External Manufacturing Manager

This new role on Akouos’s Manufacturing team provides a unique opportunity to contribute to the clinical translation of gene therapy by managing efforts that support the development and operationalization of Akouos’s manufacturing platforms.

Responsibilities:

• Serve as externally-facing point of contact for select vendors and contract development and manufacturing organizations, including person in plant during execution of Akouos’s projects
• Responsible for outsourced manufacturing of select materials to support Akouos’s programs
• Manage the review and implementation of contractual quality and legal agreements
• Develop, obtain feedback, and manage project plans, budgets, and timelines
• Review and implement manufacturing documents, and oversee tech transfer activities
• Coordinate material logistics and release with Supply Chain and QA, respectively
• Provide support to senior manufacturing staff, as needed

Requirements:

• B.S. with 5+ years of multi-disciplinary experience in biotech/pharmaceutical industry with experience working with external partners and vendors
• Technical understanding of plasmid DNA, AAV, recombinant protein, and / or synthetic nucleic acids strongly desired
• Working knowledge of upstream/downstream process development and manufacturing of biologics strongly desired
• Willingness to travel to be on site at CDMO during project execution
• Strong communication skills and ability to triage issues and determine need for management involvement
• Exceptional organizational skills with the ability to multi-task and prioritize assignments, strong problem-solving skills, self-motivated with ability to work under pressure to meet deadlines
• Understanding of FDA, EMA and ICH regulations, industry standards and quality control principles for cGMP
• Strong team player that has a customer service approach and is solution oriented
• Attention to detail and the ability to work individually, within a multi-disciplinary team in a matrix environment, as well as with external partners and vendors