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Job Opportunity
Computer Systems Validation Specialist

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 IT department of Prometic is looking for a Computer Systems Validation Specialist, to work at its location in Laval, Quebec. Under supervision of the IT Director, the Computer Systems Validation Specialist will be responsible to plan, manage and provide guidance in the development, coordination and execution of computerized systems validation, operating in a manner, as intended, consistent with regulatory and manufacturing cGMP requirements.

The mandate of the Computer Systems Validation Specialist will be mainly to:

- Ensure validation activities are consistent with Corporate and the Validation Department's strategic planning process.
- Develop IT SOPs.
- Develop and initiate validation master plans, design specifications, URS/FRS, traceability matrix, IQ,OQ,PQ validation protocols, change control, and execution of test plans for computerized systems, and business software.
- Perform Risk Assessment for Computerized Systems following GAMP 5 guidelines.
- Perform vendor audits and adherence to SOP's and corporate policies related to computer systems validation.

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- Implement and maintain computer systems validation procedures and interact with systems users, vendors & IT personnel.
- Assist cross-functional teams, in compliance with validation activities and input to use and manage computerized systems.
- Act as liaison between IT and QA to ensure that all computerized systems are in accordance with Health Canada, FDA, 21 CFR Part11 and EU Annex11 regulations.
- Plan and coordinate the work efforts of computerized systems validation activities.
- Maintain data integrity and comply with FDA, Health Canada, 21 CFR Part 11 and current Good Manufacturing Practices (cGMP), EU Annex 11.
- Serve as the SME for CSV.
- Other related duties/responsibilities as required or assigned by the supervisor.

The selected candidate will preferably hold a Bachelor's degree in Computer Sciences or a related field with a minimum of 5 years' experience in Biotechnology, pharmaceutical or similar regulated environment industry. They will have in depth knowledge of FDA guidelines and Global cGMPs relevant to 21 CFR Part 11 compliance requirements and Global Computer Systems Validation and ISPE GAMP 5 guidelines.

The subsequent competencies would be considered valuable assets: Experience with validation projects at least with one of the following systems: ERP, LIMS, MES or QMS, experience with cloud and ERP systems is a plus, experience with IT infrastructure qualification.

The following criteria are also required:

- Customer service mindset: ability to work well with internal and external suppliers/customers/ team members
- Ability to comprehend IT software and infrastructure requirements and the associated regulatory expectations.
- Ability to work with virtual teams, and to lead Computer Systems Validation projects for different sites located in Canada, USA, and UK.
- Demonstrated ability to effectively communicate (verbally and in writing), influence and lead both with and without authority;
- Possess strong analytical, planning and organizational skills;
- Ability to work independently, effectiveness at managing multiple tasks and projects, flexibility and ability to adapt quickly to new and changing situations.

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: #PLI-IT-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.