STERIMAX INC.

POSTITION: Sr. Regulatory Affairs Associate
REPORTS TO: Project Manager, Regulatory Affairs
LOCATION: Oakville, Ontario

POSITION DESCRIPTION:

Reporting to the Project Manager, Regulatory Affairs, the Sr. Regulatory Affairs Associate will prepare Post-NOC regulatory submissions for generic products and actively participate in the management of submissions for marketed products in order to fulfill Canadian regulatory requirements. The Sr. Regulatory Affairs Associate is expected to interpret regulatory requirements and ensure that they are met in support of existing commercial products within Health Canada jurisdictions. Under general supervision, the Sr. Regulatory Affairs Associate will advise on CMC regulatory and compliance-focused aspects of post-approval regulatory submissions.

KEY RESPONSIBILITIES:

- Coordinates the assembly, including requesting and/or generating, of documents to support lifecycle submissions linked to post approval changes (ANDS, SANDS, NHP Notifications/ Amendments, DINA, etc.) per established business processes and systems
- Liaises with external partners/CMOs to request documents and ensures regulatory compliance is met for the purpose of filing successful submissions
- Evaluates and ensures that submissions are accurate and meet format and content requirements as per Health Canada regulations
- Reviews, evaluates, prepares, and files deficiency responses for Level-I changes to Health Canada in a timely manner within given deadlines
- Evaluates Change Controls and prepares Level III and IV changes to ensure company compliance
- Monitors labelling updates and ensures that product labelling (i.e., Product Monograph and inner/outer labels) is accurate and compliant with relevant guidelines and policies
- Communicates effectively with internal departments (Quality, Supply Chain, Marketing, etc.) to assist in the continuation of product supply
- Contributes to an efficient and effective regulatory affairs team and uses knowledge and expertise towards a culture of continuous improvement
- Maintains current awareness of Health Canada regulatory guidelines and shares knowledge with the department

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TECHNICAL SKILLS:

- Experience in reviewing scientific information to assess technical merits and suitability of scientific rationale to ensure information is presented clearly and conclusions are adequately supported by data
- Demonstrated oral and written communication skills and the ability to communicate issues in a succinct and logical manner
- Knowledge of GMP requirements and QA/QC procedures
- Strong understanding of Health Canada and ICH regulatory guidance documents and policies
- Proficient computer skills, including MS Office applications and Adobe Acrobat; Experience with eCTD publishing tools is an asset
- Demonstrated understanding of sterile product manufacturing is preferred

LEADERSHIP SKILLS:

- Demonstrated flexibility in responding to changing priorities or dealing with unexpected events
- Capability to handle multiple priorities and balance work to achieve business goals
- Demonstrated effective leadership, communication, and interpersonal skills on business commitments and project timelines

QUALIFICATIONS:

- University Degree in Science or Life Sciences and post-graduate certification in Regulatory Affairs program
- Must have a minimum of 5 years of experience in drug submissions for Canada, preferably with parenteral dosage forms

APPLICATION PROCESS:

If interested, please visit our Careers page at http://sterimaxinc.com/careers/ and attach your resume to the form. Kindly state 'Sr. Regulatory Affairs Associate' in the *Your Message* field for ease of identification.