



Our Mission: Healthy hearing available to all.

Director of Translational Sciences

Akouos is seeking a **Director of Translational Sciences** to oversee product development activities from discovery research through to clinical evaluation. A key focus of this role is the path from research through early clinical development, with a responsibility for planning and implementing all supportive non-clinical studies, including efficacy and toxicology studies, both *in vitro* and *in vivo*. The successful candidate will work collaboratively with internal cross-functional teams and with external resources to plan and execute an overall preclinical development strategy for product candidates. A background in gene therapy is highly desirable and a proven ability to deliver novel therapeutic approaches into the clinic is essential.

Responsibilities

We are looking for someone who will:

- Provide scientific leadership to transform scientific discoveries into clinical product candidates, with the ultimate goal of developing gene therapy medicines.
- In collaboration with colleagues in discovery research, help identify targets and AAV-based drug candidates with strong proof-of-concept and safety data.
- Develop and oversee the overall pharmacology/toxicology strategy for programs throughout the drug development lifecycle, from early characterization studies to IND-enabling studies to non-clinical studies that support product licensure.
- Design, execute, and interpret *in vitro* and *in vivo* non-clinical studies under both non-GLP and GLP conditions, qualifying and managing external vendors as appropriate.
- Ensure appropriate resourcing for and execution of all non-clinical studies and comprehensive reports.
- Present analyses and interpretations of non-clinical studies to regulatory agencies and other oversight bodies in meetings and documents including scientific advice proceedings, IND/CTA applications, annual reports, safety reviews, investigator brochures, and market applications.
- Provide support for clinical and regulatory functions, including participating in the dose selection for first-in-human studies, as well as diligence activities as appropriate.
- Oversee assay development group responsible for developing & validating assays, as well as for analysis of preclinical and clinical samples.
- Ensure all translational activities, including non-clinical studies and sample analyses, are conducted in line with the highest quality standards and regulatory guidelines.
- Develop, mentor and guide a highly effective translational team.

Requirements

We are looking for someone who:

- Attained a PhD or MD, with at least 15 years of drug discovery/drug development experience in the biotech or biopharma industry.



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- Has hands-on experience taking biologics through preclinical development into the clinic, including knowledge regarding developing accompanying bioassays. Experience with the development of cell and gene therapy or ATMP products is strongly preferred.
- Is proficient in Good Laboratory Practice (GLP) requirements (21 CFR 58).
- Has experience leading a function including managing multiple programs and priorities, studies, external CROs, staff, and budgets.
- Ensures high quality and accurate documents, requiring strong writing and communication skills, as well as attention to detail.
- Manages timelines effectively through cross-functional planning.
- Has strong interpersonal skills and proven ability to work effectively in a multidisciplinary team environment

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