Position Details

- **Title:** Senior Microbiology and Quality Consultant
- **Location:** USA-TX- Austin
- **Travel:** Up to 25%
- **Experience Required:** 10+ years in medical device Quality Assurance / Design Controls and Microbiology
- **Reports to:** CEO

Job Summary

The primary responsibility of this position is to advise on and implement quality systems for medical device manufacturers with an occasional emphasis on microbiological processes. This position requires independent utilization of Quality Management System methods, including but not limited to: quality system implementation, project management, microbiological processes, design controls, validation (design, process, and/or software), risk management, design verification, and post-market activities with an emphasis on microbiological services. Must interact with consultants, clients, suppliers, and experts outside QA Consulting to communicate and implement company objectives. Client/supplier management, delegation and project management skills are required.

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 and/or Microbiological systems of QA Consulting's clients. Examples include risk planning, analysis, , sterilization validation, bioburden testing, cleanroom monitoring programs, auditing, 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 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
- Provide technical support to sterilization, cleaning, and cleanroom projects using microbiological theory and practice. Offer and implement original solutions to new problems that facilitate successful completion
- Assist with quoting of microbiology projects including bioburden, cleanrooms, cleaning and sterilization validations, and endotoxin testing
- Project manage all stages of sterilization and cleaning validations including protocol development, laboratory management, and report writing.
- 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
- ***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
- Understanding of microbiology principles (especially EO/radiation sterilization and microbiology/methodologies, , clean room technologies) and applicable ISO/AAMI/ANSI standards and USP/ASTM test methods
- 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 strong written and verbal communication both to QA Consulting staff and the clients
- 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 scientific discipline is required.
- Master's degree preferred
- ASQ Certification as a Certified Internal Auditor, or ASQ Manager of Quality/Organizational Excellence is desired

Characteristics

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