SK pharmteco

SKyvec™ AAV

SK pharmteco Offers You a Scalable AAV Manufacturing Solution from Gene to Commercial Supply

Integrated AAV vector development and manufacturing with a scalable platform optimized for yield, quality, and process efficiency. SK pharmteco provides reliable AAV production services and CDMO expertise from gene to clinic.

Built on proven platform technologies and extensive clinical expertise, SK pharmteco delivers high-yield AAV manufacturing solutions designed to support efficient process development, scalable production, and rapid, reliable progression from early research to clinical and commercial supply.

Our experienced teams support AAV programs globally with integrated development and manufacturing capabilities in North America and Europe. Leveraging scalable upstream and downstream platforms, analytical expertise, and regulatory support, we help accelerate development timelines while maintaining product quality, consistency, and supply continuity.

Benefits

Integrated technologies and expertise to support today's programs and tomorrow's vectors

- Proprietary AAV production technologies designed for reproducibility, supply continuity, and safety
- Extensive experience with natural, engineered, and shuffled capsids
- Support for diverse serotypes, transgenes, and next-generation vector programs
- Flexible manufacturing capabilities from early development through commercial supply
- Dedicated development, MSAT, and manufacturing teams enabling seamless tech transfer

Design for Developability

Quality and manufacturability considered from the start

- Early focus on potency, identity, purity, and genome integrity
- Advanced construct and regulatory element optimization
- Identification of inefficient designs before scale-up
- Reduced development risk and improved manufacturability
- Accelerated progression from gene to clinic

Protect Genome Integrity

Preserving what matters most, vector fidelity and consistency

- Sequence verification from plasmid through vector product
- NGS-enabled characterization supporting deep genomic insight
- Monitoring and preservation of ITR integrity throughout development and manufacturing
- Early detection of sequence variants and heterogeneous vector populations
- Enhanced confidence in product quality and regulatory readiness

Deliver Efficient Manufacturing

Scalable processes designed for productivity and performance

- Suspension-based manufacturing platform supporting clinical and commercial production
- Media optimization and productivity-enhancing strategies tailored to vector performance
- Higher titers and improved full capsid enrichment to reduce manufacturing burden
- Consistent performance across scales and bioreactor formats
- Modular facilities and single-use technologies enabling flexible capacity

Our suspension-based AAV platform simplifies development, reduces variability, and accelerates timelines

Optimized across multiple serotypes and transgenes

Leverages transient transfection of a HEK293 cell line using a three-plasmid system

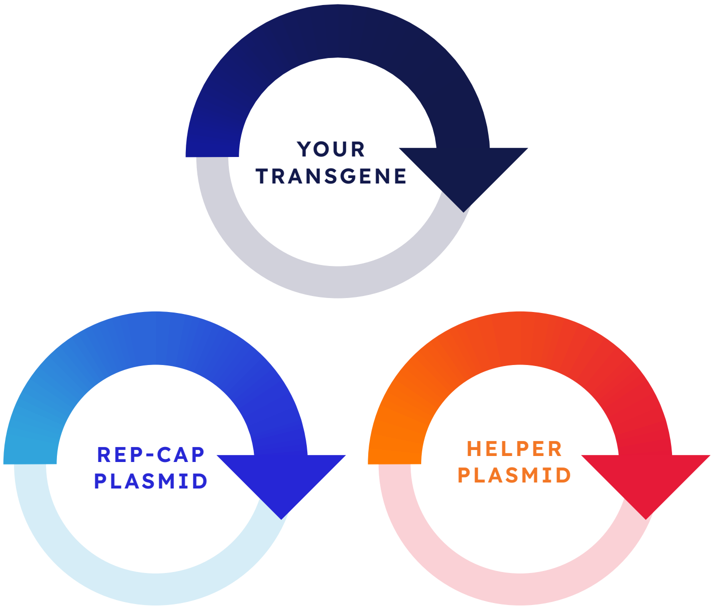
Progress from gene to clinic in as short as 8 months*

**Timeline dependent on program requirements, starting materials, and regulatory strategy*

Supported by extensive batch experience, GMP manufacturing expertise

Scalable platform from development to commercial manufacturing scales

No loss of titer between scales and consistent performance across bioreactor types



Consistent performance built into every batch

PLATFORM SYSTEM	
Serotypes	Multiple serotypes (AAV1-9, rh74, AAV11), novel capsids
Cell Line	HEK293
Platform format | Transfection	Suspension and Adherent | Triple-plasmid system
Starting Materials	Master and working cell banks | Proprietary plasmids
TITERS	
At harvest	2.5×10^{10} – 4×10^{11} VG/mL Examples per serotype: • AAV6: Up to 2.9×10^{10} VG/mL • AAV8: 2.5×10^{10} – 1.9×10^{11} VG/mL • AAV9: Up to 2.4×10^{11} VG/mL
Observed yield at 200 L	Up to 2 - 6×10^{16} VG (e.g., AAV9)
Drug Substance Titer	8×10^{12} – 5×10^{14} VG/mL Examples per serotype: • AAV6: Up to 2.2×10^{13} VG/mL • AAV8: 7.7×10^{12} – 2.1×10^{14} VG/mL • AAV9: Up to 1.7×10^{14} VG/mL
Titer range across process steps	Harvest: 5.3×10^{10} - 4×10^{11} VG/mL DS: 3.5×10^{13} - 5×10^{14} VG/mL
SCALABILITY	
Scale	Development and pilot-scale manufacturing from bench through 500 L
FULL CAPSID QUALITY	
% Full particles | Full Capsid	Crude/Affinity-purified material: 20-60% full capsids; Enriched drug substance: typically 65-75%, with examples up to 90% full capsids
PROCESS RECOVERY	
% Total Yield	As high as 70% (Range: 25-70%)
TRANSGENES	
Total transgenes	Over 40 successful transgenes
GMP BATCHES	
Total produced	Over 60 GMP batches produced

Integrated Analytical Testing

Analytical testing supports AAV programs from early development through commercialization, using qualified assays tailored to specific serotypes.

- Infectious and genomic titer
- Safety testing
- Purity
- Physicochemical characterization
- Identity and genome integrity
- Micro, stability, compendial testing, and more

SK pharmteco's AAV manufacturing success depends on aligning:

Scalability
Early phase to commercial

Quality
High productivity and process recovery

Reproducibility
Batch-to-batch consistency

Regulatory Readiness
Analytical + CMC expertise

Explore more resources:

https://www.skpharmteco.com/news-insights/?paged=1&em_segment=viral-vectors