Title: Sr. Regulatory Affairs Specialist

Division/Department: QA/RA
Type of Position: Full Time

Summit Medical, an Innovia Medical Company
Eagan, Minnesota
August 2020

Innovia Medical combines the experience and expertise of Summit Medical, Shippert Medical, Network Medical, DTR and Eagle Labs to help our medical professional partners elevate the delivery of care to improve patient outcomes. We develop products not just for our customers, but with our customers. Our collaborative approach cultivates innovative medical solutions for the global health care industry. Through excellence in design, supply chain management, manufacturing and customer service we put quality at the forefront in all aspects of our business.

Job Summary

The Senior Regulatory Affairs Specialist will provide regulatory support in any number of areas: review/analyze impact of modifications to manufacturing process, product, and packaging to the registration status of approved products and help determine the appropriate regulatory pathway, review/approve advertising & promotional materials, re-registration activities in support of US registrations, help develop regulatory strategies for new product development initiatives, and/or regulatory operations activities in archiving/assembling/publishing regulatory filings and other health authority communications.

Essential Duties and Responsibilities

- Coordinate and submit licenses and authorizations for the maintenance of existing products, international registrations and dossiers, updates to DOC (technical files), engineering and device change requests.
- Research, collect data, and respond to requests from regulatory agencies to prepare and submit documentation for marketing approvals (US, Canada and EU), as well as to provide routine regulatory information to associates and affiliates.
- Provide regulatory guidance to product development teams and responds to product information requests.
- Represent regulatory affairs in cross-functional project teams and plans schedules for regulatory deliverables on a project and monitors project through completion.
- Prepare regulatory labeling requirements specifications for new and modified products; review product labeling for existing products to ensure compliance.
- Assist in the development of best practices for Regulatory Affairs processes.
- Provide Regulatory Affairs support during internal and external audits.

- Adhere to environmental policy and procedures and support department environmental objectives.
- Other duties as assigned by manager

Desired Experience & Education

- Bachelor's degree or equivalent education and a minimum of 7 years' experience in the regulatory affairs area
- Experience with technical files, regulatory registrations, recalls, MDR's, Vigilance reports
- Good understanding and working knowledge of EU MDR, FDA and Canada medical device regulations, ISO 13485, Health Canada medical device regulations, ISO 14971 and MDSAP
- Good verbal and written communication skills in English. Ability to read, write and speak English in order to comprehend and execute internal procedures and work instructions and communication to regulatory agencies
- Must be detail oriented, have good organization skills, be self-motivated, work independently and take full ownership of his/her responsibilities
- Knowledge of Sterilization methods
- Good working knowledge of the manufacturing and quality operations.
- Proficient in Microsoft Office

We offer a full complement of benefits including health, dental, vision, life insurance, AFLAC, 401(k) and generous PTO. Come work for a growing company that offers a fun, collaborative environment with work-family balance.

Qualified applicants should send their resume, cover letter and salary requirements to **careers@innoviamedical.com**.

EOE/Disabled/Veterans