Title: **Vice President Quality Assurance & Regulatory Affairs**

Department: **Quality / Regulatory**

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 Vice President, Quality Assurance & Regulatory Affairs ("VP, QA/RA") will develop, manage, and lead the quality and regulatory functions of the Akoya Biosciences, Inc. (the "Company") working in partnership with senior management, product development, product management, manufacturing, Advanced Biopharma Solutions (ABS) operations, marketing/sales, and others, to ensure the highest possible quality outcomes and products and services that meet or exceed all regulatory requirements.

For RUO and IVD instruments, reagents, and related equipment manufacturing, this role will develop and implement effective, robust Quality Management System (QMS) processes and methods in alignment with regulatory and ISO requirements and will utilize metrics to continually improve quality processes and efficiency. In addition, this role is responsible and accountable for developing and executing the product and services regulatory strategy for Akoya including providing instruction, guidance, and regulatory interpretations to functional staff and Core Teams to achieve rapid worldwide clearance/approval/registration of products and services.

For Advanced Biopharma Solutions, this role will help support the laboratory regulatory and quality systems and activities as appropriate including supporting GLP, GCP, and GCLP compliance initiatives.

This position is hands-on in a fast-paced environment and will manage a small Quality and Regulatory team.

Duties & Responsibilities:

- Develop and maintain quality assurance and compliance polices and standard operating procedures, meeting domestic and international regulations, as well as corporate policies.
- Oversees the continuing implementation of all Quality Management System requirements and the adherence to all QMS processes, working closely and collaboratively with other Akoya functional groups.
- Harmonize the Quality System with a cloud based electronic QMS and Product Lifecycle Management system.
- Provide guidance and leadership in maintaining and continuously improving Akoya's ISO-13485 and 21 CFR 820 Quality Management System
- Initiate and achieve regulatory certifications as needed to support new product development of hardware, software, and reagents for research-use-only, investigational-use-only, Clinical Trial Assay (CTA), and regulatory approved uses.

- Interact with regulatory agencies and customers as needed.
- Provide quality leadership oversight and support of all compliance activities, regulatory agency filings, and responses
- Provide quality oversight to resolve product quality issues and improve overall product quality, working collaboratively with other functional groups.
- Implement measures to monitor the effectiveness of quality systems and drive remediation for improvement.
- Lead and oversee audits of external vendors, including contract manufacturers
- Partner with suppliers, contract manufacturer and distributors to secure the highest level of quality throughout the entire supply chain.
- Promote a quality and compliance culture and be a change agent where needed.
- Lead management review meetings and report to executive management on performance and effectiveness of the QMS.
- Drive quality initiatives in close partnership with all departments within the Company
- Lead Akoya's regulatory strategy definition and implementation
- Assesses regulatory pathways for new product and services platforms and product modifications; develops regulatory strategies and tactical plans for submissions to FDA and other regulatory agencies, as needed. Identifies and communicates potential risks and mitigations associated with regulatory strategies to stakeholders.
- Ensures that the Regulatory Affairs function is adequately represented on new product development teams.
- Ensure clinical development activities are compliant with cGCP, cGLP and FDA regulations, guidelines and standards.
- Ensure contracts, agreements, policy and customer communication are compliant to regulations and standards.
- Responsible for monitoring, interpreting, and implementing current and new regulatory strategy.
- Represents Regulatory Affairs function in interactions/negotiations with U.S. and international regulatory agencies and other external activities benefiting Akoya's business interests including trade associations, professional organizations, and standards development organizations, as well as Akoya's key Pharma customers.
- Manages the preparation and filing of premarket submissions and Technical Files.
- Designs and implements training on quality and regulatory issues for staff and for cross-functional groups across the company.
- Hires, develops and retains staff to meet business needs and to create a pipeline of talented professionals for progressively challenging and responsible roles.
- Prepares and manages QA/RA functional budget
- Oversees the development of employees, talents, process, tools and technology necessary to achieve short- and long-term goals. Also, set and align employees' goals to organizations goals.
- Perform other duties as assigned.

Required:

- Minimum 15-20 years of Quality Assurance and Regulatory experience in an ISO 13485 or 21 CFR 820 environment,
- Demonstrated experience taking products or services through the FDA approval process. PMA experience preferred
- Minimum 10 years managerial experience

- Up-to-Date knowledge of existing and emerging industry related regulations, standards and must be able to interpret regulatory requirements, determine what is necessary for compliance, and effectively communicate this information to stakeholders.
- Bachelor's Degree or master's degree in Chemistry, Biology, Engineering, or a related technical field.

Skills & Qualifications:

- Working knowledge of ISO 13485 quality management systems and 21 CFR Part 820
- Familiarity with human biomarker laboratory testing, regulatory, and quality systems requirements for research and CLIA/CAP certification preferred
- Familiarity with GLP, GCP, GCLP guidelines
- Direct experience supporting and/or leading third party audits (ISO registrars, FDA or other regulatory authorities)
- ASQ Certificate: CMQ&OE, CQE, CQA, CQT, CBA, etc. preferred
- Lead Auditor Certification and Training preferred
- Extensive Supplier/Internal auditor experience
- Experience supporting new product development in a regulated environment
- Demonstrated success in preparing, filing, and completing (including negotiations) regulatory submissions/dossiers [e.g., 510(k), pre-Submission, IDE, PMA, EU Technical Files.
- Experienced in meeting with, making presentations to, and negotiating with regulators.
- Demonstrated success in developing strong working relationships with regulators.
- Knowledge of regulations applying to medical devices and in vitro diagnostic devices in the U.S., EU and other jurisdictions, as appropriate.
- Operational Excellence/Six Sigma/Lean training or certifications preferred
- Ability to attract, recruit, mentor, and retain high-caliber professionals.
- Ability to think strategically, and to interpret and act upon complex or ambiguous issues, in both the immediate and broader context.
- Ability to communicate and interact effectively across all levels, disciplines, and regions.
- Ability to inspire, motivate, and build the confidence of teams to reach goals, steadfastly pushing self and others to achieve results.
- Demonstrates leadership through openness to diverse views, candor in assessing and articulating difficult positions, and willingness to make changes when needed.
- Experience in a senior management/leadership role
- Ability to multi-task and manage priorities
- Strong organizational skills and attention to detail
- Ability to work in a team environment and to meet deadlines is required
- Demonstrated success in supporting both growth and product support projects, including complex projects involving ambiguity and rapid change.
- Demonstrates in-depth understanding of advanced technical/scientific principles that relate to a specific product line.

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