SHIMADZU USA MANUFACTURING

TITLE: **QUALITY ENGINEER**

DEPT: **QUALITY**

EXEMPT/NON: **EXEMPT**

REPORTS TO: **QUALITY MANAGER**

EFFECTIVE DATE: **10/2024**

General Position Summary:
The Quality Engineer will support the Quality Assurance/Quality Control (QA/QC) activities for the manufacture, inspection and test of world class medical devices in compliance with ISO 13485 and FDA Part 820 Quality Management System (QMS).

Essential Functions:

1) Supports the Quality Manager in maintenance and continuous improvement of the QMS, to include training of personnel.
2) Use Data collection/Analysis techniques of test results to help trouble shoot issues identified in production.
3) Creates QMS documentation, to include development of standard operating procedures in support of the QMS.
4) Supports or leads all areas of risk analysis, root cause investigation, and corrective and preventative actions.
5) Manages all receiving, in process and out of box inspections, to include resolution of supplier caused non-conformances.
6) Performs quality system audits at supplier locations.
7) Efficiently disposition the non-conformance handling process to minimize the duration of material quarantines.
8) Own tasks associated with CAPA program and brings them to resolution.
9) Participates in the regulatory functions related to RoHs, Conflict Mineral Reporting, and REACH.
10) Works with cross-functional teams to resolve production and quality issues, with particular focus on continuous improvement.
11) Performs internal quality audits and reviews, evaluating data and compiling results for management review.
12) Monitors engineering production processes and products for adherence to internal quality requirements and standards.
13) Integral part of the Engineering Change process to review/approve work instructions/changes to ensure no adverse effects to product while still meeting device specifications.
14) Proactively reviews production environment for improvement opportunities to achieve the goal of increased product quality while maintaining efficient manufacturing process(es).

15) Working closely with manufacturing staff to ensure quality protocols are followed and documentation is correctly maintained.
16) Assists team members with various tasks.

Secondary Functions:

1) Performs duties in support of the company's certifications (example: ISO and FDA/QSR).
2) Maintains a safe and clean work environment
3) Performs other duties as assigned.

Job Scope/Demands & Complexity:

Frequent new and varied work situations
Job involves a high degree of complexity
Operate from established and well-known procedures
Contribute to the development of new concepts
Operates under minimal level of supervision

Supervisory Responsibility:

This position does not have any supervisory responsibilities. May provide training or daily coordination of duties to subordinate team members.

Interpersonal Contacts:

Has contact with others both inside and outside the organization. Internal contacts include all company personnel. External contacts may include persons at Shimadzu Corporation, customers, vendors, and regulatory agencies. Communication may involve discussions about confidential or sensitive company

Knowledge, Skills & Abilities:

1) Excellent interpersonal, communication, teamwork and organization skills.
2) Knowledge of ISO-13485 and FDA QSR.
3) Knowledge of the FDA's Part 21CFR, Section 820.
4) MS Office and statistical software skills.
5) Ability to make decisions and solve problems while using creativity, analytical thinking and independent judgment and/or action.
6) Ability to manage and prioritize multiple tasks.
7) Perform advanced math (analysis, statistics, significant data or number manipulation).

Job Conditions:

Normal office conditions with occasional exposure to production/warehouse environment.
Extensive computer work.
Working a minimum of 40 hours per week is expected, but work volume may require working more than 8 hours per day or 40 hours per week to complete essential duties of the job.
Travel domestic or internationally as required. Must have a valid passport or the ability to obtain a passport.

Education & Experience:

Minimum BS in Electrical, Mechanical or Chemical Engineering
Experience in manufacturing Quality Engineering role
Experience in an FDA environment
Certified or trained in GD&T; ASQ certified in CQE, CQM, TQM, CQI, CQA-preferred.
Proficient use of MS Windows and MS Office suite as well as statistical software: MiniTab, Statistical or JMP

I have read and understand the requirements for this position. By my signature below I attest that I am able to perform all the essential job functions of this position.

_____ _____

Employee Signature Date