

Job Opportunity

Principal Medical Writer

Prometic is an established biopharmaceutical company with widely recognized expertise in bioseparations, plasma-derived therapeutics and small-molecule therapeutics development. Prometic offers its bioseparation technologies and expertise for large-scale purification of biologics, drug development, proteomics and the elimination of pathogens to industry leaders and uses its own affinity technology that provides for highly efficient extraction and purification of therapeutic proteins from human plasma to develop and commercialize plasma-derived therapeutics. Prometic is also active in developing its own novel small-molecule therapeutic products targeting unmet medical needs in the fields of fibrosis, as well as diabetes, anemia and autoimmune diseases. Headquartered in Laval (Canada), Prometic has R&D facilities in the United Kingdom (“UK”), the United States (“USA”) and Canada, manufacturing facilities in the UK and Canada and corporate and business development activities in the UK, Canada, USA and Europe. Prometic’s common shares (the “Common Shares”) trade on the Toronto Stock Exchange (“TSX”) under the symbol “PLI” and the OTCQX International under the symbol “PFSCF”.

The Clinical Affairs department of Prometic is looking for a Principal Medical Writer, to work at its location in Laval, Quebec. Under supervision of the Senior Director, Medical Writing, the Principal Medical Writer will be responsible for working with cross-functional, multidisciplinary teams to translate clinical data, including trial and studies results and findings into presentations, regulatory and other supporting documents, including clinical abstracts, posters, and manuscripts for pipeline and/or marketed products. In close collaboration with the Senior Director, Medical Writing, the incumbent will manage and prioritize workload to ensure deliverables are completed per time and quality goals.

The mandate of the Principal Medical Writer will be mainly to:

- Participate in the planning, writing, editing, reviewing and coordinating the publication of clear and concise clinical, regulatory and other supporting documents for Prometic.
- Ensure that documents comply with regulatory, journal, or other guidelines in terms of content, format, and structure.
- Work with teams to ensure smooth and timely development of documents.
- Liaise with the electronic publisher to assist the Manager, Regulatory Affairs, in getting submissions published and submitted.
- Provide QC review support, as needed.
- Participate in the development and publication of clinical abstracts, posters, and manuscripts for assigned studies/indications.
- Assist in the analysis, synthesis and presentation of complex information.
- Exhibit flexibility in moving across development and preparation of multiple document types.
- Maintain and enhance knowledge of therapeutic area, as well as regulatory and publication guidelines.

The selected candidate will preferably hold a Bachelor’s degree or higher in a scientific discipline

with a minimum of 7 years' experience in the medical/regulatory/publication writing field, in the pharmaceutical/biotech industry or CRO environment. They will have demonstrated experience in the preparation of protocols, study reports and investigator's brochures, and be knowledgeable of GCPs as well as European Clinical Trials Directive.

The subsequent competencies would be considered valuable assets: Experience filing and maintaining CTAs in Canada and Europe; knowledge of the drug development process and principles of GXP/ICH/CTD and other global standards, with an understanding of the basic strategy for regulatory submissions; submission experience.

The following criteria are also required:

- High attention to detail.
- Knowledge of Microsoft Office applications and electronic document management systems.
- Capacity to manage/prioritize multiple projects under general supervision, work in a fast-paced environment. Flexible/willing to adapt to changing deadlines and priorities.
- Ability to work collaboratively and coordinate the efforts of team members to resolve comments and complete deliverables.

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

To apply, please send a cover letter and a copy of your resume to hr@prometic.com with the following reference: PBT/PLI-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.