REVA Medical, Inc.
JOB DESCRIPTION

Job Title: Sr. Quality Engineer

Function: Quality Assurance

Reports To: Sr. Manager of Quality Assurance

Date: 02/15/2023

Duties / Responsibilities:

Develop and implement quality test procedures, including the design of tests, testing mechanisms and test equipment.

Develop and execute test equipment IQ/OQ/PQ protocols and reports. Conduct test method qualifications and validations, including qualifications, revalidation, and overall validation schedule/plan. Develop gauge reliability and repeatability studies for test and production-related equipment. Develop equipment calibration procedures.

Develop sampling plans for incoming materials and in-process and finished product testing based on appropriate statistical methods.

Responsible for product related investigations and corrective actions. Maintain a working relationship with suppliers to ensure resolution of supplier-critical issues and investigations. This may include supplier visits to technically assist in the resolution of issues and investigations. Ensure that all corrective/preventive measures meet acceptable reliability standards and that documentation is compliant with requirements.

Participate in customer product complaint analyses, evaluation, and investigation. Perform investigational activities including evaluation of returned products and complaint trending analysis.

In conjunction with product development, participates in the updating, maintaining, and approving of risk analysis/risk management documentation.

Reviews production data and performs statistical analysis to track metrics and to analyze trends.

As part of the quality organization, reviews and approves assigned controlled documents (e.g., work instructions, quality specifications, engineering specifications, procedures, and validations protocols/reports).

Assist in "troubleshooting" problems related to the manufacture, test, validation, and documentation. Also represents quality assurance function in project team meetings.

Participates in internal/supplier audits and interact with external regulatory inspectors as subject matter expert.

Participates in and manages special projects and other duties as assigned.

Education and/or Experience

Bachelor’s degree in mechanical engineering, chemical engineering, biomedical engineering, and/or other engineering related degree

Minimum of 5-7 years medical device experience or similarly regulated ISO or cGMP/GLP environment is required.

Proven record creating and supporting validations and qualifications (e.g., Process validation, IQ, OQ, PQ) and compliance of regulated products is required.

Proven record creating and supporting risk management file maintenance (e.g., PFMEA, DFMEA, Risk File) is required.

Experience in conducting complaint/CAPA investigations.

E-beam sterilization validation and software validation experience is preferred.

Previous experience with catheters and/or medical devices is required. Interventional cardiology products experience is helpful.

Experience with regulatory requirements and guidance for component and product testing including ASTM, ISO and ICH.

Required Knowledge/Skills

Strong statistical background and practical application of statistical techniques (Six Sigma, DOE, etc.)

Demonstrated problem solving and root cause analysis skills using risk-based approach.

ASQ certification (QE, and/or Auditor) preferred.

Strong attention to detail and accuracy.

Ability to train others, work independently or in team setting required.

Effective presentation/communication skills, prioritization, and resource management skills.

Physical Demands/Working Environment

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. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is frequently required to sit or stand for prolonged periods of time, frequently in front of a computer. Must be able to travel approximately ~15% of the time.

Approvals

_____ _____
Employee Signature Date

_____
Employee Name (Print)

_____ _____
Manager Signature Date

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Manager Name (Print)