Role Profile

Senior, Regulatory Affairs Specialist/Associate

REPORTS TO: Manager/Director, Regulatory Affairs

WORK LOCATION/TIMES:

1. Head Office or other locations, as defined.
2. Working hours in accordance with Company policy or as required.
3. Travel may be required.

OVERVIEW:

The Senior Regulatory Affairs Specialist/Associate you will be responsible for simple to moderately complex submission projects/assignments. The Senior Specialist/Associate provides input into regulatory filing strategies and requirements on assigned projects, establishes and maintains submission planners and associated timelines, facilitates tactical submission team meetings, and represents Regulatory in interdepartmental meetings and projects, as assigned.

Primary Responsibilities:

- Plan, coordinate, compile and file drug product submissions for Canada and the U.S. for a variety of dosage forms (solid oral, liquids, topical semisolids and injectables) in eCTD format (e.g. DMFs, ANDS, NDS, ANDA, NDAs, S/NDSs, DINs, CTAs, NCs, INDs, provincial formulary submissions etc.) for the successful registration of drug product for domestic and international markets.
- Prepare submissions in eCTD format which involves full understanding of the use of Adobe Acrobat to create bookmarks and links.
- Prepare written responses to deficiency letters from regulatory agencies in the stated time frame.
- Plan, coordinate, compile and file post approval submissions for FDA (CBE supplement, PAS) and TPD (Notifiable Change, Supplement).
- Review Change Controls and determine filling requirements.
- Liaise with Regulatory Agencies on all aspects of the drug submission, follow up for review status and project updates.
- Review submissions prepared by Associates and Senior Associates.
- Work on complex projects which involve anticipating obstacles, develops solutions and resolving issues in a timely manner.
- 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 (including Sales & Marketing, Quality, Technical Services and Operations departments) and our partners.
- Demonstrates team leadership skills 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 - EMeA, Therapeutic Goods Administration –TGA Australia, etc.).

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- 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 Scientific Affairs Management.

Position Pre-requisites:

- Minimum B. Sc. in a Chemistry, Pharmacy or Life Science discipline combined with a minimum of five (5) years of hands-on Regulatory Affairs experience of filing Canadian and USA submissions, including electronic submissions in eCTD formats; RAC certification is an asset.
- Expertise in chemistry and manufacturing, labeling and format requirements for drug product registration for FDA (ANDA, NDA, DMF, IND) and TPD (CTA, ANDS, S/ANDS, NDS, DIN, DMF).
- Experience with Provincial Formulary submissions is an asset.
- Knowledge of the use of eCTD Software for preparing and filing submissions 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.
- Superior 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.