



Documentation Coordinator

Summit Medical, an Innovia Medical Company
St. Paul, Minnesota
June 2018

Innovia Medical combines the experience and expertise of Summit Medical, Shippert Medical and Network Medical 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 Documentation Coordinator will be responsible for maintaining the document control process, which includes making document changes, routing for review and approval, making documents effective, distribute documents and make notifications. In addition, the Documentation Coordinator will be responsible for maintaining the training process, which includes keeping the training matrix current, routing training assignments, ensure training has been completed and filing training records.

Essential Duties and Responsibilities

- Follow all procedures and work instructions defined in the Quality System Manual
- Documentation
 - Review of document change orders to confirm all steps have been completed
 - Process, implement and release document change orders
 - Maintain master documents
 - Distribute controlled documents and remove obsolete revisions
 - Coordinate training of revised documents
 - Update technical files with document changes
 - Create and/or update specifications, procedures, work instructions, forms and labels using Word, Excel, and Bartender in support of changes
 - Support inspections and audits performed by FDA, Notified Body and customers
 - Assists in compiling Design History Files
- Support agency listings and certifications: FDA, ISO 13485, Health Canada
- Support quality inspection department as needed
- Support manufacturing to keep product documentation accurate and up to date
- Support purchasing with complete documentation as required
- Support quality functions as needed

- Perform other duties as assigned by manager or supervisor.

Required Experience

- Document Control experience; medical device industry a plus!

Desired Experience & Education

- Two-year degree or equivalent experience; ability to apply learned technology to Company products and processes
- Intermediate proficiency with Microsoft Word & Excel, Adobe Acrobat, LabelView, BarTender
- Good understanding of FDA 21 CFR Regulations, Good Documentation Practices, ISO 13485:2016
- Possess excellent verbal and written communication skills in English, which includes the ability to read, write and speak to comprehend and execute internal procedures, drawings and Manufacturing Work Instructions (MWI's)
- Proven attention to details and excellent organization skills

We offer a fun, collaborative environment with full-time benefits, including health and dental (free for employee only), life insurance, supplemental AFLAC, 401(k) plan and generous PTO policy!

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

EOE/Disabled/Veterans