years experience in the Pharmaceutical Industry with a minimum of 2 years hands-on experience in Regulatory Affairs working in highly regulated markets.
- ◆ Good understanding of the drug development process is required.
- ◆ Good knowledge and understanding of ICH guidelines, with the ability to interpret and apply them.
- ◆ Electronic CTD submission experience would be an asset.
- ◆ Demonstrated ability to work both independently and as part of a multidisciplinary team.
- ◆ Strong communication (written, oral & presentation) and interpersonal skills.
- ◆ Excellent organizational skills and attention to detail.
- ◆ Excellent knowledge of Windows environment (Word, Excel, Outlook, and Access).
- ◆ Good customer service skills.
- ◆ Bilingual (English-French). Other languages are an asset.

We thank all applicants, however only those under consideration will be contacted. Qualified candidates are requested to apply on line at www.pharmascience.com under the careers section.

Pharmascience subscribes to employment equity principles for women, aboriginals, persons with disabilities, and visible minorities.