

# JOB POSTING

## CANGENE CORPORATION

*(Winnipeg or Toronto)*

### **Regulatory Affairs Associate – 18 Month Term**

Provides Regulatory Affairs support for assigned projects which may include investigational new drug, and product/establishment license preparation and maintenance, regulatory inspection and communication, adverse drug reaction reporting and ensuring operational compliance with regulations.

#### **Duties & Responsibilities:**

As per project assignments:

- Obtains and evaluates available technical documentation relative to regulatory requirements.
- Plans and executes the preparation of submissions, amendments and annual reports for US, Canada, EU or other international health authorities.
- For markets outside of US, Canada and the EU, works with regulatory contact at foreign distributor to facilitate preparation of their marketing application, post approval submission documents.
- Monitors the progress of agency review of regulatory submissions and follows up with applicable parties. Coordinates, prepares and submits response to Health Authority questions.
- Follows up with regulatory contact on their progress with the foreign agency. Coordinates, prepares and submits response to Health Authority questions.
- Effective management of regulatory submission planning and execution of plans and post-licensure maintenance to achieve aggressive timelines in support of commercial business and R&D activities.
- Provides regulatory advice/support to internal functional departments and/or product development teams.
- Monitors regulatory requirements as relevant to assigned projects/teams.
- Provides support to Health Authority inspections, as needed.
- Communication and negotiation with internal and external parties.

#### **Qualifications:**

Qualified candidates will have B.Sc. in a biological or health science. Has excellent communication, interpersonal, and organization skills. Good analytical, evaluation and negotiation skills are an asset. Ability to work and manage projects independently. Computer skills required are Microsoft Office applications and Adobe Pro. Knowledge of CTD format (Common Technical Document) is an asset. 3-4 years experience in Regulatory Affairs preferred, but relevant work experience in pharmaceutical industry will be considered. Experience with plasma derived products will be an asset.

Interested applicants should submit a résumé and cover letter to, Human Resources, 155 Innovation, Winnipeg, Manitoba, R3T 5Y3, or fax to (204) 275-4021 or email to [hr@cangene.com](mailto:hr@cangene.com).