Regulatory Affairs Associate - Mississauga

Position Description:

- Reporting directly to the Director, Regulatory Affairs and Quality, the Regulatory Affairs Associate will be responsible for supporting regulatory submissions projects. The Regulatory Affairs Associate will establish and maintain submission plans and associated timelines, participate in submission team meetings, and represent Regulatory in interdepartmental meetings and projects, as assigned.

Primary Responsibilities:

- Coordinate, compile and file drug product submissions for Canada and the U.S. for brand products and variety of dosage forms (solid oral, liquids, topical semisolids and injectables) in eCTD format (e.g. DMFs, NDS, NDAs, S/NDSs, DINs, CTAs, NCs, INDs, provincial formulary submissions etc.) for the successful registration of drug product for domestic and international markets.
- Compile submissions in eCTD format which involves full understanding of the use of Adobe Acrobat to create bookmarks and links.
- Prepare and edit written responses to deficiency letters from regulatory agencies in the stated time frame.
- Co-ordinate, compile and file post-approval submissions for TPD (Notifiable Change, Supplement), some for FDA (CBE supplement, PAS) and other International markets as required.
- Review Change Controls and determine filling requirements for Canada and some US
- Liaise with Regulatory Agencies on all aspects of the drug submission including setting up pre-submission/ scientific advice meetings, follow-up for review status and project updates.
- Review submissions for grammatical errors
- Review various product labeling components and marketing materials.
- Demonstrates strong ability to work in team settings and ability to influence without direct authority. Builds and maintains positive relationships internally and externally.
- As required, provide 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 customer 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 of filing Canadian and some experience of filing USA submissions, including electronic submissions in eCTD formats; RAC certification is an asset.
- Knowledge of the use of eCTD Software, preferably Lorenz Docubridge, for preparing and filing submissions required
- Knowledge of GMP and Quality requirements is required.
- Excellent interpersonal, written and verbal communication skills.
- Ability to 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.