



Canada Inc.

JOB POSTING

Position: Regulatory Affairs Senior Associate
(Contract, March 2010-April 2011)
Location: Mississauga, Head Office
Department: Regulatory Affairs
Reports to: Senior Manager, Regulatory Affairs

AMGEN Canada has an upcoming opening for a Senior Associate, Regulatory Affairs. The primary responsibilities include Regulatory Affairs support of clinical activities for marketed products and for products in clinical development.

General Responsibilities:

Specific Responsibilities:

- Under the guidance of the manager, participate in the preparation of regulatory submissions pertaining to the clinical aspects of products, including New Drug Submissions (NDS); Supplemental NDS; Clinical Trial Applications (CTA); Notifiable Changes and Notifications.
- Review of labeling and artwork.
- Participate in Regulatory Affairs department initiatives.
- Other Regulatory Affairs duties as required, to ensure ongoing compliance with Canadian regulations.

Selection Criteria

The ideal candidate will meet the following criteria:

- Minimum B.Sc. degree in life sciences
- 5 years of work experience in Regulatory Affairs
- Understanding of Canadian regulations, guidances, policies and other relevant practices in pharmaceutical and biological development
- Computer literacy
- Problem-solving skills, exercising sound judgment
- Capability and commitment to working both independently and as part of a team
- Excellent communication skills, both written and verbal
- Strong organizational and interpersonal skills
- Strong attention to detail and quality
- Self motivated and enthusiastic

Interested candidates should apply online at www.amgen.ca