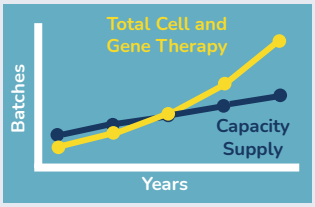
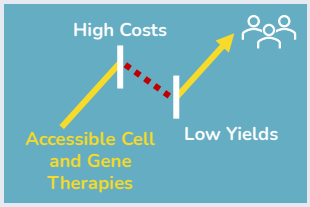
Small Gains, Big Wins: How Incremental Yield Increases Drive Major Cost-Savings in Cell and Gene Therapy Manufacturing

The Problem: Growing Demands, High Manufacturing Costs

The cell and gene therapy (CGT) industry is rapidly growing, but high costs hinder broader accessibility [1]. Insufficient yield is arguably one of the most significant contributors as CGT demand continues to grow [2]. Understanding production cost drivers is key to making therapies more accessible and affordable.





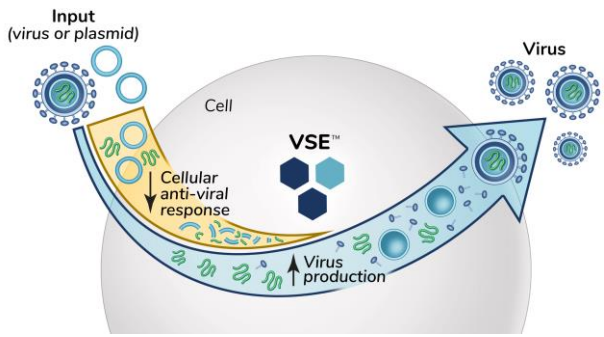
- ✓ 800+ ongoing virus products clinical trials.
- ✓ 10x increase in demand expected by 2026.
- ✓ Gap between demand and manufacturing capacity [3].

The Solution: Bioprocess Modelling to Optimize Upstream Production

Bioprocess modeling offers data-driven insights into manufacturing cost drivers to inform the long-term feasibility of production strategies [2]. Considering key modeling output metrics provides a method to optimize production by maximizing upstream manufacturing yields and minimizing costs to meet production demands and increase affordability. This strategy can assess the impact of process additives on both manufacturing yields and resulting cost of goods sold (COGS).

Our [BioSolve] platform is easy for anyone who has a science or engineering background to configure. You do not need coding skills to understand what you need to change in the framework. Our database is updated annually by gathering cost data from multiple vendor companies. Those data are then averaged and benchmarked to be included in the BioSolve Process.

Dr. Yuki Abe,
Director of Sales & Marketing,
Biopharm Services Ltd.



VSEs are added before or at time of transfection/infection. VSE concentrations decrease to non-detectable limits in the final product.

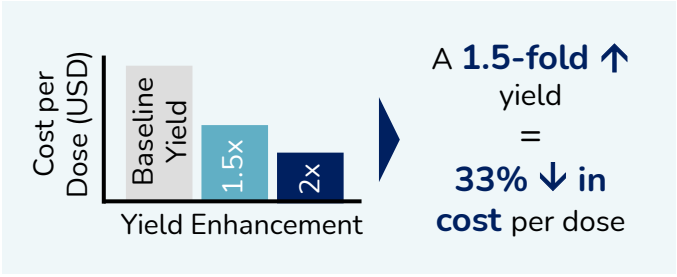
The "Secret Ingredient": Virica's Yield Enhancement Technology

Virica™'s Viral Sensitizer technology (VSE™) are small molecule cell enhancers that boost upstream viral manufacturing yields across a wide range of substrates and cell lines by temporarily dampening innate cellular defenses. The formulations can be seamlessly integrated into manufacturing processes as a simple upstream media additive.

We can model a large-scale manufacturing process and layer process economics to gain foresight and forecasting ability to understand how a pipeline can be built out. As part of Virica's offering, we have curated our BioSolve Process models to include our VSEs and the magnitude of the cost savings because of increased yield.

Andrea Vervoort,
Technical Lead, Virica Biotech™

The Result: Small Yield Enhancements Lead to Significant Savings in COGS



We use the BioSolve Process 8.3 software (Biopharm Services Ltd.) to model a generic upstream transfection based viral vector production process and demonstrate long-term impact of VSEs. We screened VSEs for their ability to improve the production of adeno-associated and lentiviral vector in HEK293 SF suspension cells and HEK293 adherent cells, respectively. Implementation of VSEs resulted in 1.5 to 4-fold upstream yield enhancement across multiple production formats, leading to meaningful decreases in COGs and significant long-term savings. In fact, even an incremental 1.5-fold yield increase leads to a 33% reduction in COGs.

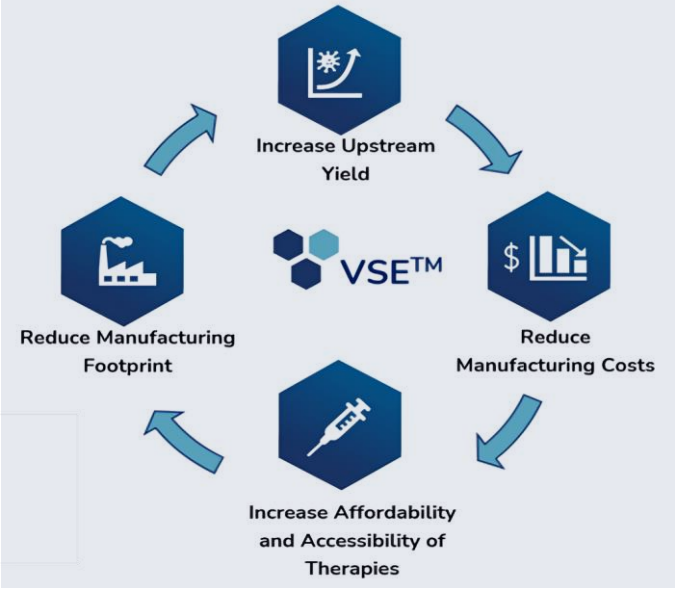
The modelled reduction in cost savings associated with using upstream process additives, such as our VSEs, has the potential to produce more affordable and accessible CGTs. This is achieved by addressing the often-neglected innate cellular defenses to uniquely enhance viral vector manufacturing yields.

The Impact: Reduced Manufacturing Costs, Increased Access to CGTs

Incremental yield improvements can drive significant cost savings. Increasing productivity helps ease manufacturing bottlenecks and cost drivers like the demand for larger bioreactors. Even an incremental yield enhancement can lead to a significant reduction in COGS. Enabling technologies can provide additive increases to yield and are options for manufacturers to meet target demands. Virica uses bioprocess modeling to evaluate the impact of process changes and make informed decisions to drive down manufacturing costs of life-saving CGTs.

By optimizing your manufacturing process, you can:

Increase **Yield** | Reduce **Cost** | Reduce **Waste**



Keywords: Virica Biotech™, viral sensitizer technology, VSE™, viral vector biomanufacturing, high-throughput assay, BioSolve Process, adeno-associated viral vectors, cost of goods sold, product yield.

References:

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