Title: **Sr. Software Quality Engineer**
Department: **Quality**
Location: **Marlborough, MA**

About Akoya Biosciences:
As 'The Spatial Biology Company®', Akoya Biosciences' mission is to bring context to the world of biology and human health through the power of spatial phenotyping. The company offers comprehensive single-cell imaging solutions that allow researchers to phenotype cells with spatial context and visualize how they organize and interact to influence disease progression and treatment response. Akoya offers two distinct solutions, the CODEX® and Phenoptics™ platforms, to serve the diverse needs of researchers across discovery, translational and clinical research.

Position Summary:
This individual will be responsible for Quality Assurance activities related to the complete life cycle of new/modified software and firmware products. This is a hands-on role where the Software Quality Engineer will apply diversified knowledge of software engineering, software verification, recognized software development standards, quality principles and practices, medical devices, and accessories. This position will report to Assoc. Dir. of Quality Assurance.

Duties & Responsibilities:

- Responsible for quality system support for R&D projects, generation and/or review of software documentation, provide inputs to software R&D designs, develop test strategies for software systems, improve quality processes as they apply to software systems.
- You will partner with Product Development to review requirements that will ensure appropriate level of rigor to software validation and verifications.
- You will lead Risk Management activities throughout the product development life cycle. Perform formal risk analysis, develop software risk control measures and mitigations, and create SFMECA in support of risk management according to ISO 14971 requirements.
- You will partner with PD to define design verification and validation test requirements that will ensure appropriate objective evidence is available to support the acceptance criteria.
- Partner with software QA and development team in executing Software test and quality assurance including software verification strategies, test scripts, and traceability to requirements.
- Partner with product development team, including managing activities for risk management, quality planning, design input, design output, design verification/validation, and design transfer.
- Provide quality support for the change control process including quality approval of design changes/enhancements, bug fixes, and infrastructure changes.
- Work with development team and ensure the product Design History Files (DHF) and Technical Files are meet the standards and maintained.
- Provide quality engineering input for any global regulatory filings for software device and combination products.
- Responsible for oversight of verification and validation for software device and combination products.
- Provide quality support/oversight for the document control process.
- Ensure support for ISO 13485 certification, MDSAP, MDR and other Regulatory Audits and Regulatory filings for software application devices and/or combination products.

- Provide quality engineering support and expertise in the investigation of complaints, CAPA/Deviations, field corrective actions, and medical device vigilance reporting.
- Ability to work productively on a cross-functional team model.
- Perform other duties as assigned.

Skills & Requirements

This position is in a fast-paced environment requiring communication and relationship building skills to manage and foster long-term relationships with suppliers. The ideal candidate will possess the following:

- Bachelor's Degree in Engineering or equivalent technical discipline required, and 5+ years of Quality/Regulatory experience in a medical device or other regulated industry, with a minimum of 2 years' software Quality Assurance and/or Quality Engineering roles
- Knowledge and experience with SDLC processes along with software development methodologies such as Agile Software Development, Waterfall Model, etc.
- Preferred knowledge of FDA QSRs, ISO 13485 Design Control Procedures, IEC 62304 and ISO 14971 with primary emphasis on ISO 13485:2016, MDSAP, ISO 14971, MDD/MDR, and 21 CFR Part 820.
- Understand and working knowledge of IEC 62304, EN ISO 14971, AAMI TIR 57, 97 (Medical Device Security), IEC 60601-4-5IEC 62443-3-1 (IT Security) , IEC 30111 (IT Sec., Venerability Processes), FDA Software Guidance or similar standards,
- Highly developed written and oral communication skills and be able to work in a team environment
- Must have good problem-solving skills and be able to work independently, Working knowledge of Corrective Action & Prevention method for nonconformity mitigation.
- Must be organized, detail-oriented, and adaptable according to evolving situations at hand.
- ASQ Certified Software Quality Engineer (CSQE) preferred.

Akoya Biosciences, Inc. proudly affords equal employment opportunity to all qualified persons regardless of race, color, religious creed, national origin, age, military status, sexual orientation, disability, genetic information, gender identity, gender expression or gender unless based upon a bona fide occupational qualification.

Apply at: careers@akoyabio.com