Position Details

- **Title:** Quality and Regulatory Consultant
- **Location:** USA-TX- Austin
- **Travel:** Up to 25%
- **Experience Required:** 4-10 years in medical device Quality Assurance / Design Controls and Regulatory Affairs

Job Summary

The primary responsibility of this position is to advise on and implement quality systems for medical device manufacturers with an added emphasis on regulatory processes. 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, post-market activities, and regulatory strategies/submissions/correspondence. 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 and/ or Regulatory Processes of QA Consulting's clients. Examples include risk planning, regulatory strategies, regulatory submissions, auditing, inspection methods and procedure development
- 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 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 or Associates to generate and release Document Change Requests and implement document controls
- Review prints, data, procedures, and test protocols/ reports for accuracy and technical application of standards (ISO, AAMI, ASTM)
- Perform supplier qualification and internal audits for Clients
- Assist with quoting of regulatory projects including regulatory strategies, submissions, and clinical evaluation reports
- Ensure compliance to FDA, ISO, local, state, federal, and other applicable national and international regulations on behalf of QA Consulting clients.
- Prepare, analyze, and submit regulatory documentation to domestic and international governing agencies
- Project manage regulatory projects for domestic and international medical device companies including FDA submissions (510(k), IDE, PMA) and Technical File/ CE Mark submissions (EU MDR)
- Develop and implement regulatory strategies
- Generate and perform annual literature review and updates of Clinical Evaluation Reports (CERs)
- Liaison with regulatory bodies
- ***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 CFR820, ISO 13485 and ISO 14971
- 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 multiple sized companies, from start-up through fortune 500 firms
- Time management and strong written and verbal communication both to QA Consulting staff and the client
- Demonstrates ownership for the integrity of work
- Able to work independently and consider options for completing work
- 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 in scientific discipline is required, Master's degree preferred
- ASQ Certification as a Certified Internal Auditor or ASQ Manager of Quality/Organizational Excellence is desired
- Regulatory Affairs Certification (RAC) through RAPS is desired

Characteristics

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