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Job Opportunity
Validation Process Specialist

Prometic Bioproduction Inc. ("PBP") undertakes the development and manufacture of high-value plasma-derived therapeutic biosimilars for Prometic's current and future clients, in a state of the art facility.

Prometic Bioproduction Inc is experimenting a substantial growth. In order to support operations expansion, the Manufacturing Sciences department of PBP is looking for a Validation Process Specialist, to work at its plant in Laval, Quebec. Under the supervision of the Manager, Manufacturing Sciences, the Validation Process Specialist will be responsible for all activities related to manufacturing process validation and cleaning validation for Drug substance and drug product. It includes protocol preparation, revision, execution in a GMP environment. The incumbent will also participate in trouble-shooting and activities, CAPA, and in preparation of regulatory submission supporting documentation. The Validation Process Specialist will be a key player within Manufacturing Sciences group and will strongly support regulatory compliance for processes validation for new and established products.

The mandate of the Validation Process Specialist will include:

- Perform process validation and qualification activities for bulk drug substances and drug products.
- Assist in scale-up of processes, including risk assessment study for the process validation.
- Participate in the identification of critical quality attributes, critical process parameters, and control strategies for new and established processes.
- Write and review process and cleaning validation protocols and assist in the execution of qualification batches and data reporting.
- Prepare, coordinate and follow-up cleaning validation of critical equipment.
- Coordinate validation and qualification activities with various departments and contractors.
- Make recommendations for process improvement.
- Initiate and follow up on change control, deviations, investigations and exception reports related to new or existing products and validation, qualification activity.

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- Write, review and approve SOPs related to Process Validation activities.
- May participate in process Technology transfer.
- Other related duties/responsibilities as required or assigned by the manager.

The selected candidate must hold a Bachelor in Chemistry, Biochemistry, Biology or in a related field with a minimum of five (5) years knowledge and working experience with all aspects of validation (Process and Cleaning) preferably related to a biopharmaceutical development organization. Preferably relevant experience with biologics or biotechnology derived product. The candidate has knowledge and understanding of regulations for cGMP and ICH guidelines.

The following criteria are also important assets:

- Advanced computer and software skills (Excel, Word or equivalent).
- Excellent verbal and written communications skills in English and French is needed.
- Basic knowledge of statistics tools.
- Ability to operate both autonomously and within functional team settings including qualified professionals of other departments.
- Recent experience in cleaning validation activities is an asset.
- Experience in troubleshooting, change control
- and investigation is also an asset.

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 with the following reference: PBP-MSC-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