



Intrinsic Health Sciences Inc., a Canadian consultancy whose focus is to address the toxicology and regulatory challenges associated with the development of products (pharmaceuticals, biologics, medical devices, consumer products, natural health products and cosmetics), is always looking for people with strong scientific skills, creativity and enthusiasm to join our team. Intrinsic has immediate openings for a Regulatory Affairs Associate and a Senior Administrative Assistant/Submission Coordinator in our Mississauga location. We aim to offer our employees an environment that encourages professionalism, creativity, independence and continual learning. The assets of any knowledge-based company are its people, and we believe strongly in investing in those assets by offering training and mentoring of our staff. Like all successful organizations, we are committed to growing and advancing our employees' careers by providing them with new responsibilities and opportunities within the company.

### **Regulatory Affairs Associate**

The position would involve providing a full range of regulatory support to the Senior Manager and Vice President of Regulatory Affairs, including submission preparation and document authoring.

#### **Job Description:**

- Preparation of regulatory submissions (NDS/NDA, IND/CTA, DIN submissions) for Health Canada, FDA and possibly other regulatory agencies.
- Preparation of CTD modules, *e.g.* quality from source data on behalf of Intrinsic clients.
- Preparation of Health Canada or FDA specific templates *e.g.* QOS, PSEAT, Question Based Review summary.
- Understanding of the regulatory process for drug development, support with regulatory research as needed to assist in the development of regulatory strategies.
- Critical assessment of data and documents to identify gaps compared to regulatory requirements for US and Canada.
- Client interaction as needed to coordinate document production and review activities.

#### **The successful applicant(s) would ideally have the following qualifications:**

- Minimum BSc in Life Sciences.
- A **MINIMUM** of 3 to 5 years of hands on experience in regulatory submission preparation, **EXCLUDING** student co-op level experience is a firm requirement for this position.
- Candidates **MUST** have experience in new active substance submissions.
- A regulatory CMC background is preferred; concomitant experience/comfort with clinical aspects of drug development is an advantage.
- Good working knowledge of Canadian regulations, guidance and policy; working knowledge of FDA requirements is an advantage.
- Experience with electronic submissions is an advantage.
- Intrinsic is also seeking excellence in the following attributes:
  - Attention to detail.
  - Ability to multi-task and coordinate project activities.
  - Written and spoken communication.
  - Computer skills, particularly using MS Word and Adobe.
  - Initiative.

Good interpersonal skills, with the ability to work well in a team.

Please submit a CV and cover letter in confidence to Joscelyn Wilcox at [healthsciences@intrinsic.com](mailto:healthsciences@intrinsic.com) or via fax at 905-364-7816.