Sr. Quality Engineer

POSITION SUMMARY:

The **Sr. Quality Engineer** (SQE) reports directly to the Sr. Director, Quality Assurance and will be responsible for management and execution of assigned quality projects in order to meet quality assurance objectives. The SQE shall have prior experience working within an FDA compliant Title 21 section 820 environment and the ability to work cross-functionally to support rapid growth and continuous improvement.

PRIMARY DUTIES AND RESPONSIBILITIES:

- Leads detailed root cause investigations and coordinates timely action implementation with the CAPA process
- Creates and updates quality system procedures working on cross-functional teams to align best practices, procedures, and applicable regulations (FDA, ISO, etc.)
- Responsible for creation of inspection models, inspection prints, gaging, or other inspection documents and detailed testing requirements to insure receipt of quality product
- Support concurrent engineering efforts by participating in design development projects representing quality assurance and the customer (supplier and end user)
- Responsible for creating and maintaining product and process risk management files to meet FDA and ISO standards
- Reviews product and documentation non-conformances and recommends inspection, product and/or quality system modifications
- Interfaces with supplier quality representatives concerning issues with quality assurance and assures that effective corrective action is implemented
- Lead auditor for vendor onsite and desktop audits
- Participates in quality system audits (FDA, ISO, Internal, etc.)
- Evaluates product changes and directs appropriate disposition of product through the company's change control system
- Develop, execute and analyze quality-reporting measures

KNOWLEDGE, SKILLS, AND ABILITIES:

- Must be able to use MS Office computer software including Word, Excel, PowerPoint, and Project
- Must be a team player; must work collaboratively and productively with other business partners to meet company goals and objectives
- Must be willing to travel ~10-30% of the time for vendor visits, audits, process troubleshooting, etc.
- Must demonstrate a strong sense of ownership and accountability
- Must demonstrate strong interpersonal and verbal/written communication skills
- Must be extremely detail oriented and able to demonstrate strong organizational and communication skills
- Ability to interact with remote manufacturing and quality resources to insure product meets company standards for manufacturability, reliability and cost-effectiveness
- Expertise in inspection techniques, critical measuring, and measurement variation
- Ability and willingness to be a productive member of cross-functional teams to assist in the creation of quality documents for assigned projects, as required by applicable medical device standards and internal procedures

MINIMUM REQUIREMENTS:

Education and Experience: Bachelor's degree in Engineering, Science, Technology or a related discipline with 5 years of progressive medical device engineering experience (Manufacturing, Development or Quality Engineering) within an FDA compliant Title 21 section 820 environment

Certified Quality Auditor, Biomedical Auditor or ability to obtain certification within first year of hire

WORK ENVIRONMENT:

This job operates in a professional office environment. This role routinely uses standard office equipment such as computers, phones, photocopiers, and fax machines. The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job.

While performing the duties of this job, the employee is regularly required to talk or hear. The employee frequently is required to stand; walk; use hands to finger, handle or feel; and reach with hands and arms.

This job description is not a contract and does not affect the at-will nature of your employment relationship with Treace Medical Concepts, Inc., Furthermore, this job description is not intended to be all- inclusive and does not and cannot address every responsibility or duty you may be expected to perform during your employment. Treace Medical Concepts, Inc., reserves the right to modify or amend this job description at its discretion, without prior notice.

All qualified applicants considered regardless of ethnicity, nationality, gender, veteran or disability status, religion, age, gender orientation or other protected status.