

Advances in viral vector manufacturing




Balancing speed, scale, and quality through choices in viral expression strategy

MADE WITH
CONSIDERATION & CARE

No one viral expression system is right for every situation. There will always be tradeoffs and choices to make. This infographic is intended to provide thinking points to help you consider options before deciding which path to take.









Speed, scale, and quality tradeoff questions to ask

Whether you are going to the clinic or commercial, there are tradeoffs and decisions to make related to speed, scale, and quality. It's important to ask questions to make the most informed decisions possible. Some questions to consider:

 SPEED	<ul style="list-style-type: none"> • How much time do you have for process development? • Will you be able to risk making changes in later phases to gain speed to the clinic today?
 SCALE	<ul style="list-style-type: none"> • What is your clinical indication and how many doses do you anticipate needing? • How might efficacy impact dosing requirements and viral titer needs?
 QUALITY	<ul style="list-style-type: none"> • How might viral expression system impact Critical Quality Attributes (CQAs)? • How can you ensure process and product characterization align to meet regulatory requirements?

Weighing the advantages and challenges of viral expression systems

Some viral expression systems offer advantages in speed but challenges in scale, others offer advantages in scale but present challenges in product quality or efficacy. To find the right expression system for your unique therapeutic, it's important to weigh the advantages and challenges of different options. Here are some high-level tradeoffs to consider:

Transient adherent	Transient suspension	Baculovirus Sf9	Producer cell line
<p>Low process development requirements, but challenges with scale-up even with new advances such as fixed bed bioreactors (FBRs)</p> <p>Speed </p> <p>Scale </p>	<p>Advantages in ease of scale-up (with some limitations), but challenges related to increased need for process development related to transition to suspension</p> <p>Speed </p> <p>Scale </p>	<p>Offers best in scale-up potential, but challenges with quality due in part to differences in insect cells compared to mammalian (post-translational modifications)</p> <p>Scale </p> <p>Quality </p>	<p>Best option for quality, consistency, and scale, but challenges related to extensive process development needed to create a stable cell line</p> <p>Speed </p> <p>Quality </p>

Having options in expression systems ensures you can find the right path for your therapeutic

While the viral vector market is dominated by adeno-associated viruses (AAV) and lentiviral vectors (LV), there is also a range of less commonly used vectors. If you have a novel system, we're excited to learn about that too. Regardless of your vector strategy, you can be confident that we have the experience and resources to smoothly manage any project and any choice in vector expression system.

Vector manufacturing modalities*		
AAV	■ Adherent + Suspension	■ Suspension + HSV
	■ Producer cell line + Ad	■ Suspension + Baculovirus
ADENOVIRAL	■ Adherent + Suspension	
HERPESVIRAL	■ Adherent + Suspension	
LENTIVIRAL	■ Packaging/producer cell line	■ Adherent + Suspension
	■ Packaging/producer cell line	■ Adherent + Suspension

■ Mammalian cells
 ■ Mammalian cells transient transfection
 ■ Mammalian cells infection
 ■ Insect cells

* Additional manufacturing modalities also available; inquire for more information

Is speed to clinic of the utmost importance?

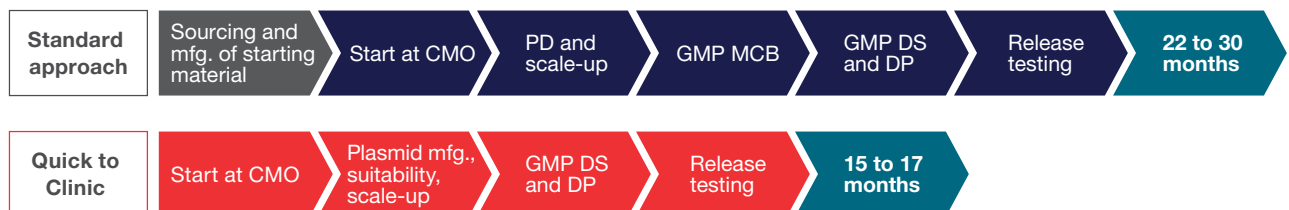
You've worked through all your options and weighed all the advantages and challenges of different expression systems. If you found speed to the clinic is of the utmost importance, Patheon™ Quick to Clinic™ viral vector program might be just what you're looking for.

Patheon Quick to Clinic viral vector is an all-inclusive manufacturing platform that spans plasmid manufacturing, process optimization, and cGMP manufacturing and utilizes optimized, IND-ready platform processes for LV and AAV manufacturing, with scalability up to 200 L. With Quick to Clinic™ viral vector, you can:

- **Reach milestones faster**—Shorten time from discovery to clinic by more than six months compared to standard process development.
- **Effectively manage risk**—Implement a proven, all-inclusive platform backed by supply chain and commercial license assurance, next-gen analytics, and phase-appropriate regulatory support provided throughout the product lifecycle.
- **Build for commercial success**—Leverage a trusted partner bringing 20+ years of GMP viral vector manufacturing experience with 500+ viral vector cGMP clinical and commercial lots produced for 130+ viral vector products globally.

START YOUR PROGRAM TODAY BY LEVERAGING:

- ✓ Optimized, IND-ready processes
- ✓ Platform-qualified analytics
- ✓ Bundle option (process materials, licenses, plasmids, cell banks, etc.)



Over six months in time savings when compared to a standard process development program
Projected timeline inclusive of all plasmid manufacturing and optimization work

Learn how Thermo Fisher Scientific can help you choose the right vector expression modality for your unique viral vector product.