Job Description

Job Title: Regulatory and Quality Associate

Department: Regulatory and Clinical Affairs

Reports To: VP of Regulatory and Quality

Summary of Position
This position acts under direct supervision and is responsible for developing regulatory strategies, preparing regulatory submissions, and obtaining approvals necessary to introduce new or revised products to market worldwide. This position is responsible for the hands-on execution associated with projects in medical device manufacturing regulatory compliance. This position is also responsible for supporting the quality management system (QMS) activities, maintenance, and records to ensure compliance with regulatory agencies and the Boulder BioMed QMS. Will work within cross-functional teams with quality, R&D, manufacturing, operations, management, outside vendors, clients, and other personnel, as necessary.

Essential Duties and Responsibilities
• Assist in maintaining the electronic QMS system and review records for adequacy and consistency • Generate and modify QMS procedures and forms to ensure regulatory compliance • Review documentation to ensure compliance with internal and external quality and regulatory requirements • Prepare regulatory strategies and associated documentation • Participate in design control and development activities, e.g., quality control planning, risk management, hazard analysis, test plans and protocols, inspections, and design reviews to challenge design and compliance requirements (safety, performance, and reliability) • As required, identify continuous improvement opportunities, generate action plans, and implement • Participate in closures of CAPAs, Complaints, and NCRs • Prepare summary and status of the quality system based on quality data/metrics • Support engineering functions, R&D, and operations, as necessary

Supervisory Responsibilities
• None

Authorities for Position
• QMS support, maintenance, and records

Competency Required for Position
• 3+ years in medical device Regulatory and Quality • BS or higher • Salary range: $60,000-$88,000

Qualifications Required for Position
• Familiarity with ISO 13485, US FDA QSR, CE Marking, MDR, and other international regulatory requirements • Strong analytical and problem-solving skills: attention to detail • Proficient in Microsoft Word and Excel • Excellent verbal and written communication skills • Strong interpersonal skills and the ability to work with cross-functional teams

Work Environment
• Generally, a desk position using PC laptop computer • Some functions may be performed remotely

Employee name:	**Date:**
Manager / Supervisor:	**Date:**