



UPSTREAM PROCESS DEVELOPMENT LEAD

Akouos is building the leading gene therapy company focused on hearing disorders. Our objectives are to **restore** the inner ear's ability to produce functional proteins required for hearing, **rejuvenate** structures of the hearing circuit critical for high-fidelity signal transduction and inner ear homeostasis, and **reinforce** healthy hearing with local, enduring protein production to protect against drug-, noise-, and age- associated ototoxicity.

Ensuring delivery to the right cells, in the right amounts, and at the right time is central to our ability to restore and preserve hearing. Recombinant adeno-associated viruses (AAVs) can be harnessed as powerful vectors that are capable of safely and efficiently delivering therapeutic nucleic acids to the nuclei of target cells. Akouos's initial focus is on delivery of AAV gene therapies to treat hearing loss in genetically-defined patient populations.

Akouos launched in 2017 with backing from 5AM Ventures, New Enterprise Associates, and Partners Innovation Fund.

Akouos is seeking an innovative candidate to drive and lead the upstream process development for the manufacture of AAV-based gene therapies. The ideal candidate for this position is an experienced Scientist or Engineer with a strong background in AAV manufacturing technologies and an excellent track record in gene therapy upstream process development. The successful candidate would have experience in cell culture process scale-up, process optimization, and tech transfer for GMP manufacturing. The successful candidate will thrive in a collaborative, scientifically-stimulating, and fast-paced environment.

RESPONSIBILITIES

We are looking for someone who will:

- Drive and lead upstream process development of AAV production and technical transfer to internal / external GMP MFG.
- Implement and develop innovative vector production technologies based on current learnings in the field and QbD strategies.
- Generate and maintain appropriate cell and plasmid banks for use in development and GMP manufacturing.
- Develop protocols for vector production in shake flasks, wave bioreactors, and stirred tank bioreactors.
- Perform monitoring of cell viability/growth and cell culture metabolites from cultures.
- Develop intellectual property, publishing scientific papers, present at conferences and other tasks related to the company's scientific and business interests.
- Provide scientific expertise and guidance in clinical AAV production, development and innovation.
- Author and review appropriate CMC documents for regulatory filings.
- Participate in internal project and external CMO teams as a subject matter expert.
- Demonstrate leadership and foster a team environment.
- Write, prepare and present technical data, technical reports and standard operating procedures (SOPs) for internal use and tech transfer.

- Manage a group of scientists focused on developing and implementing Akouos's upstream production platform

REQUIREMENTS

- Degree in chemical engineering, biology, biochemistry, chemistry, biotechnology or a related field.
- PhD in relevant subject matter (e.g. cell culture production of protein biologics) with 3-5 years relevant process development experience or an MS with 5-8 years relevant experience.
- Previous experience with developing mammalian cell culture manufacturing processes is a must.
- Prior experience with HEK293 based AAV manufacturing processes is preferred.
- Proficient with aseptic techniques and the use of shake flasks, wave-based bioreactors, and stirred tank bioreactors at various scales.
- Prior experience with cGMP/cGLP regulatory guidelines related to pharmaceutical biologics development is a plus.
- Prior experience managing a team, co-ops or direct reports is desired.
- Prior experience with tech transferring to a cGMP facility is desired.
- The candidate must be well-organized, goal-focused, and detail-oriented.
- The candidate must have outstanding verbal and written communication skills.
- Ability to lead and work independently in a collaborative, scientifically stimulating, fast-paced environment.

Qualified applicants should submit their resume to careers@akouos.com.

Akouos is committed to equal employment opportunity and non-discrimination for all employees and qualified applicants without regard to a person's race, color, sex, gender identity or expression, age, religion, national origin, ancestry, ethnicity, disability, veteran status, genetic information, sexual orientation, marital status, or any characteristic protected under applicable law.