14 ½ S Clinton Street
Iowa City, Iowa 52240

info@iotamotion.com
iotamotion.com

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iotaMotion is hiring a Design Quality Assurance Engineer

About the position:

iotaMotion develops and commercializes robotic-assisted surgical technologies. The first commercially available product is iotaSOFT® Insertion System, which controls the insertion of a cochlear implant to improve outcomes for surgeons and subsequently patients. As a member of our team, you will have the opportunity to engage with surgeons to optimize their treatment of those with hearing loss.

The Design Quality Assurance Engineer drives design control, design history file, and continuous improvement support with high visibility. Work with high-performance cross-functional team to ensure safety, quality, and compliance of launched products while continuously improving their commercial value. Products include internally developed systems and Sourced Finished Medical Devices.

Design Quality Assurance engineer works in close partnership with Research and Development and supporting functions (supply chain, manufacturing engineering, operations, post market), and focuses on protecting the design intent of a product to meet safety, efficacy, regulatory, and business requirements. The Design Quality Assurance Engineer will report directly to the EVP of Operations.

Position responsibilities include but are not limited to:

- Develop, update, and maintain Design History File and work with RD for Design Input / Output documentation (Product Specification, Component Specifications, and Prints)
- Drives Risk Change assessment process: generate, update, and maintain product risk management tools (i.e. Hazard Analysis, Fault Tree, FMEAs) This includes leading Risk management efforts of the design process and working with design team and management team on managing product and process risks
- Actively participate in the Design Change process for systems to ensure the proposed changes to the products are systemically and thoroughly analyzed and assessed through the Design Control process
- Proactively investigates, identifies, and implements best-in-class Design Quality Engineering practices by promoting continuous improvement in design control activities and use of quality tools with design team
- Support Post Market activities such as assessment and or alignment of risk based on post market signals, field assessments. Contributes to design input requirements from experience with previously reported problems, company products, and/or other similar products
- Monitor field performance of recently launched and established medical devices against risk assessments. Analyzes and investigates returned product to determine the cause for return
- Support the verification, validation, and usability testing to meet or exceed internal and external requirements
- Develops master test plans that encompass design verification and validation activities

- Creation, evaluation, and validation of product and process test methods
- Evaluates test protocols and reports to ensure that the testing is sufficient to meet regulatory requirements and quality objectives
- Interact with software changes for alignment with system level design impact assessments
- Partner with R&D and Operations to determine and implement Design Controls based on Risk Management, Customer Needs, and Manufacturing Input
- Acts as an effective leader or team member in supporting quality disciplines, decisions, and practices
- Applies systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving design quality issues, which may include NC and CAPA ownership, core team member and coordination
- Other duties as assigned or required

Requirements:

- Bachelor's degree in mechanical, electrical, computer engineering, or related discipline
- 3 years of experience in design assurance, new product development, or related medical device or regulated industry experience
- Working knowledge of US and International regulations including 21 CFR 820, Medical Device Directive / Medical Device Regulation, EN ISO 13485, IEC 62304 and EN ISO 14971
- Experience owning Design History Files for development projects
- Experience building out design controls through user needs, inputs/outputs
- Strong communication skills (verbal & written)
- Demonstrated use of Quality tools/methodologies
- Experience with medical standards compliance

Preferred qualifications:

- Experience with medical electrical systems or capital equipment
- Experience design changes, complaint risks, and corrective action
- Ability to effectively work and collaborate in a remote environment
- Previous medical device system engineering development experience

Interested and qualified applicants please submit your resume and cover letter to jobs@iotamotion.com

iotaMotion is an equal opportunity employer and does not discriminate based on race, color, sex, age, disability, sexual orientation, gender, religion, marital status, or any other characteristic protected by law.