Position Details

- **Title:** Senior Regulatory Consultant
- **Location:** Remote
- **Travel: up to 20%**
- **Type:** Contract
- **Experience Required:** 10+ years in medical device (including IVD) Regulatory Affairs

Job Summary

The primary responsibility of this position is to advise on US and international medical device regulatory processes. This position requires utilization of US FDA and international regulations to develop procedures, regulatory strategies and submissions, agency correspondence and post-market compliance 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

- Implement processes and procedures and conduct analyses to sustain and improve the Regulatory Processes of QA Consulting's clients. Examples include risk planning, regulatory strategies, regulatory submissions, auditing, inspection methods and procedure development
- Conduct post-market activities including complaints handling, MDR and IVDR evaluations, and CAPA assessments
- Responsible for effectively communicating with QA Consulting, 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
- Work with suppliers, regulatory agencies, 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, IEC)
- Assist with quoting of regulatory projects including regulatory strategies, submissions, and clinical evaluation reports
- Ensure compliance to FDA, ISO, 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
- Assist with Client QMS transitions and implementation to EU MDR 2017/745 and EU IVDR 2017/746
- Project manage regulatory projects for domestic and international medical device companies including FDA submissions (510(k), IDE, PMA) and Technical Documentation/ CE Mark submissions (EU MDR/ EU IVDR)
- 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 CFR 820, ISO 13485, ISO 14971, EU MDR 2017/745, EU IVDR 2017/746 and MDSAP.
- Ability to understand 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
- Regulatory Affairs Certification (RAC) through RAPS is desired

Characteristics

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