

QUALITY ASSURANCE SPECIALIST – MEDICAL DEVICES

As a result of our exciting growth, we have an outstanding opportunity for a full-time Quality Assurance Specialist to direct and implement the company's quality system design, controls and continuous improvement to assure product quality and safety. If you thrive in an innovative, dynamic, team oriented environment, Cardiocom can offer you the opportunity for a successful career in the medical device healthcare industry.

Responsibilities:

- Develop and maintain quality systems, processes and procedures
- Conduct internal audits and manage external audits
- Manage corrective and preventive action system
- Manage supplier selection, evaluation and monitoring
- Manage product complaints
- Manage risk management process throughout product life cycle
- Compile, analyze, trend and present QMS metrics
- Gather and prepare data for and lead product quality safety meetings and management review meetings
- Work closely with Regulatory to ensure labeling meets international regulatory requirements

Requirements:

- Bachelor's Degree in Life Sciences or Engineering or related field
- 5+ years experience in Quality Assurance or Quality Control in the medical device industry
- Hands on experience building a Quality Management System from ground up
- Working knowledge and experience with quality systems regulations and guidelines, FDA regulatory requirements, ISO 13485, cGMP, Medical Device Directive (MDD), In Vitro Diagnostic Device (IVDD) and Canadian Medical Device regulations
- ASQ or CQA Certification
- Experience performing internal audits (lead Auditor certification preferred)
- Six Sigma training/certification preferred
- Strong statistical data analysis knowledge
- Ability to read, interpret, understand and implement regulations and regulatory requirements
- Experience in product and process related validation including UL 60601
- Experience in software validation activities for medical devices
- Must be able to generate technical reports and protocols
- Excellent verbal and written communication skills and work with all levels of company
- Demonstrated project management skills
- Excellent communication skills and technical writing
- Ability to work independently with minimal supervision

Salary, Benefits and Other:

- Salary based on experience
- Cardiocom offers a dynamic team environment with a great benefits package that includes medical, dental, vision, 401K, flex spend, life and PTO
- Excellent opportunity for growth and advancement

Please send your resume and salary requirements to jobs@cardiocom.com

For more information on Cardiocom and its services, call (888) 243-8881 or visit cardiocom.com

Local candidates only please.

Keywords: Regulatory, Quality, ISO, Medical Device