Title: Design & Quality Assurance Engineer

Division/Department: Engineering
Type of Position: Full Time

Summit Medical, an Innovia Medical Company
Eagan, Minnesota
April 2021

Innovia Medical combines the experience and expertise of Summit 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 Design & Quality Assurance Engineer will assure new, modified, or transferred products conform to the requirements and establish compliance within the quality system. Maintains/creates Design History Files for current and new products and supports the Regulatory department on Tech File compliance. Will also support the quality department in processing complaints, CAPA's, document changes and supplier quality.

Essential Duties and Responsibilities

- Follow all regulations, standards, procedures and work instructions defined in the Quality System Manual
- Execute and support on-time completion of Design Control Deliverables
- Ensure DHF content completion, integrity, and regulatory & standards compliance; will collaboratively communicate & resolve gaps
- Support internal & external audit responses
- Support product re-certifications
- Lead or support execution of biocompatibility and sterilization qualifications
- Lead or support Risk Management activities
- Define and implement Verification and Validation activities
- Facilitate project plans and reviews
- Write/update manufacturing work instructions as needed
- Process document change requests (DCR's) promptly, accurately and completely
- Support manufacturing, helping to produce products meeting Summit Medical quality standards, cost targets, and production schedules
- Develop processes that are safe, mistake proofed, and easy to follow instructions using design for manufacturing principles

- Support Customer audits, and audits performed by the FDA, Notified Body, OSHA, etc.
- Review, investigate and document CAPAs
- Develop compliant electronic design history files
- Back up Quality Engineering when needed
- Perform other duties as assigned by supervisor or manager

Experience & Education Requirements

- Bachelor's Degree in Manufacturing Engineering OR equivalent
- 5-8 years of Medical Device experience
- Software proficiency
    - Microsoft Word, Excel, PowerPoint, Project, Solidworks, Minitab, eQMS systems
- Manufacturing process knowledge including:
    - Lean Manufacturing
    - Packaging and labeling
    - Clean room and sterilization processes
- Experience with small to large semi-automated equipment implementation including:
    - Working with outside equipment manufacturers for quotes
    - Design inputs/outputs
    - Validations (FAT, SAT, IQ, OQ, PQ)
- Materials selection knowledge including physical properties and biocompatibility
- Good understanding and working knowledge of FDA medical device regulations, ISO 13485, Health Canada medical device regulations, European medical device regulations, ISO 14971

Preferred Skills & Abilities

- Possess excellent verbal and written communication skills and organizational skills
- Mechanical aptitude with capability to install, assemble, repair and maintain production equipment

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.

*Please note: This position is primarily based at the offices located in Eagan, MN.

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

EOE/Disabled/Veterans