Job Description

Job Title: Senior Quality Engineer

Department: Quality and Regulatory

Reports To: Director of Quality and Regulatory

Summary of Position

This position under direct supervision is responsible for supporting the quality management system (QMS) activities, maintenance, and records to ensure compliance with regulatory agencies and the Boulder BioMed QMS.

This position is accountable for ensuring compliance to the QMS by maintaining the documentation required to support the certifications necessary to sell medical devices in the US and other countries. Will work within cross-functional team(s) with quality, R&D, manufacturing, operations, management, outside vendors, clients, and other personnel as necessary.

Essential Duties and Responsibilities

- Participate in and/or lead quality design control and development activities including design planning, quality control planning, test plans and protocols, design history file management, design reviews, etc. to challenge design and compliance requirements (safety, performance, and reliability)
- Generate and modify QMS procedures and forms to ensure regulatory compliance
- Review all documentation to ensure compliance with internal and external quality and regulatory requirements
- Participate and/or lead closures of CAPAs, Complaints, and NCRs as they arise
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- Work with suppliers to ensure quality and performance requirements are fulfilled
- Review Preventative Maintenance and Calibration for equipment for compliance
- Perform evaluation of nonconformances including Root Cause Analysis and Corrective/Preventative Actions for CAPAs, Complaints, and NCRs
- Participate in and/or lead quality design risk activities including overall risk management, risk plan and report writing, hazard analysis, and risk management file management.
- Participate in and/or lead deployment of Quality Management Systems to clients

Additional Responsibilities

- Support FAI, receiving, in-process and final inspection activities
- Evaluate processes, methods, and equipment for adherence to good manufacturing practices (GMP) and other regulatory agencies for compliance

- Maintain the electronic QMS system and review records for adequacy and consistency
- As required, identify continuous improvement opportunities, generate action plans, and implement
- Prepare summary and status of the quality system based on quality data/metrics
- Support engineering functions – R&D and operations – as needs arise

Competency/Qualifications Required for Position

- 7+ years experience in Quality Engineering
- Salary range: $102,000-$130,000
- BS or higher in engineering discipline
- Familiarity with ISO 13485, US FDA QSRs, CE Marking, MDD, and other international requirements as required
- Knowledge of quality control processes and statistical techniques
- Understanding of manufacturing processes and techniques
- Strong analytical and problem-solving skills; strong attention to detail
- Proficient in Microsoft Office products
- Excellent verbal and written communication skills
- Strong interpersonal skills and the ability to work with cross-functional teams