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Project Engineer-Medical Devices (Design)

Hiring organization
BioLink 360

Employment Type
Full-time

Industry
Medical Device

Job Location
Cleveland, OH

Date posted
December 14, 2022

Description

Location: Cleveland, OH

Position Type: Hybrid

Salary: 80-120K, depending on level of experience

Our client is a company that is focused in the medical device industry is hiring a Project Engineer. Engineers with background in design, development, sustaining and QMS backgrounds could find a fit here. This opening is due to company growth!

This company is focused on custom product development for the medical device industry with clients all over the world. This company is dedicated to bringing innovation to market and has developed complex medical devices for a variety of surgical specialties such as spine, orthopedics, general surgery, dental, ophthalmology, urology.

The person hired will be a salaried employee who will work on a team that handles full cycle product development and post-market surveillance activities. There is a wide range of projects simultaneously.

The Engineer hired will be responsible for overseeing the manufacturing of design prototypes and production parts, working directly with clients and internal team members to meet deliverables.

This position is a full time, salaried role with full corporate benefits.

This is a small team of tenured Design and Quality Engineers and Regulatory Affairs SMEs who work closely together. This is an environment that fosters professional development, engineering excellence and a creative approach to the industry's toughest product design and quality challenges.

Responsibilities

• Interface with quality, operations, and vendors to ensure manufactured products meet design intent
• Create and maintain device history files per FDA, ISO and other regulations
• Assist with development and/or revision of Quality System procedures and processes.
• Assist with internal and supplier audit development, implementation, and execution
• Serve as a company representative during external audits by Regulatory and Third Party Auditors
• Design Control documentation assistance
• Validation and Testing Protocol Development
• Perform gap assessments against new and revised Quality Modules, Quality Directives, and ISO requirements

Qualifications

• Bachelor's Degree in Engineering, Science, or health-related field
• 4-10 years' related work experience in the medical device industry, with Design and Development
• Working knowledge of FDA and other regulatory authorities with experience supporting compliance.

AND/OR

• Quality Systems development, implementation, and training experience
Experience with ISO 13485, FDA, MDR (Medical Device Regulation), and CMDR (Canadian Medical Devices Regulations) compliance requirements and training
• Experience with Risk Management per ISO 14971
• Experience with FDA remediation, Warning Letters, 483 Observations, and Recalls