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Probio launches cGMP AAV manufacturing services at new Hopewell facility

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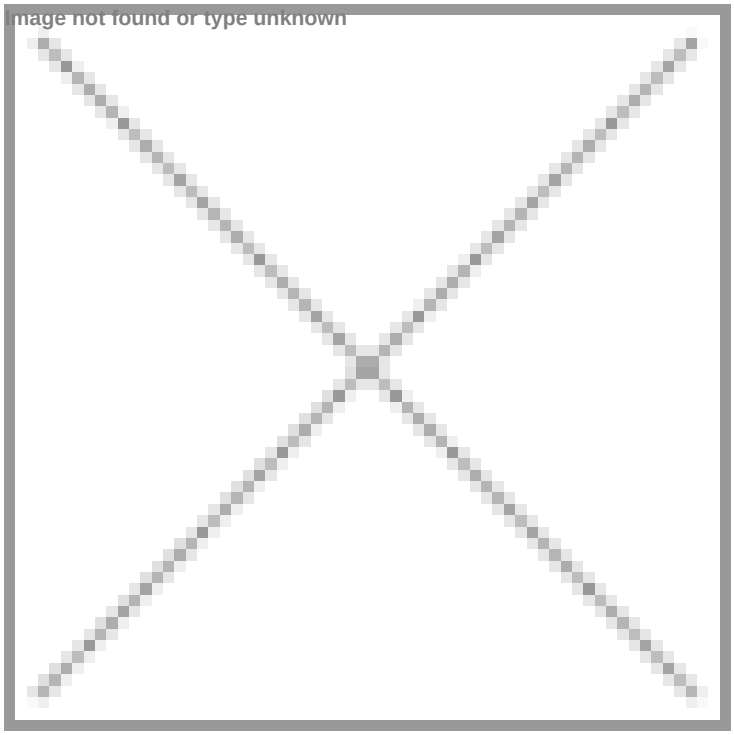
State-of-the-art 128,000 sq. ft. site delivers fully integrated, end-to-end viral vector manufacturing solutions to accelerate gene therapy development from early clinical to late-phase programmes.



ProBio, a leading contract development and manufacturing organization (CDMO) specializing in gene and cell therapy, announced the launch of its cGMP Adeno-Associated Virus (AAV) manufacturing services at its 128,000 sq. ft. state-of-the-art facility in Hopewell, New Jersey. This strategic expansion is designed to meet growing industry demand for high-quality viral vector production and reflects ProBio's ongoing commitment to supporting the advancement of life-changing gene therapies.

The Hopewell facility is purpose-built to provide end-to-end AAV manufacturing solutions that align with global regulatory and quality standards. ProBio's new capabilities offer clients fully integrated services—including GMP plasmid DNA production, AAV vector manufacturing, and final drug product formulation and aseptic fill/finish—within a single U.S.-based location. This streamlined approach simplifies coordination, reduces handoffs, and accelerates timelines across the drug development lifecycle.

"At ProBio, we recognize that every gene therapy program represents a critical opportunity to change lives," said **Allen Guo, Chief Executive Officer of ProBio**. "Our new GMP AAV manufacturing platform reflects our mission to help developers navigate complex manufacturing challenges with speed, precision, and scientific integrity."

The Hopewell team brings decades of hands-on experience in biologics and viral vector manufacturing, with a track record of supporting the development and commercialization of approved therapies. "The launch of our GMP AAV services is the result of deep cross-functional collaboration and reflects our commitment to delivering high-quality, end-to-end solutions for our partners," said **Michael Vreeland**, **US Site Head**. "Our experts have built and scaled manufacturing systems for some of the industry's most advanced therapeutics, and they're now applying that same expertise and dedication to every program at ProBio."

Key Features of ProBio's GMP AAV Manufacturing Services include:

- **Scalable, Phase-Appropriate Manufacturing:** Flexible batch sizes from **50L to 200L**, with capability for **2x200L** concurrent runs—supporting early clinical to late-phase programs.
- **Fully Integrated Platform, Single-Site Solutions:** From high-quality plasmid production and AAV vector manufacturing to final drug product fill/finish, ProBio streamlines the entire process under one roof—reducing complexity, saving time, and accelerating developer's path to clinic.
- **Resilient U.S.-Based Supply Chain:** By prioritizing domestic sourcing for key raw materials, ProBio ensures greater supply stability, faster lead times, and unwavering quality—empowering gene therapy developers to move forward with confidence.
- **Accelerated Timelines Through In-House Analytics:** Comprehensive internal QC and analytical capabilities enable fast, phase-appropriate release while maintaining the highest standards of precision and compliance.

To enhance operational effectiveness and ensure seamless compliance, ProBio has embraced digitalization through the implementation of a fully electronic Quality Management System (QMS) powered by Veeva. This system enables real-time electronic approval and traceability of key GMP documentation, including batch records, deviations, change controls, and CAPA events—supporting both regulatory alignment and execution speed.

"What differentiates our AAV platform is the combination of flexible manufacturing architecture and built-in quality by design," said **Lance Marquardt, Director of AAV Manufacturing Operations at ProBio**. "Our processes are engineered to support a wide range of serotypes, production scales, and clinical milestones—while ensuring rigorous in-process controls and regulatory alignment at every step."

With this launch, ProBio continues to position itself as a strategic partner for gene therapy innovators—offering agile, phase-appropriate manufacturing solutions that evolve with the needs of each program.