Senior Regulatory Affairs Specialist
Job Location – CA – Montreal, QC

Position Summary:

The Senior Regulatory Affairs Specialist (RAS)- will support the Global business concerning pre and post market matters and ensure success of the business through completing assigned tasks with minimal supervision for change control activities, product promotional activities, labeling review activities, product registration and listing database experience, global product registrations requests, export/import activities, and post market actions and associated activities. The incumbent will provide other regulatory support as assigned by their supervisor.

Duties and Responsibilities:

- Assure through actions that regulatory compliance for CVT medical devices products are maintained.
- Prepare and update Technical Files to MDD/MDR requirements and associated documents to ensure regulatory compliance for CVT medical devices are maintained.
- Assist in developing the processes and procedures for cybersecurity, Software (e.g., SaMD, firmware, MDDS) and development of apps as well as regulatory strategies and submissions.
- Review and load new product listings, product delisting, registration of new manufacturing sites, etc. into the registration and listing databases. Maintain renewals and the up-to-date information for all appropriate registration and listings databases.
- Complete inquiries and requests from internal and external sources in regard to import/export processes and practices and customs holds.
- Complete all training as required and maintain training plans, records, etc.
- Maintain the organization and the security for all regulatory paper and electronic files.
- Develop, write, implement and maintain RA procedures.
- Complete regional RA requests and provide the requested documents i.e. CFG's, LOA's, documentation, etc.
- Review, comment and approve/disapprove change control requests which affect the marketing of medical devices.
- Complete a Letter to File following all US FDA regulations and guidance's.

- Review and approve/disapprove labeling change request, advertising and promotional request, field communications, etc. in accordance with CVT standards and procedures and labeling regulations and guidance's.
- Execute, manage and close post market activities i.e. recalls and corrections.
- Prepare and submit all reporting activities associated with a removal or correction with US FDA and associated OUS Competent Authorities and Regional CVT RA team's requirements.
- Keep informed about new and revised regulatory requirements.
- Support as requested by supervisor with all other request for information and documentation associated with regulatory laws and regulations

Qualifications:

- A minimum of a bachelor's degree in Science, Engineering, Medical Technology or Nurse required. An advanced degree and/or Regulatory Affairs Certification (RAC) is preferred
- Minimum of at least 5 years of experience in medical device Regulatory Affairs is required.
- Understanding of the regulatory framework for medical devices (hardware and software), as well as cybersecurity.
- Understanding of the Quality System Regulations ISO 13485:2016, recalls and correction and labeling requirements required. International experience with recalls and corrections and labeling requirements is desirable.
- Experience with Class I, II, sterile medical devices.
- Familiarity with Class III, products desirable.
- Authored and implemented a minimum of 3 standard operating procedures.
- Experience with electronic submission is preferred
- Experience with US/EU submissions.
- International Regulatory Affairs experience is desirable.
- Self-starter with the ability to work independently.
- Good time management and problem-solving skills.
- Strong interpersonal and collaborative skills.
- Ability to execute both reactively and proactively and in a timely manner.
- Ability to conduct thorough research of regulatory requirements and related issues to identify potential solutions and available options.

- Ability to plan, manage and execute project-based tasks often with tight deadlines
- Strong analytical skills with good judgment making capabilities.
- Demonstrated organizational skills.
- Strong oral and written communication skills.
- Proficiency with Microsoft Office (Excel, Word, PowerPoint), Adobe Acrobat and Internet-based regulatory resources, Track wise, Documentum etc.

Desired, but not required experience:

- Experience with Biologics or Combination Products
- Experience with FDA electronic submission (e.g., FURLS, Gateway, etc.)
- Experience with UDI requirements
- Experience managing a post market action in the US
- An advanced degree and/or Regulatory Affairs Certification (RAC)
- Familiarity with Class III, cosmetic or OTC products
- International Regulatory Affairs experience

Working Conditions:

This position is based in a standard office environment, though remote working may be required due to COVID-19 or other circumstances.