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# Job Opportunity
## Associate Director, Biometrics

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 Medical Affairs department of Prometic is looking for an Associate Director, Biometrics, to work at its location in Laval, Quebec. Under supervision of the Chief Medical Officer, the Associate Director, Biometrics, will oversee all biostatistics, statistical programming, and data management activities to ensure timely and accurate delivery of statistical designs, analyses, and reports and regulatory submissions. They will provide strategic statistical input to drug development including feasibility assessments, development plans, complex study designs, cross-study statistical methodology, interpretations, regulatory submissions and follow up. The incumbent will contribute to establishing and driving compound level program functional strategy for resourcing, processes and standards to achieve quality and maximize efficiency. They will work closely with Clinical Development, Regulatory Affairs, and Clinical Operations to plan and implement clinical studies as part of a larger clinical development plan, and to analyze and interpret clinical study data. They will also be accountable for the production of biostatistics deliverables and oversight of statistical programming and data management activities.

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The mandate of the Associate Director, Biometrics, will be mainly to:

- Lead biostatistics function and oversee statistical programming and data management activities across the organization;
- Ensure accurate, statistically valid deliverables included in protocols, statistical analysis plans, study reports, manuscripts, and regulatory submission documents;
- Collaborate with eCRF design and vendor management;
- Collaborate with statistical programmers on summary and analysis of trial data;
- Coordinate achievement of major statistical deliverables and milestones in collaboration with other functions;
- Leverage standardization to maximize global data integration and interpretability;
- Provide statistical leadership and support for feasibility assessments, clinical development plans, complex study designs, regulatory meetings, submissions and follow up;
- Responsible for providing statistical leadership for preparation of marketing applications (NDA/BLA) to FDA, EMA or other worldwide regulatory agencies;
- Apply innovative statistical approaches to the design of studies and to the analysis/reporting of study results (e.g., modeling and simulation, adaptive design and /or Bayesian approaches);
- Provide statistical support to the preclinical and manufacturing process development functions as needed;
- Keeps abreast of literature/advancements in science/medicine/technology in own and related fields of the drug development program.

The selected candidate will preferably hold a PhD in Statistics/Biostatistics and at least 7 years of relevant pharmaceutical experience, or a MSc and at least 10 years of experience. They will have a comprehensive knowledge of statistical methodology in design and analysis of clinical trials, including Bayesian modeling and adaptive design. They will be familiar with regulatory requirements relating to clinical development of drugs and biologics. They will also have BLA/NDA experience, including eCTD submissions, as well as with major statistical software such as SAS, SPSS, R. They will be knowledgeable of CDISC requirements for SDTM and AdaM, and have an understanding of the application of statistical principles in the design and analysis of nonclinical studies and bioprocessing experiments, and data interpretation.

The following criteria are also required:

- Excellent verbal and written communication and inter-personal skills.
- Flexible, well-organized, and have the ability to work well under pressure.
- Strong teamwork ability/commitment and individual initiative.
- Good collaborative and demonstrated leadership skills with the ability to work with a cross-functional team.

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: PBL/PBT/PLI-Med-1701. 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.