

We are currently seeking candidacies for a

## QUALITY ASSURANCE (QA) SPECIALIST

Green Cross Biotherapeutics is seeking an experience QA Specialist to add to their team in Montreal. You must possess a strong knowledge of cGMP regulations for Canada and US and a strong knowledge in sterile or biotech manufacturing environment. The Quality Assurance Specialist is responsible for the activities and quality systems necessary to ensure product released to the market is in full compliance to regulatory standards and Green Cross Biotherapeutics (GCBT) requirements.

### *The challenges of the job...*

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#### Your **key duties and responsibilities** include:

- Perform day-to-day activities, among others:
  - Approval of analytical testing results for in-coming material, intermediate and finished Products
  - Batch Records approvals for Intermediate and Finished Products
  - Protocols and Reports related to Installation / Operational / Performance Qualifications
- Release or Rejection of In-Coming, Intermediate and Finished Products in SAP
- Resolve and Approve any investigations, non-compliance and quality incidents related to Product Quality and Quality Systems
- Approve Change Requests related to GMP documents / processes
- Perform investigations for Customer Complaints
- Perform Annual Product Reviews for all Finished Products
- Develop and Report Quality Metrics to management
- Generate new procedures and revise existing procedures, as required
- Ensure the integrity and traceability of all data generated and reported

### *Do you have...*

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#### The following **qualifications and skills**:

- A University Degree (BSc) in Chemistry, Biochemistry or Microbiology
- A minimum of 5 years of experience in QA within the biopharmaceutical or pharmaceutical industry
- Strong knowledge in sterile or biotech manufacturing and solid understanding of cGMP regulations
- Good computer skills
- Strong organizational skills, including attention to detail, ability to multi-task and meet deadlines
- Ability to rigorously apply, follow and maintain rules, regulatory requirements, procedures and processes
- Bilingualism (French and English) both spoken and written

Our biopharmaceutical company was a greenfield project and is now positioned to launch its activities. We are growing rapidly, join our dynamic team!

Forward your cv and presentation letter to [Careers@GreenCrossBT.com](mailto:Careers@GreenCrossBT.com)

Visit us at [www.GreenCrossBT.com](http://www.GreenCrossBT.com)

NOTE THAT ALL OUR EMPLOYEES MUST SUCCESSFULLY PASS A PRE-EMPLOYMENT MEDICAL TO WORK IN OUR PHARMACEUTICAL ENVIRONMENT.

### *About us...*

As a global leader in healthcare, GCBT provides safe and effective solutions for the evolving needs of the industry. Headquartered in Yongin, South Korea since 1967, we specialize in the development and manufacture of plasma derivatives, preventive vaccines, recombinant proteins and therapeutic antibodies.

After more than 50 years in business, we are an internationally recognized specialty biopharmaceutical company. GC Pharma employs over 5,000 people in its 15 subsidiaries worldwide. Our GCBT Montreal subsidiary (located in the St-Laurent TechnoParc) is the only intravenous immunoglobulin (IVIG) and albumin manufacturing plant in Canada. This state-of-the-art facility marks the beginning of a new chapter in the history of the Canadian biopharmaceutical industry.

The products manufactured in this facility will provide key therapeutic solutions for the treatment of patients with infectious and immune diseases, severe burns and those needing blood-volumizing agents.