

DOCUMENT CONTROL SPECIALIST (MEDICAL DEVICE)

Cardiocom is seeking a full-time Document Control Specialist with medical device experience to ensure all company Quality System documentation is in compliance with corporate policies, FDA QSR/GMP and ISO 13485. This position will manage the control, review, change, retention, distribution, and archiving of documents/records, as well as assist in the development of policies and procedures as they apply to Quality Systems document control.

Responsibilities include:

- Provide Good Manufacturing Practices (GMP) documentation support to company
- Ensure that all policies, procedures, etc. are compliant with current regulations and that only current, approved policies/procedures are utilized company-wide
- Write, revise, update, control and maintain all QS documentation including but not limited to: Standard Operating Procedures (SOP's), Work Instructions, Forms, Design History Files, Technical Files, Device Master Records, Device History Records/Files, Batch Records, Bill of Materials, Risk Management Plans/Reports/Files, Instructions for Use, Labeling, Drawings, Specifications, Test Plans/Reports, etc.
- Initiate and complete Change Orders
- Manage and monitor CAPA's
- Assist with and/or conduct internal audits
- Train new employees on ISO/QSR and required procedures/work instructions/forms

Qualifications include:

- BA/BS degree or equivalent work experience in a related field with at least one year document control experience in the medical device industry
- Detailed documentation skills
- Ability to organize and manage large quantities of documentation
- Excellent written and verbal communication skills
- Superb time management and organizational skills
- Advanced computer skills including MS Word, Excel, Adobe Illustrator and InDesign
- Excellent time management, detail, accuracy and organization skills
- Prefer experience with FDA submissions, Notified Body and other regulatory authorities
- Knowledge of FDA QSR, ISO 13485 and CMDCAS/CMDR regulations and requirements preferred
- Must be able to work in a fast-paced environment
- Self-directed individual who works well under minimal supervision

Cardiocom is a high growth, dynamic telehealth company providing opportunities for leadership and growth, excellent pay and benefits. We are located in Chanhassen, MN.

Interested candidates should email their resume and salary requirements to jobs@cardiocom.com.

For more information on Cardiocom, please visit our website at cardiocom.com

KEYWORDS: document control, documentation