Title: Sr. Quality Engineer

Division/Department: Quality and Regulatory
Full Time

Summit Medical, an Innovia Medical Company
Eagan, Minnesota
October 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 Sr. Quality Engineer develops, establishes and maintains Quality Engineering methodologies, systems and practices that meet quality and customer requirements. The Sr. QE drives quality improvements focused on New Product Introductions, Product Transfers and Marketed Product Support. This position will provide sound, systematic problem-solving methodologies in identifying, prioritizing, communicating and resolving quality issues. Supports quality disciplines, decisions and practices. The Sr. Quality Engineer will perform root cause analysis and identify appropriate actions for Corrective and Preventive Actions (CAPAs) and Nonconforming Material systems, will be involved in complaints investigations, document changes, maintaining the calibration system, supplier management, and will supervise Quality Inspectors

Essential Duties and Responsibilities

- Follow all regulations, standards, procedures and work instructions defined in the Quality System Manual
- Sound knowledge of inspection principles and techniques
- Sound knowledge of validation principles
- Ability to interpret Quality Standards for implementation
- Analytical Problem Solving- ability to identify problems, define problem statements clearly and accurately, apply structured and disciplined methodology to identify data-driven root causes
- Investigate and document CAPAs
- Update or create procedures, work instructions, forms and labels using Word, Excel, Label View, etc.

- Maintain the Calibration System
- Review and release sterile product
- Review document changes as assigned
- Support the compilation of technical files including usability engineering reports, risk management files, etc.
- Perform internal, supplier and design history file audits, as needed
- Evaluate and Assess Suppliers
- Assign and review deviations
- Support inspections and audits performed by Customers, FDA, Notified Body, OSHA, etc.
- Perform other duties as assigned by supervisor or manager

Education & Experience Requirements

- Bachelor's Degree required in a Technical or Scientific discipline
- Minimum 8 years of experience in a medical device design and manufacturing environment
- Ability to apply learned technology to Summit Medical products and processes
- Software proficiency: Microsoft Word, Microsoft Excel, Adobe Acrobat, LabelView, BarTender
- Strong background in FDA 21 CFR Regulations, ISO 13485, Health Canada Regulations, European Medical Device Regulations, 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

- Previous supervisory experience a plus, but not required
- 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