Title: EU MDR Regulatory Affairs Specialist

Division/Department: Quality and Regulatory
Full Time

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

Innovia Medical combines the experience and expertise of Summit Medical, Shippert Medical, Network Medical 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 EU MDR Regulatory Specialist will serve as a Regulatory Subject Matter Expert to the implementation and sustaining of the new EU MDR regulation. This role shall include keeping up to date on EU MDR regulation, providing technical guidance on EU MDR regulation, keeping European technical files current, complete annual Canadian registration, complete customer/distributor surveys/questionnaires and actively participate in internal and external audits.

Essential Duties and Responsibilities

- Follow all procedures and work instructions defined in the Quality System Manual
- Maintain technical files (including: essential requirements, risk assessments, clinical evaluation reports, usability reports, etc.)
- Review product design and manufacturing changes for compliance with applicable regulations
- Provide technical guidance on EU MDR regulation intended meaning
- Review protocols and reports to support regulatory submissions
- Review device labeling and marketing/advertising materials for compliance with applicable regulations
- Perform annual regulatory registrations
- Manage product recalls, MDR's and Vigilance
- Support inspections and audits by Notified Body and Customers
- Create and/or revise standard operating procedures (SOPs) related to regulatory processes
- Perform change notifications to regulatory agencies
- Maintain Certificate of Foreign Government
- Participate in gap assessments for any changes made in relevant standards documents.
- Perform other duties as assigned by manager or supervisor

Education & Experience Requirements

- Bachelor's degree or equivalent education and a minimum of 7 years' experience in the regulatory affairs area within an CE registered/FDA registered/ISO certified medical device company
- Experience with technical files, regulatory registrations, recalls, MDR's, Vigilance reports
- Good understanding and working knowledge of EU MDR, FDA 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

Preferred Skills & Abilities

- Certified auditor
- Regulatory experience in a medical device company

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