Title: **Senior Complaint Handling Specialist, Instruments**
Department: **Research & Development QPS**
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 Complaint handling senior specialist – Instruments, will be assigned the responsibility of day-to-day processes of product compliant handling, issue investigations, working across functions on issue escalation, managing complaints' priority to serve customers in a timely manner, and working with cross functional teams on identifying root cause and working through corrective actions for Akoya's electromechanical software -controlled instruments. Responsibilities will include complaints handling, working with cross-functional teams on issue escalation, root cause analysis and issue resolution. Responsibilities will include data analysis, data reporting, management reporting, issue closure, communicating action to internal teams as well as contract manufacturers. This will also include documenting issue and closure in QMS database.

This individual will also participate in related QA processes such as product non-conformance, quality improvement, corrective action closure and providing management reports for management review. The individual will contribute to new processes as the QMS grows and will have opportunities to grow within the Quality group.

Duties & Responsibilities:

- Complaints handling and Corrective actions in regulated environment.
- Be responsible for documenting, escalating, and closing product complaints, non-conformances, process Quality issues, CAPAs.
- Work closely with cross functional complaint response, and document issues and corrective actions in complaint handling system.
- Reporting Complaints data.
- Document and Change Control management in the electronic document management system.
- Maintain documents, logs, records etc. in compliance with Company procedures.
- Support Supplier Control processes, completing supplier evaluation forms and building supplier files in the QMS.
- Scanning/archiving completed packages. Maintains controlled documents in the QMS database.
- Assist with and arranging documents related to training.

Skills & Requirements

- The individual must have knowledge of complaints handling, reporting and workings required to address customer complaints in a regulated environment such as FDA cGMP, ISO 13485 or similar.
- This individual must be able to understand technical aspects of electromechanical software-controlled diagnostics instruments.
    - They must be able to work across functions for issue escalation, root cause analysis and issue resolution in a timely fashion.
- The individual should be able to report data and create charts etc. to escalate quality issues in a creative, collaborative, and timely manner.
- Knowledge of quality management applications such as Arena or Trackwise will be ideal.
- Core values must include commitment to customer and operations excellence with demonstrated ethics and integrity.
- Minimum Associates Degree or related equivalent experience (5-6 years). Bachelor's degree preferred.
- Minimum 5 years of compliant handling, root cause analysis and working cross functionally to support product improvements.
- Experienced in complaint handling process in an In-vitro diagnostic, medical device, or pharmaceutical industry.
    - Electromechanical software-controlled diagnostic devices preferred.
- Complaints' data analysis, data querying and reporting.
- Basic understanding of EU and FDA standards and regulations relating to diagnostic medical devices preferred.
- Excellent attention to detail and organizational skills. Strong time management, communication, and leadership skills.

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