Position Details
 Title: Quality Associate
 Location: USA-TX- Austin
 Job Type: Full-time
 Travel: Up to 25%
 Experience Required: 3-5 years in medical device industry Quality Assurance/Design Controls
 Reports to: Operations Manager

Job Summary
The primary responsibility of this position is to work with Consultants and Quality Specialists to implement quality systems for medical device manufacturers. This position requires utilization of Quality Management System methods, including but not limited to, quality system implementation, design controls, generation of validation protocols and reports (design, process and/or software), risk management, design verification, and post-market activities.

Principal Duties and Responsibilities
 Implement processes and procedures and conduct analyses to sustain and improve the Quality Management Systems of QA Consulting’s clients. Examples include risk planning, risk analysis, design controls, verification and validation, and inspection methods and procedures.
 Work with Consultants to generate deliverables for clients relevant to pre-market and post-market quality activities.
 Work with Quality Specialists to generate and release Engineering Change Notices and implement document controls.
 Prioritize activities and allocate resources for greatest effectiveness.
 Perform Quality functions including procedure writing, and inspection and testing.
 Perform research and analyze data.
 Write technical protocols and reports (verification and validation) based upon relevant standards and data.
 Responsible for defining production and inspection methods, monitoring performance, and handling nonconformances.
 Conduct post-market activities including complaints handling, MDR evaluations, and CAPA assessments.
 Work with suppliers, laboratories, clients, and other group members to assist with implementation and effectiveness of client deliverables.
 Review prints, data, procedures, and test protocols/ reports for accuracy and technical application of standards (ISO, AAMI, ASTM, and IEC).
 This is not an exhaustive list of duties or functions

Knowledge, Skills and Abilities
 Time management and excellent communication skills, both written and verbal, and be able to communicate clearly with employees, contractors, and clients
 Must have understanding of the medical device quality system regulations 21 CFR 820 and ISO 13485 and quality tools such as: design controls, quality system auditing, inspection methods, statistical sampling plans, gauging studies, design verification and validation and process validation
 Must have experience in technical documentation methods (e.g. laboratory notebook)
 Ability to apply mathematical concepts such as statistical inference and probability (knowledge of Minitab is helpful)
 Ability to apply logic, creativity and scientific thinking to a wide range of intellectual and practical problems
 Demonstrate ownership for the integrity of work
 Strong written and verbal communication skills

Education
 Bachelor’s degree in engineering or scientific discipline and minimum 3-5 years experience in medical device industry quality assurance/design controls
 ASQ Certified Quality Technician, ASQ Certified Quality Inspector, and/or ASQ Certified Internal Auditor is desirable
 Technical documentation methods (e.g., laboratory notebook)

Characteristics
 Deadline driven
 Able to work efficiently, independently and as part of collaborative team
 Proactive communication and planning skills
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<th>ECN</th>
<th>Description</th>
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<td>Initial Release. Supersedes FRM-6.2-8.</td>
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