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

SCIENCE sets us apart

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 Manager / Senior Manager** at our Mississauga, ON, Canada location. This position involves strategic oversight and project management of regulatory submissions to Health Canada and the United States Food and Drug Administration (including Clinical Trial Applications, Investigational New Drug Applications, New Drug Submissions and New Drug Applications). The successful candidate will have a broad base of Canadian 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 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 Manager / Senior Manager

Responsibilities include:

- Preparation of regulatory submissions (CTA, IND, NDS, NDA *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.

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- 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.
- Management of a portfolio of Intrinsik's clients; this involves direct contact with the client, and management of not only scientific and regulatory aspects, but also business aspects such as contracts and budgets.

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 8-10 years of hands-on experience in Canadian Regulatory Affairs.
- Experience in the preparation and maintenance of new active substance submissions (both investigational and marketing applications).
- Understanding of the regulatory process for drug development.
- Sound knowledge of the current Canadian regulations, guidance and policy; and working knowledge of FDA requirements is an advantage.
- Familiarity with Health Canada /FDA processes and procedures.
- Strong project management skills.
- Prior experience with electronic submissions and strong computer technical skills.

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.