Responsibilities:

• In partnership with senior management, establish quality philosophy, policies, practices, procedures, and standards by which all Akouos operations are performed; provide quality assurance input to Akouos's strategic goals
• Develop and oversee a quality management system for Akouos's GxP activities; lead implementation and ensure effectiveness across departments
• Design, implement, and maintain QA and GxP compliance programs and infrastructure, including document control/change control processes, internal/external audits, deviation review and tracking, investigations, and corrective and preventative action
• Manage training programs for Akouos representatives overseeing or performing GxP activities and serve as an in-house advisor on GxP compliance
• Provide guidance in preparation for and serve as an Akouos representative for regulatory inspection and diligence activities
• Perform vendor qualification and oversight, including for GLP study testing facilities, Contract Reach Organizations supporting clinical activities, and CDMOs; maintain quality agreements
• Enable sustainable compliance with international quality standards and applicable programs and initiatives; proactively identify compliance issues/risks, within the organization and with its external partners, and regularly report to senior management on compliance activities and findings
• Foster relationships across the organization to encourage discussion and evaluation of best practices for continuous improvement of quality and compliance across programs and functions
• Create and develop Akouos's dedicated, in-house Quality Assurance team to meet evolving business needs and across various functions, including non-clinical study oversight, clinical compliance, and product quality

Qualifications:

• Bachelor’s degree in a life science required; Master’s Degree or PhD in management or scientific discipline a plus
• 10+ years of relevant work experience in biotechnology/pharmaceutical Quality Assurance
• Solid and demonstrable knowledge of international GxP regulations and guidelines, industry practices, and experience implementing Quality Systems in a regulated environment
• Ideal candidate will have broad experience in product development, clinical operations, regulatory compliance, GxP auditing, and at least 5 years of direct management experience
• Strong organization and time management skills
• Excellent attention to detail with an ability to perform critical review of various types of documents
• Outstanding written and verbal communication skills
• Ability to independently solve problems, lead projects, and influence teams
• Crisp decision-making, following appropriate consultation.
• Experience identifying and evaluating risks, and executing efficient and effective mitigations
• Demonstrated ability to work as a team player with multi-disciplinary project teams
• Proficiency with commonly used word processing, database systems, document management, and other software.