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R&D Engineer (Medical Device Design)-San Diego

Hiring organization
BioLink 360

Employment Type
Full-time

Industry
Medical Device

Job Location
San Diego, CA
Remote work possible

Date posted
March 8, 2023

Description

Our client is a company that is focused in the medical device industry, and they are hiring a Project Engineer with 4-8 years of experience. The person hired will be a salaried employee who will work full cycle product development and post-market surveillance activities, and be working on a wide range of projects simultaneously. The person hired into this role will have a solid background in product design, including 2D/3D CAD design and Geometric Dimensioning and Tolerancing (GD&T) experience. This person 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 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.

Are you an Engineer looking to utilize a breadth of skills and knowledge, working with a variety of technologies without having to change jobs, or be siloed in one area?

Do you enjoy a small, family-like environment where people help each other be their best? (and offers a chance to work remotely)?

If so, this is the opportunity for you! Apply now to learn more about how you can catapult your career in the industry!

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
• 2-10 years' related work experience in the medical device industry

Experience Required:

• Working knowledge of FDA and other regulatory authorities with experience supporting compliance.

• 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