ACIC / Methapharm is expanding and looking for highly qualified and experienced professionals to join our Scientific Affairs team in the areas of regulatory affairs, pharmacovigilance, quality and technical services.

We are currently actively recruiting for the following permanent, full-time position:

Senior Regulatory Affairs Co-ordinator

POSITION SUMMARY

Supports the preparation, submission, tracking, indexing and archiving of regulatory submissions, including original submissions, amendments, deficiency responses, annual reporting; contributes to the development and maintenance of information systems and supports other members of the Scientific Affairs team, as required.

KEY RESPONSIBILITIES INCLUDE:

- Maintains the regulatory submission schedule and regulatory commitments tracker and provides updates on submission activity status.
- Issues notifications and compiles reports on submission activity, as required.
- Provides formatting support and technical assistance of regulatory submission documents to ensure they meet company submission-ready standards.
- Collects various documents needed for regulatory submissions and completes and/or reviews regulatory forms and administrative documents.
- Assists in bookmarking and hyperlinking of documents in the eCTD format
- Assists in the compilation and submission of electronic applications through the secured gateway
- Compiles Annual Reports and submits to Regulatory Agencies.
- Supports submission of drug safety reporting documentation to fulfill regulatory agency requirements/ commitments (ie. PADER submissions to US FDA), as required.
- Fulfills CPP requests by coordinating compilation of the required documentation and completing and/or conducting peer review of the application form; submits and closely tracks and follows up on CPP issuance by regulatory agencies and tracks/processes renewals as required.
- Creates and/or maintains regulatory submission lifecycle management information, summaries and information database systems.
- Distributes and/or tracks the review of new/revised regulatory guidance documents for impact to current standards; supports the implementation of changes to standards, as required.
- Schedules/coordinates activities related to submission review meetings and assists with the logistics of other departmental meetings, as necessary.
- Authors and/or contributes to standard operating procedures, work instructions or creation of document templates related to the Regulatory Affairs activity.
- Responsible for:
    - quality of work
    - ensuring documentation and systems are maintained in a well-organized and easily retrievable manner
    - adherence to deadlines
    - escalation of conflicts in prioritization and/or issues for appropriate resolution/direction
- Provides back-up to RA Coordinator or other members of the RA team, as required.
- Other duties as assigned by Regulatory and Scientific Affairs Management.

PRE-REQUISITES FOR POSITION:

- Post-secondary education or equivalent
- Minimum 5-years experience in Regulatory Affairs or related area in the Pharmaceutical Industry.
- Knowledge and experience in supporting regulatory submission activity and maintaining regulatory information systems
- Knowledge and experience in compiling/publishing electronic Common Technical Document (eCTD) in Docubridge (or equivalent eCTD builder) and submitting through secured gateways
- Quality-oriented with strong attention to detail
- Good judgement and critical thinking ability
- Very well organized with multi-tasking ability
- Excellent written and verbal communication and interpersonal skills
- Proficiency in MS Office with expertise in Microsoft Word, PowerPoint and Excel
- Working knowledge of Adobe Acrobat PDF, Bookmarks and internal hyperlinking.

WORK LOCATION/TIMES:

Head Office (Brantford) – 8:30 am to 5:00 pm

BENEFITS:

RRSP Matching | Health Benefits | Disability & Life Insurance Package