

QUALITY ENGINEER – CONTRACTOR

JOB SUMMARY:

This position represents the quality organization as an integral team member on development projects for medical devices. The Quality Engineer (QE) ensures compliance to QMS and design control process and procedures. They ensure adherence to customer and regulatory requirements are demonstrated and help to ensure successful transfer of the design to manufacturing.

MAJOR DUTIES AND RESPONSIBILITIES:

- Support the Viveve Quality Policy and Quality System
- Participate in Development of In-house Product Service and Repair processes
 - Develop processes and written procedures for product investigation, servicing, and repair
 - Work closely with Operations and Engineering in process development, execution, and improvement
 - Coordinate management of written process procedures, product travelers, and related records
 - Provide final Quality sign off on all serviced item documentation
- Support Risk Management and related documentation, including risk assessments, FMEA, Risk/Benefit Analyses, etc.
- Work cooperatively with contract manufacturers and external parties, and support supplier management
- Develop and maintain device history records
- Support execution and reporting of system verification and validations
- Serve as Subject Matter Expert during internal and external audits
- Cross train to support other quality system areas, including product inspections, testing, nonconforming material reports, etc.
- Complete projects and tasks in a timely manner consistent with corporate objectives. Keep management informed of changes in work schedule and/or workload
- Analyze data and present it in appropriate formats
- Regularly recommend and implement improvements in the department
- Support company goals and objectives, policies and procedures, Good Manufacturing Practices, and FDA/MDD regulations
- Partner with Regulatory to provide technical assistance for submissions as needed

SKILLS/QUALIFICATIONS/COMPETENCIES:

- Self-starter, motivated to learn new skills
- Cooperative, collaborative, and team-oriented worker
- Strong verbal and written communication skills
- Excellent computer skills
- Excellent attention to detail

EDUCATION REQUIREMENTS:

- Bachelor's degree, or equivalent work experience required
- Engineering background / degree preferred

EXPERIENCE REQUIREMENTS:

- Minimum 1 year quality engineering experience in medical device, 2-3 years preferred
- Experience in product servicing preferred
- Experience with device service records, travelers, and device history records preferred