14 ½ S Clinton Street
Iowa City, Iowa 52240

info@iotamotion.com
iotamotion.com

August 9, 2023

iotaMotion is hiring a Director of Quality Assurance

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.

This individual will serve as the Director of Quality Assurance. The Director of Quality Assurance will report directly to the EVP of Operations.

Position responsibilities include but are not limited to:

- Responsible as Quality Management Representative for FDA and ISO requirements.
- Actively represent Quality Assurance function on product/process development teams.
- Manage department resource allocation across multiple product lines, provide guidance and development opportunities for department employees.
- Establish and install a vision for QA team, define objectives, manage team performance and coordination of assignments. Lead and develop members in the Quality department.
- Provide Quality Engineering leadership by direct management and development of Quality personnel and indirect management and development of Engineering and audit resources.
- Aggressively identify opportunities to proactively assure compliance to all applicable internal, domestic and international quality regulations, FDA, US 21 CFR 820 (QSR), ISO 13485, etc.
- Aggressively identify and manage activities related to adding value to the organization through risk reduction, cost improvement, and budgetary responsibility.
- Provide strategy and structure for New Product Quality with CAPA investigations, executions, and collaboration in the early stages of product development including, but not limited to customer/supplier interaction, product inspection and testing.
- Report on the performance of Quality Systems to company management for review and ensure management reviews are held.
- Provide Quality Leadership for the business unit and provide reports on Product Life Cycle Management, CAPA and Risk Management, etc.
- Lead the investigation of complex product problems to identify and manage corrective actions resulting from problem investigations.
- Provides input to design and manufacturing documentation including material specifications, drawings, inspection procedures, and manufacturing procedures, to ensure that the resulting products can be adequately manufactured and tested.
- Lead and/or participate in the supplier selection process and specification reviews with suppliers to ensure that purchased items meet company specifications.
- Specifies quality characteristics and inspection plans for components and subassemblies.
- Evaluates and dispositions nonconforming materials and products used in development builds, to arrive at the most economical disposition, while meeting all quality system requirements.
- Leads development and implementation of at least one family of product or process control procedures [e.g. Lean, Six Sigma, Risk Management, Process Control, etc.]

14 ½ S Clinton Street
Iowa City, Iowa 52240
info@iotamotion.com
iotamotion.com

- Leads scheduled and impromptu audits of the quality management system as performed by registrars, regulators, and customers.
- Other duties as assigned or required.

Requirements:

- BS degree in Technical or Bioscience Field, or 10 years' experience as Quality Engineer/Manager Medical device industry under FDA US 21 CFR 820 and ISO 13485 Medical Device experience preferred.
- Experience with risk management assessments and techniques, preferably in accordance with ISO 14971.
- Experience with product development and quality principles and practices.
- Experience leading and facilitating audits as well as managing teams managing remote teams internationally is preferred but not required.
- Strong interpersonal, organizational and project management skills are required.
- Demonstrated ability to work productively with individuals at all levels inside and outside the organization, with an ability to influence key company and customer decision makers.
- Demonstrated proficiency with best-in-class data analysis tools, statistical process control software, customary PC office applications such as Word, Excel and PowerPoint required.
- Ability to travel, both internationally and domestically 10% of time.

Working Conditions:

- Work Environment: Office and Manufacturing Plants as needed
- Atmospheric Conditions: Indoors
- Temperature Extremes: None
- Materials, Tools and Equipment Used: Computers, microscopes, hand tools, automation, and lasers as needed.

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.