REVA Medical, Inc.
JOB DESCRIPTION

Job Title:	Manager, Quality Assurance
Function:	Quality Assurance
Reports To:	Vice President, Regulatory Affairs and Quality Assurance
Date:	7/6/2022
Status:	Exempt

Summary of Essential Duties and Responsibilities

Responsible for managing company quality assurance systems including management review, document control, internal and external audits, complaint handling system, CAPA, training, and supplier quality system.

Prepare reports to management on the performance of the quality system, including periodic management reports, management review meetings, and other reviews and recommendations for system improvements.

Responsible for management/implementation of document control system. Assist with the development, review and approval of quality system and manufacturing documents, processes & procedures.

Perform and/or oversee the completion of internal audits. Coordinate, support and facilitate third party regulatory audits/assessments.

Perform and/or oversee complaint handling. Manage supplier quality and CAPA systems.

Participate on project teams as the representative for Quality. Assist in the development and implementation of applicable product performance quality standards, product evaluation plans and risk assessment activities in the product development process. Ensure compliance to design control procedures and applicable external standards (i.e. ISO, 21CFR).

Conduct and/or oversee in-process and final product lot release.

Maintain applicable skills to stay abreast of quality, regulatory, compliance and technical developments in the Medical Device industry.

Perform other quality related duties as assigned.

Education and/or Experience

Bachelor's degree in chemistry, biology, engineering, life sciences or other similar technical field. A combination of education level and experience will also be candidate for position in lieu of Bachelor's degree.

Minimum of 5 years related Quality Assurance experience in a medical device, or similarly regulated ISO, QSR/GMP/GLP environment is required.

Proven record of providing the Quality Assurance input to compliance of regulated products.

Demonstrated ability to work at all stages of product development.

Previous management experience is desired but not required.

Interventional cardiology products experience is helpful, but not required.

Required Knowledge/Skills

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

Ability to train and lead others.

Ability to work independently to accomplish Quality Assurance tasks and participate effectively as part of project teams.

Frequent computer/report work, and administration of quality system programs and resources.

Demonstrated problem solving and analytical skills

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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 occasionally.

Approvals

_____ _____
Employee Signature Date

_____
Employee Name (Print)

_____ _____
Manager Signature Date

_____
Manager Name (Print)