

Senior Quality Assurance 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 Quality Assurance Advisor. The person in this position will report directly to the President of the company.

Qualifications:

- Minimum undergraduate University degree in Life Sciences or a related scientific field
- 5+ years Quality Assurance experience in pharmaceutical industry
- Excellent knowledge of the Canadian Food and Drugs Act, GMPs, GLPs and relevant policies and guidelines
- Working Knowledge of regulations governing drugs, medical devices and NHPs in Canada
- Familiarity or working knowledge of regulations in foreign jurisdictions
- Problem solving and decision making skills
- Business savvy with the ability to provide effective options to 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 basic computer skills
- Established contacts within Health Canada is an asset
- Previous managerial experience is an asset

Responsibilities:

- Advise clients on regulatory strategy in the development and implementation of their GMP quality systems including drafting SOPs and Worksheets
- Plan and conduct independent audits to assess compliance with regulations, guidelines and operating procedures
- Evaluate audit findings and prepare compliance reports
- Prepare and support regulatory submissions for site registration (drug, medical device, NHPs) to domestic and foreign regulatory authorities
- Identify clients' issues and develop alternate strategies
- Facilitate regulatory inspections for pharmaceutical, medical device and NHPs licences through effective negotiation and communication with agencies
- 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 providing a superior customer service management approach and innovative, appropriate to business needs advice
- 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