

SKyvec™ Lenti

SK pharmteco Offers You Flexible Lentiviral Manufacturing Solutions for Both *Ex Vivo* and Next-Generation *In Vivo* Therapies

Accelerate your program with an experienced lentiviral vector CDMO offering scalable, regulatory-ready manufacturing for cell and gene therapy programs. SK pharmteco delivers flexible LVV production services, analytical support, and manufacturing expertise for both *ex vivo* and *in vivo* applications.

SK pharmteco delivers flexible platform and custom solutions to support efficient progression from preclinical development through early- and late-phase clinical stages and onto commercial supply, including complex and rare disease applications.

Integrated lentiviral vector development and manufacturing facilities in North America and Europe, supported by scalable production platforms, analytical expertise, regulatory guidance, and transparent technical collaboration. Our teams help advance programs efficiently while maintaining product quality, consistency, and supply continuity globally.

Benefits

- Platform-based and customized development solutions
- Full-lifecycle support from plasmid design through fill-finish
- Clinical and commercial manufacturing capabilities
- Consistent vector performance and reproducible manufacturing
- Established strategies to minimize RCL risk
- Integrated analytical, cell banking, and regulatory support

Optimized Workflows Without Compromising Process Quality

- Process innovations enabling next-generation *in vivo* lentiviral applications while improving performance for *ex vivo* therapies
- Improved impurity clearance supporting lower residual HCP and host cell DNA levels
- Enhanced infectious vector recovery and manufacturing efficiency
- Accelerated downstream processing with high recovery
- Reduced manufacturing burden through fewer batches and streamlined timelines
- Robust, reproducible workflows designed for consistent performance from development through commercialization

Key Differentiators

- Proprietary plasmids, optimized transfection and downstream processing workflows, and NGS-enabled characterization designed to support vector performance and supply continuity
- Flexible manufacturing solutions supporting both suspension and adherent processes
- Scalable development strategies enabling efficient transition from early development to GMP manufacturing
- Experience supporting a wide range of lentiviral vector designs, from conventional VSV-G systems to engineered, retargeted, and alternative envelope platforms
- Dedicated technical teams enabling efficient technology transfer and process consistency
- Agile manufacturing networks featuring modular suites, single-use technologies, and scalable clinical-to-commercial supply

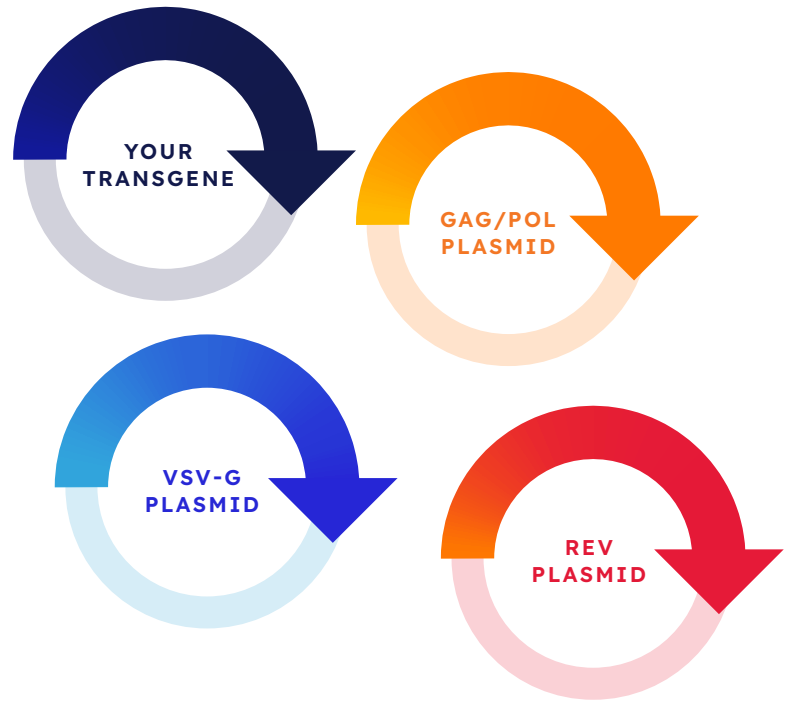
A structured and scalable LVV platform designed to accelerate development while maintaining robust and reproducible manufacturing performance.

