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Job Opportunity
Quality Assurance 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 Life Sciences Inc. is experimenting a substantial growth. In order to support operations expansion, the Quality department of PBP is looking for a Quality Assurance Specialist to work at the office located in Laval, Quebec. Under the supervision of the Manager, Quality Assurance. The Quality Assurance Specialist will assist the QA Manager with developing, implementing and executing quality assurance processes and practices that support the manufacture of FDA-regulated biologic products and other related regulatory activities. Assist in managing and monitoring systems and processes, promoting an organizational culture of excellence. Ensure that performance and quality of products conform to established standards and regulatory requirements. Requires the ability to analyze complex issues, work independently and the flexibility to meet changing business and stakeholder needs.QA in keeping a quality system for activities related to Good Manufacturing Practices "GMP" and control processes documents in accordance with the international standards and requirements

The mandate of the Quality Assurance Specialist will include:

- Maintains the Quality Managing System for Prometic Bioproduction, Inc. (PBP) to ensure that PBP facility and projects are in compliance with current Good Manufacturing (cGMP) practices.
- Responsible for the Quality Assurance assessment, review and approval of deviations, investigations, OOS and change control requests, in accordance with industry standards and requirements.
- Responsible for training oversight and coordinating necessary training for new employees.
- Manages procedure system (SOPs) including change control system, CAPA, OOS and deviations.
- Ensures operations documentation meets established requirements for cGMPs.
- Participates in reviewing and approval of systems and equipment validation protocols and reports, as well as assist in validation execution plan.
- Full batch record reviewing and approval in support of batch final release.

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- Perform record review to ensure compliance to relevant procedures.
- Responsible for the final product release (BDS and DP).
- Provides guidance to staff and oversees quality of manufacturing, validation and technology transfer projects and documentation.
- Oversee and authorize shipping of GMP material.
- Prepares and issues master batch records and product labels.
- Oversees the storage of products.
- Responsible for the rejection of expired and / or unsuitable material and products and oversees the segregated storage of these materials and products.
- Assists in the managing of the Stability program and oversee the shelf life of clinical trial material lots.
- Assists in writing, reviewing and approval of Prometic SOPs.
- Assists in the review of product specifications and in the preparation of trend reports and product reviews.
- Develops and implements plans to be fully prepared for FDA audits or other accreditation bodies.
- Conducts audits of cGMP compliance in-house and generates associated audit reports.
- Oversee and follow-up on internal QA issues, manufacturing CAPAs and supplier corrective action requests.
- Implement and maintain customer complaint and recall program.
- Receives and investigates customer complaints.
- Prepare monthly trending analysis reports.
- Perform, as necessary, Quality Risk Assessments.
- Review for regulatory compliance, drug product labels.
- Other related duties/responsibilities as required or assigned by the manager

The selected candidate will hold a Bachelor in Chemistry, Biochemistry, Biology, Pharmacy, or in a related discipline. A minimum of three (3) to five (5) years knowledge and working experience with all aspects of quality assurance, which relate to a pharmaceutical development organization. Directly relevant experience with biologics or biotechnology derived products. A thorough knowledge and understanding of Canadian, US FDA and European regulations (GMP), as well as experience with GLPs, GCPS and ICH regulations and guidelines.

Work environment:

- Workplace: Office.
- Equipment used: computer, telephone, fax, printer.
- There are travel requirements between offices (5 min away walking distance)

The following criteria are also required:

- Be able to work independently and in cross-functional team settings.
- Excellent analytical skills,
- Attention to details,
- Flexibility and strong work ethics to meet demanding timelines

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

To apply, PBP-QA. 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.