SKyvec™ Adeno

SK pharmteco Offers You a Robust, Scalable Adenoviral Manufacturing Solution

Our flexible adenovirus manufacturing platform combines high-yield upstream production with a streamlined downstream process architecture to improve recovery, reduce operational complexity, maintain high purity, and support regulatory-ready manufacturing from development through commercial scale. Backed by deep adenoviral process development and manufacturing expertise, it is an adaptive platform built for adenoviral vector development.

From virus banking through drug substance and drug product manufacturing, our adaptive platform built for adenoviral vector development combines high-yield upstream production with integrated downstream process engineering to improve recovery, reduce operational complexity, and support scalable, high purity, and regulatory-ready performance.

With global operations in North America and Europe, we support efficient progression from early development through commercial supply across gene therapy, vaccines, and oncolytic applications to meet your program's needs.

Successful adenovirus programs defined early

Our adaptive platform integrates a structured framework with process architecture decisions made early in development, creating alignment across construct design, cell line selection, harvest, purification, formulation, analytics, viral clearance, and banking. These factors directly influence yield, scalability, process consistency, and regulatory readiness across development stages.

This is why early alignment of critical quality attributes (CQAs), including potency, identity, purity, and genome integrity, as well as strategies to reduce replication-competent adenovirus (RCA) risk, are incorporated from the start.

Tailored to Your Program

- Adaptive development strategy, flexible enough for program-specific complexity
- Platform-based and custom solutions
- Supports first-generation, helper-dependent/gutless, and oncolytic adenoviral programs, with experience across Ad5 and simian adenoviral systems
- Integrated analytical testing, cell and viral banking, and regulatory support

Key Differentiators

- Suspension-based upstream platforms for improved scalability
- Adherent adenovirus platform available for flexibility
- Integrated upstream and downstream design for process consistency
- Process development aligned with GMP production conditions from bench to 500 L
- High throughput reactor screening using Ambr® 250
- Ensuring consistent process performance and control of critical parameters during technology transfer, supported by dedicated Process Development and MSAT teams.

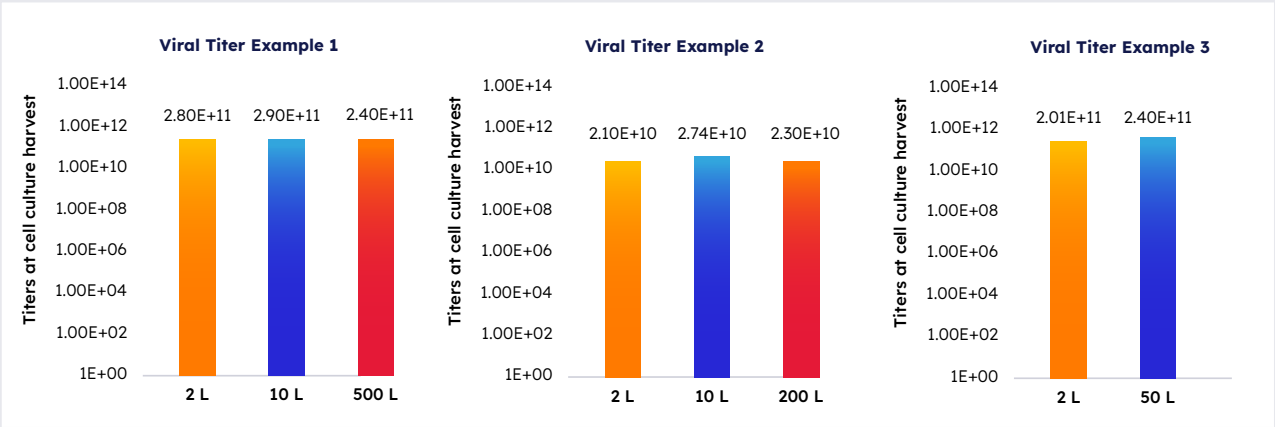
Downstream Innovation

- Replacing traditional chromatography-heavy workflows with a streamlined hybrid purification process (AEX membrane-based capture + 1-2 flow through polishing columns)
- Combining clarification, TFF, and AEX membrane capture
- Flow-through polishing to simplify downstream processing

Adenoviral manufacturing requires more than a rigid, one-size-fits-all platform. SKyvec Adeno applies an adaptive framework that links cell line selection, harvest, purification, formulation, analytics, viral safety, and banking from the beginning. The most important question is not whether a CDMO has an adenoviral platform, but whether it knows when a standard approach is not enough.

Key Features

- Consistent virus harvest titers from bench to pilot scales (1×10^{10} - 5×10^{11} VG/mL)



- >70–85% downstream recovery
- ~50% reduction in processing time versus adherent-based processes
- ~70% reduction in buffer consumption
- Improved impurity clearance (rHCP)
- Scalable, manufacturing-friendly process without ultracentrifugation
- Maintains infectivity and capsid integrity

Manufacturing Advantages

- Our suspension-based adenovirus manufacturing platform simplifies development (including membrane-based capture and FT polishing), reduces variability, and accelerates timelines
- Reduced buffer consumption and improved process economics
- Simplified scale-up and technology transfer
- Flexible operations with room-temperature intermediate holds
- Closed, single-use cGMP manufacturing
- Integrated upstream and downstream process consistency
- Experience supporting both clinical and commercial adenoviral programs

Consistent performance built into every batch

PLATFORM SYSTEM	
Serotypes	First-generation, helper-dependent/gutless, and oncolytic adenoviral programs, with experience across Ad5 and simian adenoviral systems
Cell Line	HEK293, CAP® producer cell, and others
Platform format	Suspension (Adherent available)
TITERS	
Titers at harvest	1×10^{10} - 5×10^{11} VG/mL (consistent across scale)
SCALABILITY	
Scale	Bench to 500 L
PARTICLE-TO-INFECTIVITY RATIO	
VP:IU ratio	<20:1
DOWNSTREAM PERFORMANCE	
Downstream Processing Time	3-5 days (vs conventional DSP 7-10 days)
Total Downstream Recovery	>70-85%
AEX Step Recovery	>90%
Host-Cell DNA Clearance	>4-log reduction
Residual HCP Clearance	4-log; improved HCP profile vs ultracentrifugation-based process
OTHER PROCESS DETAILS	
Buffer consumption	500 L (vs conventional processes using 1,500 L)
TRANSGENES	
Total transgenes	Experience across 7+ transgenes to date

Integrated Analytical Testing

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

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

SK pharmteco's Adeno 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