

PRINCIPAL REGULATORY EXPERT – MEDICAL DEVICES

As a result of our exciting growth, we have an outstanding opportunity for a full-time Principal Regulatory Expert to lead and direct activities to ensure compliance with worldwide regulatory requirements. 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 regulatory strategies for new and modified medical devices
- Write and submit international and US regulatory product submissions and registrations (e.g., 510(k), etc.)
- Assess regulatory implications for device changes and prepare required documentation
- Research regulatory requirements and advise senior management of new or developments in worldwide regulations as necessary
- Provide input to R&D and Manufacturing to ensure worldwide regulatory requirements and standards are incorporated in the product development process and design/manufacture of products
- Reviewing specifications, protocols, reports, change orders, nonconforming materials, complaints, risk management, product failure analysis, etc. and analyze/recommend changes
- Write and manage Technical Files for products
- Review and provide input to device labeling and marketing/advertising material
- Participate in the maintenance of the Quality Management System

Requirements:

- Bachelor's Degree in Regulatory Science, Engineering, Life Sciences or combination of education and experience providing equivalent knowledge
- 8-10 years medical device industry experience in Regulatory and/or Quality Management System and Design Control
- Experience with US, EU and Canadian medical device regulations and submissions
- 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
- 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