**Title: Senior Quality Assurance Compliance Lead**
**Location: Marlborough, MA**

**About Akoya Biosciences, Inc.**

Akoya Biosciences, Inc., The Spatial Biology Company™, with offices in Menlo Park, CA and Marlborough, MA is a well-funded and emerging growth company that is developing powerful imaging tools to enable scientists and clinical researchers to gain a better understanding of complex diseases such as cancer and autoimmune disorders. Our CODEX® platform enables the assessment of more than 40 protein markers in a sample and is ideally suited for biomarker discovery. Our Phenoptics™ platform, the industry standard for multiplex IF/IHC provides the assay robustness and throughput necessary for translational and clinical research required in clinical trials. Our partnerships with the academic community and our customers have resulted in a robust pipeline of future products.

**Summary:**

Senior Quality Assurance Compliance Lead is responsible for ensuring Akoya product, procedures, systems, and processes effectively meet Quality requirements and business needs for product development through commercialization and post-market quality assurance. This position will provide support to cross functional teams in assessment of current state and ensuring compliance with regulations and guidelines. This position will provide QA oversight to projects, assignments, and training.

The successful candidate will be a seasoned professional with experience in quality systems and product design transfer and commercialization in a medical device and/or diagnostic industry. This role is a part of ensuring Akoya's mission is achieved through quality standards and procedures, primarily responsible for Quality oversight of work performed internally and at assigned Vendor(s).

This position will provide an assessment of compliance, manufacturing, and testing oversight internally and at CMOs. This will serve on cross-functional project teams such as tech transfer and validation. This position will administer and maintain the Quality Management System (QMS) and processes related to the QMS. This individual will be quality focused, organized and help ensure compliance to established processes in accordance with regulatory requirements and Company policies and procedures.

**Duties & Responsibilities**

**A) Quality and Compliance:**

- Prepare, maintain, and review internal policies, procedures, systems, and processes, to ensure compliance to federal and international regulatory requirements and guidelines.
- Assist QA management in monitoring and driving key performance quality metrics. Ensure quality directives and policies are effective and implement action to ensure compliance.
- Assist QA Management on collection of data and preparing presentations, meeting minutes and report out on the management review.
- Improve quality management systems related to the product lifecycle from development to commercialization, overseeing activities related to technology transfer and sustaining engineering.

- Support internal audits, audit follow-ups, issue tracking and closure. Compiles and maintains vendor documentation to support pivotal supplies
- Audits – tracks internal audit observation responses and effectiveness assessments. Maintain controlled document database for the QMS and Quality department.

**B) Quality Engineering**

- Change Control process - Create policies and procedures, manage specification changes, completed packages and trends and reports process performance.
- Specifications and changes - Assists Product Development (PD) and Quality Assurance (QA) in documenting specifications, changes, change logs etc. to support product development.
- Investigations and CAPA – assist R&D teams in ensuring deviations, CAPAs and investigations are fully addressed and close in a timely fashion. React decisively to a wide range of non-conformance events, CAPAs, and other quality/compliance indicators.
- Support QA related functions as needed such as authoring and/or reviewing dossiers,
- Perform product release activities and Contract Manufacturing Organization site management including Qualifications, Investigations, risk assessment reports and support onsite presence during manufacturing as needed.
- Oversee reagent stability program. Ensure Investigations and CAPAs are assessed, followed-up on and closed in a timely fashion.

**C) Regulatory and Documentation:**

- Software CE marking related activities, compliance, and Safety compliance, sustaining Quality, Technical File review, Labeling, Maintenance of Technical Docs.
- Compliance to regulations - Assists QA, Product management and R&D department on regulatory and compliance related matters, and phase appropriate applicable regulations and Company policies to ensure it is d be done right first time.
- Performs other QA duties as assigned, review of protocols, reports, and other compliance documentation as applicable.
- Assists in creating management review presentations, generates trend and status reports for monthly updates for Quality function head.
- Maintain controlled document database for the QMS and Quality department.
- Maintains the internal training program database, assists with delivering training on QA procedures, works with management to develop and revise training curricula and materials. Perform data integrity reviews of compliance related documentation.

**Experience and Qualification:**

- Bachelor's degree, minimum 7 years of experience in a quality and/or compliance related role in a Medical device, diagnostic or biotech.
- Demonstrated knowledge of Quality Management System processes, regulatory requirements, quality requirements, and compliance.
- Ability to effectively communicate within all levels of the organization around concepts of compliance, CAPA, risk management, and quality improvement.
- Experience with cGMP, CE Marking and governmental regulations related to diagnostics / medical device manufacturing.
- Experience in understanding manufacturing processes, product assembly, compliance, and Quality Assurance management.
- Demonstrated knowledge of Quality Systems and cGMP within a regulated environment.
- Experience with electronic systems (eQMS) preferred
- Excellent organizational and time management skills with a strong attention to detail
- Strong interpersonal communication skills; acts with urgency and passion. Enjoys helping others
- Ability to work both independently and with a team in a collaborative, fast-paced setting.