2911, ave Marie-Curie
Montreal QC H4S 0B7
www.greencrossbt.com

We are currently seeking candidacies for a

QA DOCUMENTATION SPECIALIST

Green Cross Biotherapeutics is seeking a **Documentation Specialist** to add to their Quality Assurance team in Montreal. You must possess strong organisational skills and enjoy working in a dynamic environment. The Documentation Specialist is responsible for maintaining, filing and archiving GMP documentation (i.e. SOPs, Batch Records, Training Records, Audit Reports, Analytical Results, etc.) and Regulatory Affairs documents to ensure compliance with cGMPs and internal GCBT SOPs. This position interacts with employees from multiple functions within the organization.

The challenges of the job…

Your **key duties and responsibilities include:**

- Hone and maintain a filing and archiving strategy within the documentation center
- File and archive all Quality and Regulatory documents within the documentation center
- Prepare Batch Records and other documents for the Document Management System (DMS)
- Manage the issuance and lifecycle of SOPs, Training Records and other document types (Specifications, Methods, Master Batch Records) utilizing the DMS, as required
- Assist personnel within the organization with concerns regarding DMS and documentation requirements
- Maintain records relating to operations in good order and in compliance with the record retention schedule and archiving requirements
- Monitor, track and report on SOPs, Specifications, Training Records, Pharmacovigilance Reports and other document types in various states
- Develop and report Quality documentation management metrics to management
- Generate new procedures and revise existing procedures as required
- Prioritize the completion of tasks in a timely manner
- Train personnel on the DMS and the procedure management process, as required

Do you have…

The following **qualifications and skills**:

- A College degree (DEC) in Library, Information or Archival Studies, or in another related field
- A minimum of 2 years documentation experience in the Biopharma, Pharma or Healthcare Industry
- Solid understanding of cGMP regulations with regards to documentation control and ability to rigorously apply, follow and maintain rules, regulatory requirements, procedures and processes
- Excellent computer skills with MS Office and Adobe Acrobat (QMS knowledge is an asset)
- Strong organizational skills, including attention to detail and ability to multi-task and meet deadlines
- Good verbal and written communication skills (French and English) and good interpersonal skills

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
Visit us at www.GreenCrossBT.com

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.