Intrinsik Corp.
6605 Hurontario Street., Suite 500
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Regulatory Affairs Senior Associate - CMC

Intrinsik Corp., is a North American consulting firm focusing on the regulatory challenges associated with the development of new products (pharmaceuticals, biologics, medical devices, consumer products, natural health products and cosmetics). We are continuing to grow, and will always welcome candidates with strong scientific skills, creativity and enthusiasm to join our team.

Intrinsik has an immediate opening for a **Regulatory Affairs Senior Associate – CMC** at our Mississauga, ON, Canada location. This position involves authoring Chemistry, Manufacturing and Controls (CMC) documentation for regulatory projects related to marketing applications as well as clinical trial applications/investigational new drug applications for the US and Canada. The CMC team at Intrinsik authors documents for a wide range of novel and innovative biologic and small molecule products.

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.

Responsibilities include:

- Authoring of the CMC modules from source data for regulatory submissions for Health Canada and the US Food and Drug Administration.
- Critical assessment of data and documents to identify gaps compared to regulatory requirements for Canada and the US.
- Assist in the development of regulatory strategies for CMC and support with regulatory research as needed.
- Quality control of the content of outgoing documents and regulatory submissions.
- Client interaction, as needed, to coordinate document preparation and review activities.
- Assist in preparation of electronic submissions for regulatory authorities.

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

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- Minimum BSc in Life Sciences.
- A minimum of 5 years of hands on experience in regulatory submission preparation.
- Candidates must have experience in the preparation of the CMC modules (both investigational and marketing applications). Experience with biologics is strongly preferred.
- Understanding of the regulatory process for drug development.
  Good working knowledge of Canadian and/or US regulations, guidance and policy.
- Prior experience with electronic submissions is strongly preferred.

The successful applicant(s) would ideally have the following attributes:

- Excellent attention to detail.
- Ability to multi-task and coordinate project activities.
- Strong written and verbal communication skills.
- Initiative, with the ability to research and complete projects in an independent manner.
- Good interpersonal skills, with the ability to work well in a team environment.

Interested candidates may submit their resumes via e-mail to Heather Wilson at hwilson@intrinsik.com. We thank all candidates for applying; however, only those considered for an interview will be contacted by Human Resources.