SENIOR QUALITY ENGINEER

JOB SUMMARY:

This position represents the quality organization as an integral team member on development projects for medical devices. The Senior Quality Engineer 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 Design Control Management System
    - Develop processes and written procedures for design control
    - Work closely with Operations and Engineering during design process
    - Coordinate management of design control records
    - Develop and maintain design history files
- Participate in Product Development Processes for new products and product improvements
    - Ensure Quality requirements are considered and met
    - Control design phases and ensure design objectives are completed
    - Support product validation efforts
    - Manage design control records
- Support production line moves and new line/site/supplier qualification, as necessary
    - Support production line moves between facilities
    - Validate new and changed production, sites, and new lines
    - Ensure quality requirements during project are met and supported
    - Support qualification processes for new facilities and new suppliers
- Work cooperatively with contract manufacturers and external parties
- Support Risk Management and related documentation, including risk assessments, FMEA, Risk/Benefit Analyses, etc.
- Plan, Execute, and Report on component and system verification and validation
- Analyze data and present it in appropriate formats
- Present design records and documentation during internal and external audits
- Cross train to support other quality systems, 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
- Regularly recommend and implement improvements in the department
- Support company goals and objectives, policies and procedures, Good Manufacturing Practices, and FDA/MDD regulations.
- Other duties as assigned.

SKILLS/QUALIFICATIONS/COMPETENCIES:

- Experience in design quality engineering required
- Experience in product and design verification and/or validation required
- Experience with product sterilization / sterilization processes preferred
- Experience with medical device software design preferred

- Experience with radiofrequency preferred
- Excellent computer skills
- Excellent attention to detail
- Self-starter, motivated to learn new skills
- Cooperative, collaborative, and team-oriented worker

EDUCATION REQUIREMENTS:

- Bachelor's degree required
- Engineering background / degree preferred

EXPERIENCE REQUIREMENTS:

- 5-10+ years of experience: at least 5 years in a medical device environment, medical device design preferred

Salary range: $45-$55 / hour

Viveve, Inc. is an equal opportunity employer.