14 ½ S Clinton Street
Iowa City, Iowa 52240

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iotamotion.com

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iotaMotion is hiring a Quality System Specialist

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 Quality System Specialist. The Quality System Specialist will report directly to the EVP of Operations.

Position responsibilities include but are not limited to:

- Perform QA document control functions, including document login, tracking, processing, review, distribution, release and archiving of documents
- Coordinate the revision, review, and approval and obsoleting of SOPs and other GMP documents. Responsible for ensuring area managers perform annual review of all cGMP documents and SOPs
- Confer with document originators to resolve discrepancies and compiles required changes to documents
- Organize and ensure accurate and reliable filing systems for GMP documents
- Maintain in house training programs including training matrix, training files and annual audit of training files
- Maintain key aspects of the quality system such as: IQOQ, document control, CAPA, Change Control, Deviations, OOS's, Annual Product Review, and others
- Actively participate in internal audits, customer audits and other activities as assigned by manager

Requirements:

- Associate degree in scientific discipline
- 2-5 years of hands-on experience with document management in a regulated industry–pharmaceutical or medical device industry–with direct document control experience.
- Knowledge of QMS, eQMS
- Proficient at reviewing and editing documentation
- Familiar with cGMP's and the ability to follow standard operation procedures
- Excellent written, verbal and interpersonal communication skills
- Strong critical thinking and problem-solving skills
- Ability to prioritize multiple responsibilities and manage deadlines accordingly
- Communicate effectively with all members of organization and all levels of management
- Exceptional attention to detail and high level of accuracy & organization
- Ability to work independently with minimal supervision in a fast-paced environment
- Ability to adapt quickly to changing policies and procedures
- Exhibit a quality mindset and a willingness to develop yourself and others.
- Proficient with Microsoft Office and Adobe Acrobat

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Nice to Have:

- Bachelor's degree in scientific discipline
- Audit or inspection experience
- Demonstrated knowledge of cGMP's, 21 CFR 210 and 211 and other regulatory agency requirements sufficient to apply to quality operations and compliance

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.