Our Mission: Healthy hearing available to all.

Director/Sr. Director Quality Assurance

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.