

About Apotex:

Apotex is the largest Canadian owned pharmaceutical company, and the largest producer of generic medicines in the country. We have an incredible team of bright, passionate, and committed individuals who are proudly dedicated to our mission of bringing a growing array of high quality, affordable medicines to healthcare systems in 115 countries around the globe. We are looking for the cream of the crop to join our team!

We offer competitive pay, exceptional career development, state-of-the-art facilities, and the opportunity to work with leaders in the field. But we also offer something more... the satisfaction that comes from knowing that the “product” we produce will improve the quality of human lives, and in some cases, save them. Our products, most importantly, are also accessible by people from all economic backgrounds. We’d love to hear how you could contribute to the team!

Job Summary:

Responsible for the review and evaluation of safety documents related to products developed and /or marketed by ApoPharma. Responsible for analysis, assessment and reporting of safety information. Responsible for leading risk management activities, including signal detection. Responsible for writing assigned clinical safety assessments and safety sections of clinical study reports, periodic safety reports, scientific and regulatory documents.

Job Responsibilities:

1. Conduct medical and scientific review of AE/ADR reports originated from clinical trials, market and other potential sources including identification of requirement for follow-up information
2. Provide regulatory assessment of the cases for expedited reporting in various jurisdictions
3. Lead Signal Detection and Risk Management activities
4. Conduct periodic review of safety data from clinical trials
5. Perform review of medical coding of adverse events
6. Write assigned aggregate safety reports (PSUR, DSUR, annual IND) and safety section of Investigator’s Brochure and other scientific or regulatory documents for investigational and marketed products
7. Contribute to generation and review of SODs related to Medical Safety and Medical Information
8. Conduct literature reviews on products developed or under development by ApoPharma and when assigned, consult with academic experts on medical matters related to safety of the ApoPharma products
9. Ensure that activities listed above are performed in compliance with applicable laws, regulations, guidelines and ApoPharma SODs
10. Inform Head of Medical Safety of new developments (major changes in regulations, new guidelines) in medical/drug information and safety fields
11. Review assigned responses to product information requests prepared by Associate, Pharmacovigilance or other divisions of ApoPharma
12. Assist Head of Medical Safety in responding to requests for safety information from regulatory authorities or third-parties worldwide
13. Work as a member of a team to achieve all outcomes
14. Performs all work in accordance with all established regulatory and compliance and safety requirements and ApoPharma SODs
15. All other duties as assigned

Job Requirements:

1. MD or, RN with experience in pharmaceutical industry or regulatory agency. PharmD may be considered
2. Minimum 3 years of pharmacovigilance experience
3. In depth understanding of relevant safety and pharmacovigilance ICH guidelines as well as relevant clinical trials regulations
4. Good knowledge of the US FDA and EMA PV regulations
5. Experience with safety databases (ARGUS preferred)
6. Good knowledge with medical terminology (e.g. MedDRA and WHODRUG).
7. Excellent scientific and clinical knowledge
8. Excellent quality planning and organization of work
9. A spirit of integration and analysis
10. Ability to work under pressure. Ability to manage multiple tasks in an efficient manner
11. Quality of judgment and evaluation of situations
12. Strong interpersonal and verbal/written communication skills
13. Demonstrated effective organizational and time-management skills
14. Ability to establish and maintain effective working relationships with coworkers, management and customers
15. Proven ability in the implementation of new initiatives and receptive to change in demands and workload

Please respond via email with your resume to nwilkes@apotex.com.

At Apotex, we are committed to fostering an inclusive, accessible work environment, where all employees feel valued, respected and supported. Apotex offers accommodation for applicants with disabilities as part of its recruitment process. If you are contacted to arrange for an interview or testing, please advise us if you require an accommodation.