Process Development – AAV Platform

About Tevard:

Tevard Biosciences is pioneering mRNA-modulating therapies to cure a broad range of genetic diseases. The privately held biotechnology company was founded by MIT Professor and Whitehead Institute Founding Member Harvey Lodish, with life science entrepreneurs and executives Daniel Fischer and Warren Lammert, fathers of children with rare genetic diseases, and scientific co-founder Jeff Coller, a Bloomberg Distinguished Professor in the Department of Molecular Biology and Genetics at the Johns Hopkins University School of Medicine. Tevard is exploring the use of its novel Suppressor tRNA, Enhancer tRNA, and mRNA modulating platforms in neurological disorders, heart disease, and muscular dystrophies.

Position summary:

The PD/CMC Lead – AAV Platform will bring leadership capabilities and be a subject matter expert (SME) for AAV Process and Analytical Development. The ideal candidate for this position is an experienced Scientist/Engineer with a strong background in AAV biology, manufacturing and prior 3rd party management experience. The candidate should be proficient in upstream and downstream development, process scale-up, process optimization, and tech transfer to GMP manufacturing. This person will collaborate across functional areas to ensure project advancement, rapid and best in class execution, and communication of challenges/opportunities.

You will contribute by:

- Manage a team of scientists and engineers to develop and optimize AAV vector production and purification processes from early-stage research through to commercialization.
- Collaborate with CDMO's cross-functional teams, including Analytical Development, Manufacturing, and Quality, to establish process requirements, identify process risks, and develop strategies for process improvement.
- Implement process development best practices, including statistical process control, Design of Experiments (DoE), and Quality by Design (QbD) principles, to ensure the development of robust, efficient, and scalable manufacturing processes.
- Develop and execute project plans, budgets, and timelines for process development programs to meet company goals and milestones.
- Implement technology transfer protocols to transfer CDMO's manufacturing processes to internal and external manufacturing facilities for GMP production.

- Author and review CDMO's technical reports, process development protocols, and regulatory submissions to support the development and commercialization of AAV gene therapies.
- Keep abreast of industry trends, new technologies, and emerging regulatory requirements to ensure our AAV process development programs are aligned with best practices.
- Working closely with Tevard's tRNA and disease biology teams to ensure smooth transitions between groups with appropriate high-quality data packages generated
- As part of Tevard's Research leadership team, provide scientific insight and guidance in projects/platforms, including strong scientific thinking and hypothesis development and help advance tRNA therapies towards the clinic

Preferred Qualifications:

- PhD in Biotechnology, Bioengineering, Chemical Engineering, or a related field, with a minimum of 5 years of experience in AAV process development and manufacturing.
- Strong understanding of AAV vector design, production, and purification, including experience with suspension cell culture, virus production, and downstream purification processes.
- Experience with process development best practices, including statistical process control, DoE, and QbD principles.
- Proven track record of leading cross-functional teams to achieve process development goals, including experience with project management, budgeting, and timeline management.
- Experience with CDMO's tech transfer protocols and regulatory submissions for AAV gene therapy manufacturing.
- Excellent communication, leadership, and team-building skills.

Experience with preclinical stage gene therapy programs and knowledge of phase appropriate technical considerations around viral vector molecular design, titer, potency, and purification.

Title will be commensurate with experience.

Contact:
Interested candidates please send CV and cover letter to careers@tevard.com

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