Intrinsik Corp., is a North American 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. We currently have an opening for a Senior Study Manager.

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 modern successful organizations, we are committed to growing and advancing our employees' careers by providing them with new responsibilities and opportunities within the company.

The position would involve providing support to senior toxicologists related to:

* Home-based office (in Canada), requirement to travel to the head office in Mississauga, Ontario one/two times annually;
* Travelling (including international) required (<20%);
* Writing and/or reviewing scientific study plans, protocols and proposals;
* Reviewing and executing study plans and protocols;
* Sourcing and qualifying appropriate CROs for studies;
* Executing projects through management and oversight of nonclinical research activities and budgets (including invoicing) for studies conducted by external service providers (CROs);
* Ensuring scientific quality of all projects as well as their delivery to be on-time and on-budget;
* Managing study monitoring, including pre-placement and in-process study audits of critical activities;
* Performing quality checks to ensure study activities are in conformance with the requirements specified in applicable GLP regulations, protocol requirements and SOPs;
* Qualifying CROs through conduct of GLP-driven facility inspections in compliance with FDA 21CFR Part 58;
* Assessing all aspects of CROs (i.e., facilities, equipment, personnel, methods, procedures, records, etc.) for built-in quality management systems to ensure that quality is incorporated into the execution of the studies;
* Solving scientific and logistical problems;
* Understanding data analysis and presentation of data;
* Reviewing and finalizing reports in accordance to GLPs; and
* Authoring of integrated nonclinical summaries for regulatory filings.

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

* Undergraduate or advanced degree in a life science or related field of study, preferably a M.Sc. in toxicology;
* A minimum of 5 years experience in a CRO, preferably as a Senior Study Manager with a background in toxicology or pharma/biotech environment, managing outsourced drug development programs;
* Practical experience in project management;
* Experience with direct interaction with clients in a consulting capacity is an asset;
* Strong proficiency with literature searching;
* Excellent verbal and written communication skills, including strong interpersonal skill with the ability to effectively communicate with colleagues and clients at all levels;
* Strong organizational skills with the ability to multi-task (multiple projects/issues) and adapt to dynamic work situations where priorities are subject to change at any time;
* Strong interpersonal skills, with the ability to work independently as well as in a team environment.
* Ability to adhere to standard operating procedures (SOPs) and general guidelines involved in conducting a project; and
* Strong computer expertise (Microsoft Outlook, Word, PowerPoint, Access and Excel).

Interested candidates may submit their resumes viae-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.