Intrinsik Corp.
6605 Hurontario Street., Suite 500
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Phone: 905-364-7800
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Senior Associate, Regulatory Affairs

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

Intrinsik has an immediate opening for a **Senior Associate, Regulatory Affairs** at our Mississauga, ON, Canada location. This position involves strategic oversight and project management of regulatory submissions to Health Canada (including Clinical Trial Applications and New Drug Submissions). The successful candidate will have a broad-base of regulatory experience, and must be able to provide leadership, mentor staff, and develop and execute strategy. The successful candidate must also be able to generate submission content (*i.e.,* review and, if necessary, author scientific documents) for use in regulatory submissions.

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 to our employees.

This position would involve providing support to the regulatory team:

- Preparation of regulatory submissions (CTA, NDS, *etc*.) and related documentation, such as pre-submission meeting briefing documents.
- Authoring of content for regulatory submissions, regulatory strategy documents and other reports for Intrinsik's clients.
- Preparation of CTD Module 1 documents.
- Preparation of Health Canada specific regulatory templates (*e.g.* QOS, CPID, PSEAT, CS:BE).
- Interpretation of regulatory requirements and guidance.
- Regulatory and/or scientific paper-based research as needed.
- Client interaction, as needed, to coordinate document preparation and review activities.
- Quality control of content of outgoing documents and regulatory submissions.

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- Canadian post-market experience.

The successful applicant would ideally have the following qualifications:

- Minimum BSc in Life Sciences.
- Postgraduate Certificate in Pharmaceutical Regulatory Affairs.
- >5 years of hands-on experience in Regulatory Affairs.
- Experience in the preparation and maintenance of new active substance submissions
- Understanding of the regulatory process for drug development.
- Sound knowledge of the current Canadian regulations, guidance, and policy.
- Familiarity with Health Canada processes and procedures.
- Strong project management skills.
- Prior experience with electronic submissions and strong computer technical skills.

The successful applicant would ideally have the following attributes:

- Excellent attention to detail.
- Ability to multi-task and coordinate project activities.
- Excellent verbal and written communication skills, including strong interpersonal skills, with the ability to effectively communicate with colleagues and clients at all levels.
- Initiative, with the ability to research and complete projects in an independent manner.

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.