



Our Mission: Healthy hearing available to all.

### **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