Integrated LVV production framework supporting early-stage, pivotal, and commercial programs

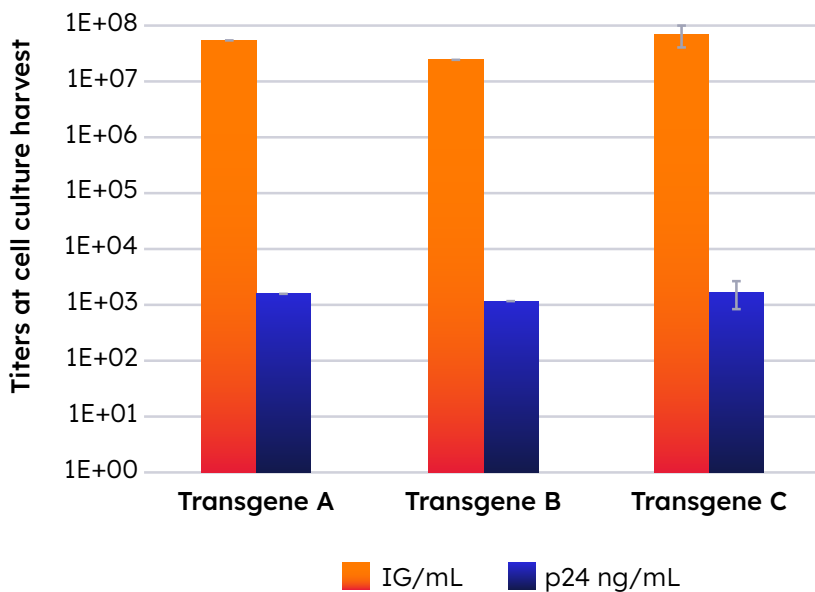
Proprietary HEK293 transient transfection platform utilizing a proven four-plasmid manufacturing system

Accelerated pathways enabling progression from gene to clinic in as little as 8 months*

**Timeline dependent on program scope, starting materials, and regulatory requirements.*



Representative productivity data across multiple transgenes at 200 L scale



Extensive GMP experience supporting IND filings and clinical advancement

Scalable manufacturing capabilities supporting diverse vector designs and transgenes

Consistent performance across scales to reduce risk and streamline development

Consistent performance built into every batch

PLATFORM SYSTEM	
Cell Line	Proprietary HEK293 Cell Line (or other commercially available cell lines)
Platform format Transfection	Suspension (Adherent as needed) 4-plasmid system; VSV-G, VSV-G-modified, and other pseudotypes
TITERS	
Infectious titers at bulk harvest	1 - 3×10^7 TU/mL p24: 3 - 5×10^9 VP/mL; up to 1×10^{10} VP/mL (upstream production dependent)
Observed yield at 200 L	1 - 5×10^{12} TU (suspension)
Drug substance titer	1×10^8 - 1×10^{10} TU/mL (suspension) (depending on concentration factor, upstream production/titer, LVV construct)
Drug product titer	$2.6 - 4.3 \times 10^9$ TU/mL
SCALABILITY	
Scales	Suspension: up to 500 L Adherent: Up to 50 m ²
RECOVERY	
Observed process yields	15-40% (harvest to DP)
RESIDUAL HCP CLEARANCE	
% Clearance	95%
TRANSGENES	
Total transgenes	Over 20 successful transgenes
GMP BATCHES	
Total produced	Over 40 GMP batches produced

Integrated Analytical Testing

Analytical testing supports LVV programs from early development through commercialization, using qualified and program-specific assays tailored to lentiviral vectors.

- Functional and infectious titer.
- Physicochemical characterization
- Microbiology and stability
- Purity
- Identity and genome integrity
- Compendial testing, and more

SK pharmteco's LVV 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