



i3 CanReg is a company dedicated exclusively to regulatory affairs consulting for the pharmaceutical, biotechnology, and medical device industries, serving clients in the United States, Canada and Europe. i3 CanReg is a one-stop global regulatory solution for companies of all sizes and at all stages of development. Services include the conduct of regulatory assessments and strategy development, quality and compliance (CMC, GMP Services), Pharmacovigilance, medical writing, due diligence, regulatory operations (electronic and paper publishing) and training.

**i3 CanReg, a UnitedHealth Group company, is currently seeking candidates for multiple openings in Dundas, Ontario. To apply, please visit: [www.i3careers.com](http://www.i3careers.com)**

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**Req. # 327095 Manager, Medical Services in our Medical Services Group**

- Respond to Medical Information Enquiries, for Clients' products. This includes availability on a shared rotating schedule 24/7 by cell phone.
- Review literature search/articles for responses to Medical Information Enquiries.
- Enter data for adverse reactions into safety database. Review and submit Individual Case Safety Reports (ICSRs) to health authorities as per Clients' agreement.
- Prepare and review Periodic Safety Update Reports and other safety related reports for submission to regulatory health authorities.
- Monitor and interpret worldwide regulations pertaining to pharmacovigilance.
- Identify client issues and develop effective solution strategies.
- Build and maintain a positive and productive liaison with internal and external contacts, including interfacing with potential Clients.
- Present Medical Information and Pharmacovigilance services to clients and during training seminars. (Minimal travel is anticipated within Canada/US.)
- Effectively prioritize, coordinate and complete multiple projects within established timeframes.
- Participate actively in other business related projects (business opportunities, client specific issues, regulatory changes, etc.) and strategic planning.

Qualifications:

- 3-5 years medical information and pharmacovigilance experience within the pharmaceutical industry.
- B.Sc. or Advanced degree in Pharmacy or other Life Science.
- Bilingualism (English/French) is preferred.

**Req. #: 321122 Regulatory Affairs Manager for U.S. Group**

- Manage day to day regulatory issues for clients.
- Effective preparation of regulatory files in accordance with the Food & Drugs Act and facilitation of new drug approvals and amendments through effective communication with the FDA.
- Review of study reports, protocols, summaries and product labeling.
- Manage and ensure maintenance of positive and productive liaison with internal and external contacts, including regulatory agencies, clients, and related institutions.
- Act as a primary contact for clients and FDA.
- Identify project, client and FDA issues and develop alternate strategies for consultation when required.
- Tracking, interpreting and communicating key changes in US FDA regulations to internal and external stakeholders (clients) to ensure compliance with FDA regulatory requirements.
- Provide mentorship for team members and direct reports.

- Support the Director(s) goals in driving i3 CanReg forward.
- Assume responsibility for project initiation, tracking and time management, including development of client quotes, review of invoices, and addressing client issues related to billing.

Qualifications:

- A minimum of 4-6 years US regulatory experience in addition to 3-4 years of pharmaceutical experience (line management experience an asset)
- Demonstrated experience directly interacting with the FDA in relation to US submissions.
- Minimum M.Sc. in Life Sciences; Ph.D., MD or PharmD an asset
- Excellent written and verbal communication skills
- Direct experience and working knowledge of a wide range of US regulatory submission types with a demonstrated ability to interpret and utilize the Code of Federal Regulations and other FDA and ICH documents.
- Excellent computer skills with training in current software applications and knowledge of standard software used in completing regulatory submission including eCTD submissions
- Able to manage time and resources in order to meet deadlines for assigned projects
- Excellent problem solving, analytical and written/verbal communication skills

**Req.# : 330938 Regulatory Affairs Specialist (CMC)**

- Effective preparation of CMC regulatory documents in adherence to the current Regulations for submission to Health Canada/FDA/ International Agencies.
- Act as CMC lead to facilitate new drug approvals and amendments through effective communication with Regulatory Agencies.
- Review of CMC sections of submission documents from one jurisdiction and preparation of gap analysis detailing requirements and strategies for submission to different jurisdictions.
- Build and maintain a positive and productive liaison with internal and external contacts.
- Participate in and support project teams and advise other departments on regulatory issues and strategies.
- Effectively prioritize and complete multiple projects within established timeframes.
- Identify client issues and develop alternative strategies for consultation with manager, when required.
- When assigned by manager, act as mentor for selected team members(s) in order to facilitate integration to the company and required regulatory procedures.
- Quality review (technical and editorial) CMC section of regulatory submission prepared by team member(s) as assigned by manager.
- Presentation of client services and training seminars, when required.

Qualifications:

- 5-8 years regulatory within the pharmaceutical industry
- B.Sc. in Chemistry or related field, an advanced degree (e.g. M.Sc. or Ph.D.) an asset
- Pharmaceutical manufacturing experience an asset
- RAC designation an asset
- Knowledge and understanding of regulatory requirements in US, Canada and internationally as well as an understanding of the drug development process
- Detailed knowledge of CMC CTD sections (Module 2 QOS and Module 3)
- Intermediate to advanced knowledge of standard computer software (i.e. MS Office), including software used in completing regulatory submission templates (i.e. Word, WordPerfect, Adobe Acrobat)