

## REDUCED DEVELOPMENT TIME FROM R&D THROUGH COMMERCIALIZATION

### Uniquely scalable viral vector manufacturing. Only from MaxCyte.

Inadequate scalability. Variable cell transfection efficiency. Lengthy processes. Difficult-to-validate manufacturing methods. These are some of the challenges that have hindered viral vector manufacturing, particularly lentiviral or AAV vectors, in the past. But it is these very obstacles that have been overcome using MaxCyte's cell loading technology for viral vector manufacturing.

MaxCyte's technology can accelerate the manufacture of viral vectors and speed clinical development of viral vector-delivered therapeutics by:

- Vastly improving scalability
- Achieving unmatched cell loading efficiencies and cell viability
- Delivering significantly higher yield
- Providing a validated technology to satisfy regulatory requirements

When you work with MaxCyte you get an entire cell loading solution with:

- Technology access
- Customized cGMP cell handling and loading protocols
- A software-controlled system to load cells
- Expertise in cell biology and cell manipulation

The result: a reduced development time with a system that scales from R & D through commercialization.

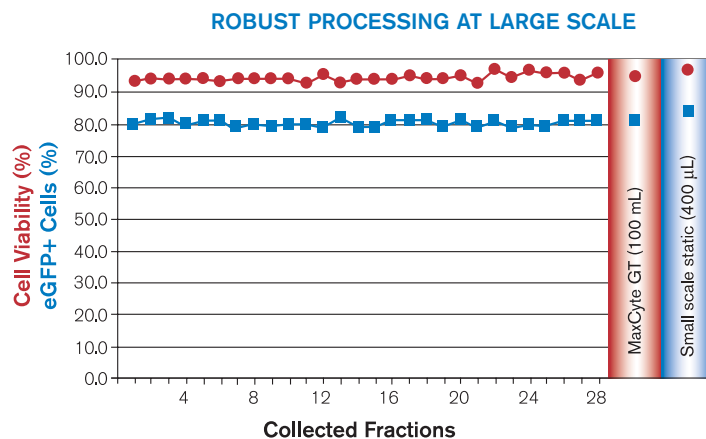
### Unmatched Consistency

One of the greatest challenges facing biotherapeutic developers is how to load routine virus-producing cell lines, such as 293 and VERO cells, with multiple DNA/RNA plasmids that code for the components to make the viral particle. For researchers making viruses on a small scale, the answer is easy enough: use a chemical transfection reagent, since typical cell lines to package viruses are relatively easy to transfect in small volumes.

However, once you are ready to move from the bench to the clinic, scale-up issues with traditional transfection reagents arise, and procedures become cumbersome, expensive and inconsistent. Furthermore, scalable and reproducible protocols for virus manufacture can take months to years to develop.

MaxCyte's technology is easily scalable, for both adherent and suspension cells (such as 293T):

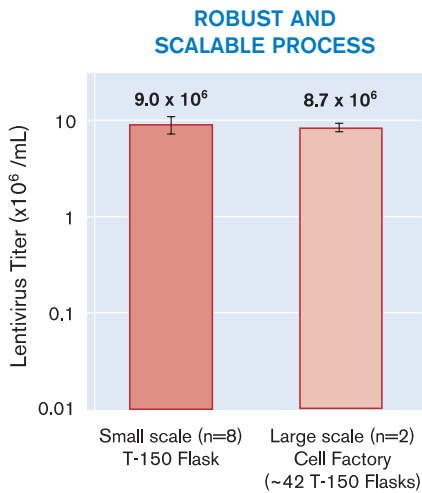
- Load cells with multiple plasmids in a software-controlled, sterile, closed environment (the technology is integrated with upstream and downstream manufacturing processes).
- Achieve consistent cell loading results from starting volumes of less than one milliliter up to multi-liter volumes on the same platform (Figure 1).
- Increase manufacturing efficiency by maximizing cell loading capability and cell viability.



