Position Description

Reporting directly to the Manager of Regulatory Affairs, the Regulatory Affairs Associate will be responsible for supporting regulatory submission projects primarily for the US market.

The Regulatory Affairs Associate, will be responsible for providing input into regulatory filing requirements, critically reviewing source documents and the preparation of initial and post market generic drug product submissions to meet Canadian and US regulatory requirements.

Primary Responsibilities

- Coordinate, author, compile and file new generic drug product submissions (ANDS/ ANDAs) for a variety of dosage forms (solid oral, liquids, topical semisolids and injectables) in Canada and the US
- Prepare written responses to deficiency letters from regulatory agencies in accordance with agency timelines.
- Coordinate, compile and file post approval submissions for Canada, the US and other international markets as required.
- Review proposed changes to determine filing requirements for Canada and the US
- Review and approve various product labeling components and marketing materials.
- In consultation with management, provide regulatory guidance and expertise to other areas of the business and our partners.
- Demonstrates strong ability to work in team settings
- Builds and maintains positive relationships internally and externally.
- As required, provides support in the preparation and execution of Health Canada, FDA and other regulatory agency inspections (pre-approval and GMP).
- Maintain current awareness of regulatory guidelines (Health Canada, FDA, ICH, European Medicines Agency - EMA, Therapeutic Goods Administration –TGA Australia, etc.).
- Participates in the development of optimal business processes and practices within the department to ensure high levels of partner support and to achieve high quality submissions. Identifies opportunities for efficiencies, business process improvements and cost reduction.
- Other duties as assigned by management

Position Pre-requisites:

- Minimum B.Sc. in a Chemistry, Pharmacy or Life Science discipline combined with a minimum of one to two (1-2) years of hands-on Regulatory Affairs experience filing Canadian and US submissions in eCTD format; RAC certification is an asset.
- Expertise in chemistry and manufacturing, labeling and format requirements for drug product registration for TPD (ANDS, SANDS, DIN, DMF) and for FDA (ANDAs, supplements)
- Knowledge of the use of eCTD software, preferably Lorenz Docubridge, for preparing and filing submissions is required
- Knowledge of GMP and Quality requirements is required.

- Excellent interpersonal, written and verbal communication skills.
- Ability to plan, coordinate and work effectively in a team-oriented environment.
- Moderate computer software skills (Microsoft Word, Excel, Access, PowerPoint, Adobe Acrobat, Document Management Systems).
- Strong organizational ability and management of multiple priorities combined with proven ability to meet strict and established timelines.