Title: Quality Engineer

Division/Department: Quality and Regulatory
Type of Position: Full Time

Summit Medical, an Innovia Medical Company
Eagan, Minnesota
May 2019

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 Quality Engineer will provide support to Quality, Regulatory, Engineering, Manufacturing, Sales, Marketing, Accounting and Customer Service. This position will be involved in processing complaints, CAPA's, document changes, performing audits, maintaining technical files and other quality and regulatory duties as assigned.

Essential Duties and Responsibilities

- Follow all regulations, standards, procedures and work instructions defined in the Quality System Manual
- Maintain the Complaint system, including documenting, reviewing, investigating and closing Complaints
- Review, investigate and document CAPAs
- Update or create procedures, work instructions, forms and labels using Word, Excel, Label View, etc. in support of quality, manufacturing and engineering activities
- Review and release sterile product
- Review document changes as assigned
- Support the compilation of technical files including clinical evaluation reports, essential requirements, usability engineering reports, risk management files, etc.
- Perform internal, supplier and design history file audits
- Back-up Documentation Coordinator and Quality Inspector as needed (Document Change Order implementation, Training, In-coming Inspection, In-process Inspection, Label Inspection, Non-conforming Material Reports
- Assign and review deviations
- Support agency listings and annual registrations
- Support inspections and audits performed by FDA, Notified Body, OSHA, etc.
- Support / Lead Customer audits
- Assist in compiling Design History Files

- Support purchasing with complete documentation as required
- Support quality function and perform activities as assigned
- Perform other duties as assigned by supervisor or manager

Desired Experience & Education

- Bachelor's Degree preferred and a minimum of 3 years medical device experience. Or, in place of a degree, a minimum of 5 years' experience in quality/regulatory in a medical device company
- Ability to apply learned technology to Summit medical products and processes
- Software proficiency: Microsoft Word, Microsoft Excel, Adobe Acrobat, LabelView, BarTender
- Good understanding of FDA 21 CFR Regulations, ISO 13485, Health Canada Regulations, European Medical Device Regulations, Good Documentation Practices, ISO 14971
- Possess excellent verbal and written communication skills in English. Ability to read, write and speak English in order to comprehend and execute internal Procedures, Drawings, Manufacturing Work Instructions (MWI), etc.
- Attention to details and excellent organization skills

Preferred Skills & Abilities

- Knowledge of drafting standards and drafting software (Solidworks, AutoCad)
- Certified auditor or auditor training

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