Title: **Quality Systems Manager**
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:
The Quality System Manager reports to Akoya's Head of Quality. This individual will be quality focused, organized, and able to work independently to build and foster Quality relationships within the organization. This individual will be responsible for all aspects of quality system activities in compliance with ISO 13485:2016 standards. This individual is responsible for managing the Corrective Action and Preventive Action (CAPA) Review Board, internal and external audits, management review, and training programs.

Responsibility also includes support of quality assurance of activities performed by the internal contract service organization supporting internal production, qualification, and maintenance. This position will also lead Akoya's quality assurance for future clinical use and companion diagnostic products under cGMP, ISO13485, and QSR Quality.

Duties & Responsibilities:

- Manage the implementation and compliance of Akoya's Quality Management System (QMS) to ISO 13485. Perform gap assessments for compliance to 21 CFR 820 and other applicable standards and regulations as the QMS grows and changes.
- Lead the CAPA Review Board and CAPA investigations, monitor CAPA system performance, report on system performance to senior leadership, and drive improvement activities across the quality management system.
- Complete the yearly internal audit schedule, communicate the schedule to all affected parties, lead internal audits, ensure audit reports are issued on time, and manage follow-up activities with auditees to ensure non-conformances are addressed in a timely manner.
- Manage external audit process, preparing internal subject matter experts for audits, and ensure that non-conformances and audit follow-up are addressed in a timely manner.
- Support and coordinate Management Review data collection, management review meeting coordination, and post meeting documentation.
- Manage the QMS Training program for Akoya and contractors in Arena Solutions. Coordinate training with other systems at Akoya.
- Supports the development, implementation and maintenance of quality assurance systems and activities considering risk and business needs such as quality plans, failure investigations, etc.
- Review documentation (records, procedures, work instructions, forms etc.) to ensure that they are accurate, complete, and compliant with the process, and requirements of the quality management system / GMP.
- Support change management activities, document control, and Arena Solutions Administration to ensure process changes are managed and approved effectively.

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 science, engineering, or related field or equivalent amount of experience.
- 7-8 years of work experience in a medical device, IVD, RUO environment, such as ISO13485, QSR or GMP.
- 2 years employee management experience preferred.
- Certification such as a Lead Auditor or ASQ strongly preferred.
- Working experience with CAPA and internal audit systems
- Superior leadership, facilitation, and communication skills
- Experience in electro-mechanical equipment or reagents is a plus but not required.
- Experience working in regulated environment is a must.
- Working knowledge of regulatory activities and requirements related to medical device / IVD.
- Experience in auditing, interpreting, and applying regulations and compliance concepts is a plus.
- A keen attention to detail is required.
- Excellent communication and interpersonal skills and ability to work independently and with cross-functional teams

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