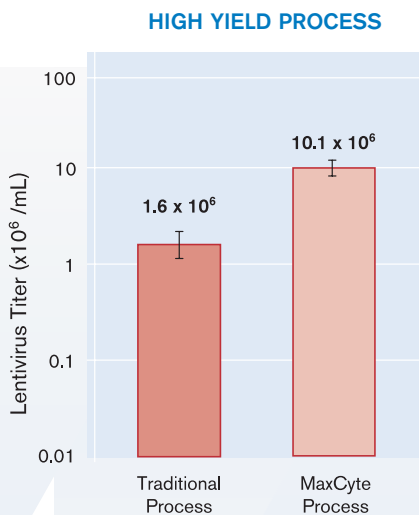
**Figure 1.** MaxCyte technology was used to transfect K562 cells with pCMV-eGFP, illustrating its utility for loading suspension cells in large volumes ( $6 \times 10^9$  cells in 100 mL). Processed cells were collected every 3 to 4 mL. Cells from each fraction of the entire pool were analyzed by FACS at 48 hours post transfection for their viability (PI exclusion) or efficiency (GFP+), which were compared to samples from standard static (400uL) transfection.

## Superior Efficiency. Remarkable Yield.

MaxCyte's technology offers high cell loading efficiencies and viability—both often exceeding 95% (Table 1). With higher cell loading efficiencies and higher post-loading cell viability, larger lots of viral vector per run can be made, reducing the number of manufacturing runs required to make quantities suitable for clinical trials and commercialization (Figures 2 & 3).



**Figure 2.** MaxCyte technology process provides reproducible viral titers and can be efficiently scaled-up to clinical/commercial scale



**Figure 3.** MaxCyte technology offers 5-10 fold higher yield for production of lentivirus vectors compared to traditional calcium phosphate transfection system.

## MaxCyte Cell Loading Technology

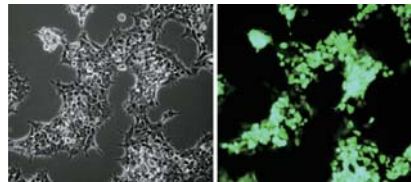
MaxCyte's proprietary technology uses electroporation to briefly make cell membranes permeable and works exceptionally well with cell lines typically used to manufacture viral vectors. MaxCyte has refined the process with a flow electroporation system that allows the scalable loading of cell volumes from the sub-milliliter level up to liter quantities (Table 1, Figure 4).

### CELL LOADING EFFICIENCIES AND VIABILITY

Cell Type	Efficiency	Viability
293T Cells	96%	95%
VERO Cells	98%	95%

**Table 1.** MaxCyte technology was used to transfect cells with either enhanced green fluorescent protein (eGFP) or dsRed fluorescent protein (dsRed). Efficiency was calculated as a function of fluorescent intensity. Cell viability was calculated by PI exclusion.

### CELL TRANSFECTION



**Figure 4.** MaxCyte technology was used to transfect 293T cells with pCMV-eGFP, illustrating its utility for loading a common virus-producing cell line. Images were taken 48 hours post-transfection.

## Validated Technology with Master File

The Food and Drug Administration (FDA) requires that manufacturing methods for any drug or biological be validated, and this can be extremely difficult with traditional transfection reagents. MaxCyte's system has a solid regulatory record. This decreases the amount of validation and paperwork required to achieve FDA approval for manufacturing and patient treatment protocols.

### REGULATORY SUPPORT

FDA Master file at CBER

Master File contains information and data to support our partners applications

Clinical use has been allowed by FDA and Health Canada

## Extensive Patent Portfolio

MaxCyte has secured extensive patent coverage in the United States, Europe and other regions, including broad-based claims to the flow-based solution and to computer controlled electroporation. The technology can be used for many clinical applications because the patent portfolio is not limited by cell type or the type of molecule to be loaded. These important advantages have made MaxCyte cell loading technology the method of choice for numerous partners.

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