

Senior Regulatory Affairs Advisor

Medical, Drug and NHP industry

Dicentra inc. is an established and expanding Canadian consulting firm located in downtown Toronto. Due to continued growth, we are seeking an experienced regulatory affairs professional. The person in this position will report directly to the President of the company.

Qualifications:

- Minimum undergraduate University degree in Life Sciences or related scientific field
- 7+ years of Regulatory experience in the pharmaceutical or related industry
- Working knowledge of regulations governing drugs, medical devices and NHPs in Canada
- Familiarity or working knowledge of regulations in foreign jurisdictions
- Excellent knowledge of the Canadian Food and Drug Acts, GMPs, GLPs and relevant policies and guidelines
- Problem solving and decision making skills
- Ability to work effectively with a team to resolve regulatory obstacles
- Business savvy with the ability to provide effective options and challenges to meet customer or business needs
- Excellent communications skills, both written and verbal
- Excellent time and project management and organizational skills
- Detail and results oriented
- Excellent computer skills (are there any industry specific skills that would be an asset?)
- Established contacts within Health Canada is an asset
- Previous managerial experience is an asset

Responsibilities:

- Advise clients on regulatory strategy and various compliance matters
- Prepare and support regulatory submissions for product and site registrations (drugs, medical devices, NHPs) to domestic and foreign regulatory authorities
- Identify client issues and develop appropriate strategies
- Facilitate regulatory inspections for pharmaceutical, medical device and NHs licenses through effective negotiation/communication with agencies
- Advise clients on product categorization
- Understand, interpret, apply and effectively communicate the applicable Canadian laws and regulations
- Liaise and effectively negotiate/communicate with government agencies
- Contribute to the company's development and growth
- Provide training on regulatory/compliance topics

We offer:

- an entrepreneurial setting with opportunity to expand your career
- a competitive salary and benefits package
- the opportunity to work with a leading edge company in a growth industry

To learn more about us, visit: www.dicentra.ca

Interested? Please respond directly to: HR Department, Dicentra, 21 Phoebe St., B002, Toronto, ON, M5T 1A8 or email to: Alicja@dicentra.ca