Position Details

- **Title:** Quality Engineering Consultant
- **Location:** USA-TX- Austin
- **Job Type:** Full-time
- **Travel:** Up to 25%
- **Experience Required:** 4-10 years in medical device Quality Assurance / Design Controls
- **Reports to:** Director of Operations

Job Summary

The primary responsibility of this position is to advise and implement quality systems for medical device manufacturers. This position requires utilization of Quality Management System methods, including but not limited to: quality system implementation, project management, design controls, validation (design, process, and/or software), risk management, design verification, and post-market activities. Must interact with consultants, clients, suppliers, and experts outside QA Consulting in order to communicate and implement QA Consulting's objectives.

Principal Duties and Responsibilities

- Fulfill Project Manager role for a distinct set of clients by serving as primary client contact within QA Consulting, translating client needs into a defined scope of work, and working with QA Consulting staff to delegate and effectively complete client deliverables
- Implement processes and procedures and conduct analyses to sustain and improve the Quality Management Systems of QA Consulting's clients. Examples include risk planning, analysis, design controls, verification and validation, and inspection methods and procedures
- Responsible for defining production and inspection methods, monitoring performance, and handling nonconformances
- Conduct post-market activities including complaints handling, MDR evaluations, and CAPA assessments
- Responsible for effectively communicating with client, meeting client deadlines, and managing client expectations
- Supporting Top Management and consulting group in the development and implementation of client objectives
- Use creative problem-solving skills to identify, solve, and/or improve process anomalies
- Perform engineering research, statistical analysis, write technical protocols/ reports using relevant standards and data
- Work with suppliers, laboratories, clients, and other group members to assist with implementation and effectiveness of client deliverables
- Work with Quality Specialists to generate and release Engineering Change Notices and implement document controls
- Review prints, data, procedures, and test protocols/ reports for accuracy and technical application of standards (ISO, AAMI, ASTM, and IEC) for electromechanical systems
- ***This is not an exhaustive list of duties or functions***

Knowledge, Skills, and Abilities

- Must demonstrate competence in the medical device quality system regulations 21 CFR 820 and ISO 13485
- Able to apply quality tools techniques such as: design controls, quality system auditing, inspection methods, statistical sampling plans, gauging studies, design verification and validation, and process validation
- Ability to apply mathematical concepts such as statistical inference and probability
- Ability to apply logic, creativity, and scientific thinking to a wide range of intellectual and practical problems
- Must have experience working with multiple sized companies, from start-up through fortune 500 firms
- Time management and communication both to QA consultants and the client
- Demonstrates ownership for the integrity of work
- Able to work independently and consider options for completing work
- Strong written and verbal communication skills
- Working knowledge of FDA regulatory premarket notification processes and labeling requirements
- Must be able to manage projects and work with team members to complete tasks on time and within budget

Education

- Bachelor's degree in Engineering (Biomedical, Mechanical, or Electrical) is preferred. Other scientific disciplines will be considered
- Master's degree in Engineering Management or MBA preferred
- ASQ Certification as a Quality Engineer, ASQ Certified Reliability Engineer, or ASQ Manager of Quality/Organizational Excellence is desired

Characteristics

- Deadline driven
- Able to work efficiently, independently, and as part of collaborative team

01	13-036	Initial Release. Supersedes FRM-6.2-13.	10 Jan 2014
02	17-001	Fixed minor typographical errors	03 Feb 2017
03	17-010	Change from reporting to "CEO" to "Director of Operations"	07 Mar 2017