Title: **Senior Quality Complaint Handling Specialist**
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 Complaint handling senior specialist, will be assigned the responsibility of day-to-day processes of product complaint handling, issue investigations, working across functions on issue escalation, managing complaint 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 and reagents. 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, Arena Solutions.

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:

- Oversee and lead Complaint processing under the guidance of Manager in compliance with FDA, MDR Quality System Regulations, country specific vigilance regulations and ISO 13485.
- Manage the timely in-flow of customer complaints, the assignment of investigation responsibilities, and expedient processing and closure.
- Lead the cross functional complaint meetings and co-ordinate focus meetings and follow up complaints to closure.
- Responsible for accurate entry / review of complaints in a database (Arena Solutions), timely manner, triaging complaints to determine complaint code and investigation level, determining whether the complaint is associated with an adverse event or medical device, documentation of follow-up communication to complainants for additional, re-assigning complaints to the appropriate, investigated, closing complaints per required timeframes, and providing responses.
- Responsible for oversight of Adverse Event reporting program to ensure compliance.
- Work closely with internal team consist of Customer care, Mfg. engineering, Quality Engineering, Service and Engineering to ensure thorough and accurate investigations and drive the initiation of CAPAs when appropriate.
- Define reports/dashboards to identify delinquency or backlog in all aspects of the surveillance process.

- Work with manager in Develop and maintain data mining tools to monitor trends and Identify process improvement opportunities to enhance surveillance and to increase efficiency.
- Manage preparation and reporting of quality data for purposes of field surveillance and as the primary input into the Management Review process.
- Collaborate with technical groups to identify product improvement opportunities; assist in establishing complaint priorities. Escalate critical complaints, trends, and high-risk complaints.
- Assist in Health Hazard Risk assessments as assigned in conjunction with Design Assurance.
- Working knowledge of FDA Medical Device Regulations including Quality System Regulation 21 CFR Part 820, and applicable international quality standards including ISO 13485:2013, Canadian MDR, EU MDR and country specific vigilance related regulations.
- Strong analytical skills including trend and statistical analysis, interpersonal, and management skills.
- Perform other duties as required.

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:

- BS degree with at least 5 years' experience in medical devices and / or Biotechnology and/or pharma with 3 yr. min specifically related to post market surveillance / complaints management.
- 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 & 14971 or 21 CFR 820, 21 CFR 806, EU MDR.
- This individual must be able to understand technical aspects of electromechanical software-controlled diagnostics instruments, reagents, and software.
    - 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.
- 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