Intrinsik Corp.
6605 Hurontario Street., Suite 500
Mississauga, Ontario L5T 0A3
Phone: 905-364-7800
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Regulatory Affairs Project Manager

Intrinsik Corp. is a Canadian consulting firm focusing on the toxicology and 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 Project Manager** at our Mississauga location. The successful candidate will have a broad base of regulatory experience, including preparation and maintenance of Clinical Trial Applications and New Drug Submissions. Specialization in authoring of Chemistry, Manufacturing and Controls (CMC) documentation for regulatory submissions will be a distinct asset.

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 Project Manager

The position involves preparation of regulatory submissions (CTA, NDS), including authoring of CTD Module 2.3/3 documents from source data. There may also be an opportunity to author documents for US regulatory submissions (e.g., IND).

Responsibilities include:

- Critical assessment of documentation, including clinical trial protocols, Investigator's Brochures, CMC data and documents
- Preparation of CTD Module 1 documents, and authoring of Module 2.3/3 documents from source data
- Preparation of Health Canada specific templates *e.g.* QOS, CPID, PSEAT.
- Interpretation of regulatory requirements and guidance.
- Regulatory and/or scientific paper-based research as needed.
- Author proposals and tracks project budgets

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

- Minimum BSc in Life Sciences.
- Postgraduate Certificate in Pharmaceutical Regulatory Affairs is an asset.
- Minimum of 5 years of hands on experience in Regulatory Affairs.
- Candidates MUST have experience in the preparation and maintenance of new active substance submissions (both investigational and marketing applications).
- Understanding of the regulatory process for drug development.
- Good working knowledge of current Canadian regulations, guidance and policy; working knowledge of FDA requirements is an advantage.
- Familiarity with Health Canada processes and procedures.
- Strong project management skills.
- Prior experience with electronic submissions and strong computer technical skills are an advantage.

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 spoken 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 email to Andrea Kalentzis, Human Resources Manager, at akalentzis@intrinsik.com.