Company: Medical Device Manufacturing  
Job Position: Full time  
Job Location: Fremont, CA  

We’re seeking a full time Quality Assurance Manager.

Job Summary:  
The QA manager is an experienced person within the medical device industry with extensive knowledge performing their function within the Food & Drug Administration (FDA) Quality System Regulations (QSRs), International Organization of Standardization (ISO) 13485:2003, Medical Device Directive (MDD) 93/42/EEC, ISO 14971:2007. The incumbent has the ability to take strategic direction and establish efficient and compliant processes throughout the organization and has strong communication at all levels. This position is to manage the quality assurance group to include incoming inspection, quality assurance, quality compliance, and quality engineering.

Travel Requirements:  
≤5% Training opportunities, Distributors, Clinical Sites, Suppliers and etc.

Job Responsibilities:  
- **Deputy Management Representative** – Understand and perform tasks described within the Quality System for Management Representative duties  
- Develop, administer and maintain quality assurance procedures and activities required to ensure that the company's processes and products are in compliance with applicable quality standards and requirements  
- Employ quality assurance methodologies in support of engineering, manufacturing and regulatory functions  
- Develop and implement quality control and inspection procedures for receipt and control of incoming materials, in-process materials and final product acceptance activities  
- Define quality control standards and test; specify test equipment and procedures  
- Establish and maintain test instrument calibration procedures and maintenance schedules  
- Establish quality assurance and quality control inspection and testing procedures  
- Identify quality assurance metrics; analyze and report trends to management  
- Review and host meeting(s) for nonconforming materials.  
- Active participant in all stages of design development, V&V testing and design control activities, ensuring quality assurance considerations and requirements met  
- Responsible for developing and maintaining sterilization validation and material biocompatibility activities  
- Should exhibit the ability to evaluate requirements for testability, design efficient test cases, and write extensive technical documentation  
- Participate in the review of product requirements, design requirements, software requirements specifications, and functional specifications
• Assist in Risk Management activities, FMEAs and ensure compliance to standards and regulations
• Assist in the failure investigation of product complaint and CAPA activities
• Assist in preparation for and conducting of regulatory agency inspections
• Review for completeness and adequacy of the Design History record for the ROBODOC Surgical System
• Other tasks as assigned.

Qualifications:
• Bachelor's Degree with a minimum of 10 years experience in the medical device industry
• Demonstrated success in a start-up, entrepreneurial work environment
• Thorough knowledge of FDA Quality System requirements, ISO 13485:2003 (Quality System) requirements, ISO 14971 (Risk Management) requirements, Medical Device Directives (MDD) requirements, Knowledge of Good Manufacturing Practices (GMP) and applicable Quality System Standards
• Familiar with EN 60601, Safety requirements for medical electrical systems
• Familiar with ISO 62304, Medical Device Software – Software Life Cycle processes
• Ability to analyze and interpret standards, technical procedures, professional journals and governmental guidance and regulation documents
• Understanding of sterilization validation and material biocompatibility requirements
• Understanding of software, electrical and mechanical engineering principles
• Excellent verbal and written communication skills
• Effective problem solving skills
• Ability to work in a team minded approach to achieve individual and company success
• Fluent in computer skills and, at a minimum, the use of Microsoft Office Word, Microsoft Office Excel, Microsoft Office PowerPoint and Microsoft Office Project programs
• Demonstrated project management skills and experience.
• Proficient in timely review of technical and clinical data.

Curexo Technology Corporation offer a fast-paced work environment, and a very competitive compensation, medical and 401K retirement plan benefits available

We are an equal opportunity employer and encourage diversity.

To apply: Please submit resume and Cover Letter to HR dept at jobs@robodoc.com

Company Overview:
The Company is a pioneer in medical robotics and world leader in image-directed, robotic products for orthopedic applications.
The Company's product allows surgeons to pre-operatively plan their surgery in a 3-D virtual space and then execute the surgery in the operating room, exactly as planned.