Job Opportunity
Senior Clinical Research Associate

Prometic Biosciences Inc. scientists are focused on developing orally active drugs that provide, inter alia, competitive advantages. Typically, these first-in-class therapeutics have efficacy and high-safety profiles and enjoy strong proprietary positions. The unmet medical applications targeted are in the fields of fibrosis, inflammation, autoimmune diseases, oncology and hematopoietic disorders. As with its plasma-derived therapeutics division, Prometic is dedicated in becoming a strong integrated player in the orphan disease markets with its small-molecule therapeutics.

The Clinical Affairs department of Prometic Biosciences Inc. is looking for a Senior Clinical Research Associate, to work at its head office in Laval, Quebec. Under supervision of the Director, Clinical Affairs, the Sr. Clinical Research Associate will monitor the progress of clinical studies at investigational sites or remotely, and ensure clinical trials are conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), ICH-GCP, and all applicable regulatory requirements.

The mandate of the Sr. Clinical Research Associate will be mainly to:

- Participate in the development and review of monitoring tools and project specific documents.
- Conduct clinical trial study monitoring activities: Ensure regulatory and protocol compliance of investigator/investigative site; coordinate sponsor's communications with sites to ensure investigators' responsibilities; manage investigative site(s), oversee investigators and site coordinators, to ensure consistency across sites and to minimize problems such as protocol deviations; initiate routine payments to clinical sites; assist with drug shipment to clinical sites, as defined per project; conduct training at the sites on all study procedures; conduct prequalification, site initiation, interim monitoring and closeout visits as required.
- Ensure audit and inspection readiness of assigned sites. Advise on pre-audit activities for GCP requirements. Prepare and follow up site audits/inspections; provide input into the CAPA preparation.
- Coach and mentor junior CRAs on various aspects of work (in house or at sites).
- Review site specific informed consents.
- Assist in the development and review of clinical research SOPs. Review, understand and comply with clinical research SOPs.
- Prepare correspondence and study documentation with appropriate archival of electronic and paper copies.
- Review data files listings.
- Assist with preparation of documents for regulatory submission; review documents for investigator site file (ISF).
- Accurately update and maintain clinical trial management systems or trackers within project timelines.
- Assist in the draft of newsletters.
- Assist in the negotiation of grants/budgets with investigators and vendors, and prepare contracts.

- Act as Prometic direct contact with assigned clinical sites.
- Assist in the organization of investigators meetings.
- Prepare and deliver presentations to investigators.
- Assist project leader in the review of monitoring reports, as needed.

The selected candidates will hold a Bachelor degree in Life Sciences or in Nursing (B.S./B.A./RN) with at least four (4) years' experience as a Clinical Research Associate in the pharmaceutical, biotechnology, biologics, medical device industries and/or at a contract research organization. The candidate must have an extensive knowledge of Good Clinical Practices (GCPs), preferably through certification. The selected candidate must be willing to travel up to 70% of their time.

The following criteria are also required:

- Strong written and verbal communication skills, in both French and English;
- Proven interpersonal, organizational and problem solving skills;
- Proven ability to manage multiple projects and effectively prioritize all aspects of clinical trials being managed; Ability to work efficiently under aggressive timelines;
- Ability to be assertive while utilizing good people skills to motivate sites personnel;
- Knowledge of electronic data capture systems;
- Good computer skills in Microsoft Office programs with emphasis on Word and Excel;
- Willingness to learn and accept new job tasks as defined by each project.

Prometic offers a competitive compensation, a flexible work schedule and a casual working environment.

To apply, please send a cover letter and copy of your resume to hr@prometic.com with the following reference: PBI-Med-1702. Prometic is an equal opportunity employer. **Only chosen candidates will be contacted for an interview**. For more information about Prometic, visit our website www.prometic.com.