Miltenyi Bioindustry

The power of a platform process for lentiviral vectors

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Lentiviral vectors (LVVs) are vital tools in cell and gene therapy but present challenges – especially around scalable, consistent cGMP production. A well-established platform process and an experienced partner can mitigate or eliminate many of these barriers. This approach improves LVV performance, safeguards supply, and supports compressed timelines for development and commercialization.

A platform process leverages expertise and efficiency

Platforms and contract development and manufacturing organizations (CDMOs) should be assessed by experience and metrics like batch success rates, deviations, and yields. Miltenyi Bioindustry's platform stands out for its reliability, predictability, and speed.

Miltenyi Bioindustry defines its LVV platform as a set of optimized upstream and downstream processes designed for consistent, high-yield manufacturing while remaining flexible to different genes of interest. Moreover, analytics are pre-qualified and included, cGMP documents are already written, and highly specialized staff are already trained. Client-supplied plasmids can be used, or constructs can be inserted into a standard backbone.

Our platform process leverages transient transfection, rather than a stable packaging cell line. This enables more flexibility to change the genes expressed as well as the envelope.

Rather than typical process development, our development workflow includes two early feasibility stages:

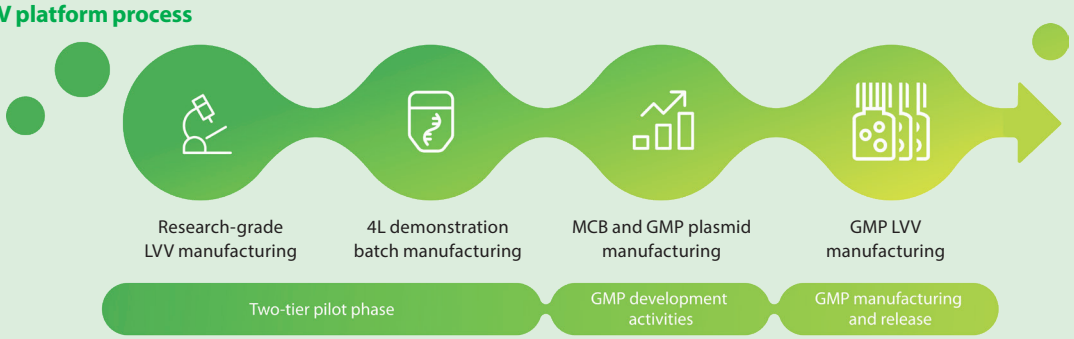
- **Molecular feasibility:** The client's construct is cloned and tested with a four-plasmid system. If the client has their own transfer plasmid, Miltenyi Bioindustry confirms its compatibility with our helper plasmids.
- **Process feasibility:** Small-scale batches are used to generate predictive yield data at clinical or commercial scale (50 L or 200 L), customized to the client's gene and construct.

This pilot phase is typically completed within six weeks. It includes opportunities for plasmid optimization and early process improvements via design of experiments (DoE), enabling better decisions on scale-up and yield enhancement before entering GMP.

Since our platform pre-qualifies all materials and follows an established GMP manufacturing process, GMP readiness looks much different. Clients are spared the time and expense of typical tech transfer activities, such as documentation preparation, engineering batches, and comparability or bridging studies.

Because of this, timelines can be reduced. While typical programs take around 12 months, optimized timelines range from 6 to 8.5 months. If a client provides a GMP-grade transfer plasmid, timelines can be even shorter.

LVV platform process



Case study: From first contract to GMP in 5 months

A clinical-stage biotechnology company developing engineered T cell therapies for autoimmune and inflammatory diseases approached Miltenyi Bioindustry for LVV production services. As this customer had both their candidate selected and a transfer plasmid available, the program required an approach and partnership that would allow them to move ahead with immediacy.

The Miltenyi Bioindustry platform process offered the benefit of being able to move the program forward at an accelerated pace, taking it from a preclinical 4 L demonstration batch scale to a GMP batch production within three months.

Overall, from the very first contract execution to GMP production, it took 5 months.

Each client is supported by a dedicated project manager (PM) from program kickoff. The PM stays with the program through all stages – preclinical to commercial – providing a single point of contact and helping maintain continuity, even if the client team changes.

Meeting cadence and communication are adjusted based on client preferences and project complexity, ensuring flexibility and proactive issue resolution.

Miltenyi Bioindustry's platform includes pre-qualified materials and a fully validated GMP process. Regulatory documentation is captured in a biologics master file (BMF), which clients can reference through a letter of authorization. Support is also available for regulatory submissions in markets without a master file system.

The combination of standardized SOPs, trained staff, and process expertise results in very low deviation rates – less than 1 deviation per production lot released per year. Miltenyi Bioindustry manufacturing teams have low turnover, contributing to consistent, replicable outcomes across projects.

While the industry average for batch success rates typically hovers between 85% and 90%, Miltenyi Bioindustry has demonstrated a >96% success rate across all GMP batches – a rate that climbs to 100% in the rare event a batch must be reproduced.

Our quality system was designed to drive these results. It requires that internal investigations into batch failures be completed within 30 days while investigations into root causes are typically completed much faster. In some cases, reproduction itself takes place in less than 30 days. Our project management team is in constant contact with customers regarding the status of both the investigation and the batch rescheduling.

Lentiviral vector manufacturing is often seen as one of the most costly aspects of gene therapy and CDMOs are frequently criticized for high costs and limited flexibility, particularly for early-stage companies.

Miltenyi Bioindustry offers an integrated pricing model: all core services – from plasmid work and training to dedicated PM and cleanroom use – are built into a single, transparent batch price. There are no added fees for transitioning between development phases, helping clients adhere to their budgets and timelines.

Experience the difference for yourself

Miltenyi Bioindustry's LVV platform combines flexibility, speed, and reliability across the program lifecycle. From early insights and regulatory support to commercial-scale manufacturing, clients benefit from deep expertise, reduced risk, and improved cost control. With consistent results and a dedicated partnership, Miltenyi Bioindustry is a strategic choice in the growing CGT landscape.

For details, please visit miltenyibioindustry.com

Metrics in this article are based on data collected through 2024. Miltenyi Bioindustry does not guarantee that any specific delivery date(s) will be met. Individual timelines may vary based on factors such as client's stage of development and specifications.

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