



REGULATORY AFFAIRS OFFICER

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Erkenningsnummer
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APOTEX

Apotex Inc. was founded in 1974, and is the largest Canadian-owned pharmaceutical company. The company has grown to employ over 6,800 people in research, development, manufacturing and distribution facilities world-wide. Apotex has also established a presence through subsidiaries, joint ventures or licensing agreements in Australia, Belgium, Czech Republic, Italy, Mexico, Netherlands, New Zealand, Poland, Turkey, and the UK, to name just a few. Healthcare professionals around the world rely on Apotex for quality and value.

Although the company's own business is developing and manufacturing generic pharmaceuticals, the success of Apotex has enabled it to diversify into a number of other health-related areas. The Apotex Pharmaceutical Group of Companies also researches, develops, manufactures and distributes fine chemicals, non-prescription and private label medicines, and disposable plastics for medical use. Apotex NV, the Belgian subsidiary of the Apotex Group of companies, is looking for a Regulatory Affairs Officer.

RESPONSIBILITIES

- Compile & submit, in a timely manner, regulatory documents according to regulatory requirements for new marketing authorization applications.
- Ensure timely registration of new products
- Ensure dossier compliance during commercialization of the product (submission/follow-up of variations/renewals/PSUR's)
- Ensure timely preparation and submissions of responses to questions raised by the regulatory authorities
- Prepare/maintain the product label/leaflet and packaging in line with the registered file, the local/EU legislation and In-house guidelines
- Provide regulatory support to other departments

PROFILE

- Master's degree in pharmacy or related scientific discipline
- Existing experience in Regulatory Affairs is a strong asset
- Good communication skills (spoken & written) in Dutch, French and English
- Good knowledge of Windows and Microsoft Office (Word, Excel, Power Point)
- Strong initiative and ability to work with minimal supervision
- Detail oriented
- Teamplayer

