### Project Manager, Regulatory Affairs - CMC

Intrinsik Corp., is a North American consulting firm focusing on the regulatory challenges associated with the development of new products (small molecules and biologics). We continue to grow, and will always welcome candidates with strong scientific skills, creativity and enthusiasm to join our team.

Intrinsik has a full-time opening for a **Project Manager, Regulatory Affairs – CMC** at our Mississauga, Ontario, Canada location. This is a hybrid position. This position involves authoring and assessment of Chemistry, Manufacturing and Controls (CMC) information for regulatory projects related to marketing applications, as well as clinical trial applications/investigational new drug applications for the US and Canada.

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 people by offering training and mentoring. We are committed to growing and advancing our employees’ careers by providing them with new responsibilities and opportunities within the company.

**Responsibilities include:**

* Author 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.

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

* Minimum BSc in Life Sciences.
* Minimum of 5 years of experience in drug development and/or pharmaceutical manufacturing.
* Experience in the preparation of the CMC modules (both investigational and marketing applications).
* Experience with small molecules or biologics.
* Understand the regulatory process for drug development.

**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.