



Job Posting Title

Senior Associate Global Safety (10 months maternity leave replacement contract)

Basic Qualifications

- Minimum Bachelors Degree in the Health or Biological Sciences.
- Minimum 3 years experience in Pharmaceutical or Biotechnology industry, including minimum 1-2 years experience in clinical and post-marketing drug safety setting.
- Sound understanding of Canadian and international adverse event reporting requirements for both clinical and post-marketing setting.
- Working experience with safety databases.
- Knowledge of requirements pertaining to Good Clinical Practice (GCP).
- Ability to work independently and as part of a team in a multitasking, deadline-oriented and high workload environment.
- Strong organizational, planning, technical and analytical skills, strong attention to detail.
- Exercising sound judgment, organizational ability, trouble-shooting and problem solving skills.
- Excellent communication (written and verbal) and interpersonal skills.
- Self motivated and enthusiastic.
- Bilingualism (French/English) would be an asset.

Job Summary:

This position reports to the Senior Manager, Global Safety and has primary responsibility for managing day-to-day activities relating to the intake, assessment and communication of safety data in compliance with Canadian Regulations and company's standard procedures. This role supports all product safety matters; provides first line responses to safety related inquiries and assists in processes development as well as pharmacovigilance training activities.

Specific Responsibilities:

- Receive, triage, evaluate and forward received domestic safety information to global safety hub in accordance with company's standard procedures and regulatory requirements
- Perform appropriate follow-ups with reporters, distribute safety related queries.
- Assess adverse events reports for expedited reportability to Health Canada and ensure reporting within required timeframes.
- Track and monitor local regulatory reporting compliance; highlight potential compliance risks to manager.
- Maintain global safety database and the local archive of safety reports.
- Maintain/update local processes for all aspects of safety data handling.
- Maintain awareness of the current product labeling on all Amgen's products.
- Liaise with study teams, medical information staff, sales representatives and other stakeholders to handle safety related inquiries and to provide guidance in safety information handling; escalate appropriate questions to manager and/or global safety hub.
- Provide safety updates and communications to management and applicable functions at Amgen Canada.
- Reconcile received safety reports with Medical Information, QA.
- Assist in safety processes QC procedures.
- Support the translation of safety related information.
- Prepare training materials and provide pharmacovigilance training to Amgen Canada staff and partners.
- Develop and maintain effective working relationships within company and with local regulatory agencies.
- Other duties as assigned.

ALL applicants must apply via www.amgen.com. Human Resources or hiring managers will not accept resumes sent via email or hard copy.