Intrinsik Corp.
6605 Hurontario Street., Suite 500
Mississauga, Ontario L5T 0A3
Phone: 905-364-7800
Fax: 905-364-7816

Senior Manager / Manager Regulatory Affairs - Medical Devices

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 Senior Manager / Manager Regulatory Affairs - Medical Devices at our Mississauga, ON, Canada location. This position involves strategic oversight and project management of medical device submissions to the United States Food and Drug Administration and Health Canada (including Investigational Testing Authorization, Investigational Device Exemption, Medical Device License, Premarket Approval, 510(k)). The successful candidate will have a broad base of Canadian and US regulatory experience, and must be able to provide leadership, mentor staff, and develop and guide regulatory 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.

Responsibilities include:

- Determining medical device classifications.
- Support with combination product drug/biologic-device regulatory submissions (CTA, IND, NDS, NDA/BLA, *etc.*) may be required.
- Preparation of medical device regulatory submissions for Class I to IV applications in Canada (ITA and MDL) and PMA or 510(k) applications in the US, including post approval changes.
- Support with preparation/review of medical device labelling.
- Authoring of content for regulatory submissions, regulatory strategy documents and other reports related to medical devices.

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- 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 other business aspects, such as contracts and budgets.

The successful applicant would ideally have the following qualifications:

- Minimum BSc in Life Sciences.
- Postgraduate Certificate in Pharmaceutical Regulatory Affairs is an asset.
- Minimum of 7 years of hands-on experience in Canadian and US Regulatory Affairs.
- Knowledge of MDSAP, ISO, MDR, QSR.
- Knowledge of the current Canadian and US regulations, guidance and policy.
- Experience working with Health Canada and FDA processes and procedures (MDB/CDRH).
- Experience in the preparation and maintenance of new device submissions (both investigational and marketing applications).
- Understanding of the regulatory process for product development.
- Strong project management skills.
- Prior experience with electronic submissions and strong computer technical skills.
- Familiarity with and understanding of the CE Marking process is an asset.

The successful applicant 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.