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Viral vector production: How CDMOs influence late-stage development success

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Viral cell and gene therapies (CGT) have transformed modern medicine by offering durable, and in some instances curable, solutions for rare and previously untreatable diseases. Although only 24 viral vector–based gene therapies have been approved to date, hundreds more are advancing through clinical pipelines. Their promise is significant, but so are the risks for CGT manufacturers. Complex biology, high-dose–related fatalities, and manufacturing variability have prompted heightened regulatory scrutiny, leaving developers with an exceptionally narrow margin for error. This is especially true at the late stage of viral vector-based gene therapy.

"By the time you're in the late phase, there's no room for error. A single misstep can unravel months or years of progress, triggering costly rework that may go all the way back to toxicology studies."
Suparna Sanyal – Commercial Development Director at Lonza

A failed batch, regulatory hold, or supply interruption can jeopardize patient access and erode investor confidence. To navigate these risks, developers in need of manufacturing support must choose a CDMO with the right expertise and infrastructure to guide programs to commercial launch.

Regulatory risks: Navigating the biologics license application

The biologics license application (BLA) process is one of the most unforgiving stages of commercialization. By this point, regulators expect evidence that the therapy will be safe, efficacious and can be consistently manufacturable. Even small gaps in regulatory filings can lead to delays, additional studies, or outright rejection. Programs most often stumble into regulatory challenges when it comes to scaling processes, analytics, and supply traceability.

Process gaps
Developers frequently want to advance early-stage processes into late phase, even when those processes lack the robustness needed for commercial manufacturing. "There's a push to the finish line," Sanyal explains. "But some elements of the process may pose safety risks or variability that regulators won't accept."

Analytical shortcomings
Potency assays, stability packages, and advanced characterization are now expected in BLA submissions. For AAV and lentiviral vectors, standard methods, such as ELISA for capsid titer and qPCR for genomic titer without considering genomic integrity of AAV and lentiviral vectors, often fail to capture the resolution the regulators are seeking. "The more we can help agencies understand why a product is likely to be safe and efficacious, the better positioned we are to pass," says Sanyal.

Supply chain traceability

Legacy materials and outdated documentation that once passed review now face intense scrutiny. Stability data, sourcing records, and compliance histories must meet today's stricter standards. Any inconsistency can trigger follow-up questions, delays, or additional studies.

Experienced CDMOs anticipate these challenges. "We work closely with regulatory agencies to predict and overcome issues before they become roadblocks," Sanyal notes, and further highlights Lonza's use of internally developed advanced analytics to characterize viral vectors and strengthen BLA submissions.

Operational risks: Avoiding tech transfer and manufacturing failures

Operational failures, such as suboptimal tech transfers, production interruptions and batch loss, can derail the commercialization of gene therapies.

Tech transfer complexity
Moving a process from a developer to a CDMO involves extensive gap assessment, alignment, transfer of protocols, and documentation including block flow diagrams, bill of materials, raw material specs, and qualified assays. "Our new product introduction process ensures all critical information is captured systematically in a phase-appropriate manner and supplemented by our own procedures as needed," says Sam Wood, Head of Commercial Development for Viral Vectors at Lonza.

Production interruptions
Beyond transfer, production interruptions remain a constant threat. Supply chain gaps or regulatory holds can halt manufacturing entirely. "This leaves patients waiting for a lifesaving therapy that could help them, but is on hold," Sanyal notes.

Batch losses
Batch failures stemming from suboptimal growth conditions, purification challenges, or scale-up issues can compound delays.

Mitigating these risks requires GMP-compliant facilities and proven operational frameworks positioned to pass multiple FDA and EMA inspections. "That means having appropriate control and segregation of virus types within the facility, validated cleaning processes, and Part 11-compliant systems," Wood explains.

Market risks: Volatility and demand forecasting

While the above challenges are within the control of the viral vector developer and the CDMO, market risk and volatility is beyond their control, says Sanyal. The AAV sector illustrates this reality: after a surge in approvals, followed by fatalities linked to high doses, regulators increased their scrutiny of these therapies while investors grew more cautious.

As a result, Sanyal says, "Therapy developers that are still pursuing this field are much more careful about their development strategies." Efforts now focus on lowering doses, improving target specificity, and enhancing efficacy without increasing exposure. Commercial demand can shift rapidly in this field and CDMOs must remain adaptable. "We grow with the product," Wood explains. "Based on anticipated demand, we can flex and tailor our capacity, whether that means campaign manufacturing, staffing adjustments, or facility redesign."

Choosing the right viral vector CDMO partner

Late-stage success hinges on selecting a CDMO with the right expertise, experience and capabilities. Viral vector manufacturing is "not a one-size-fits-all approach," says Wood, who emphasizes the need for a CDMO to have experience across the full life cycle so that they are better able to support viral vector developers from preclinical development through commercial launch. CDMOs that have built strong systems to deliver a smooth, tech transfer into manufacturing and have strong agency engagement and BLA readiness processes can also go a long way.

Over the last 25 years, Lonza Houston has been fine tuning its viral vector CDMO capabilities in process development, tech transfer, and regulatory support. Lonza has now supported over 90 diverse programs across a range of viral vector types.

> *"We have a multi-product facility that can ramp up or down easily depending on customer needs. Integration between process development and manufacturing allows us to move seamlessly from preclinical to clinical, and then commercial all under one roof. That's what makes us a unique player in the CDMO business for gene therapies."*
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> **Sam Wood – Head of Commercial Development for Viral Vectors**

Ultimately, investing in the right CDMO partner delivers financial, reputational, and clinical benefits and ensures therapies reach patients without costly setbacks.

Discover how Lonza can help you navigate late-stage viral vector development and commercialization.

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