



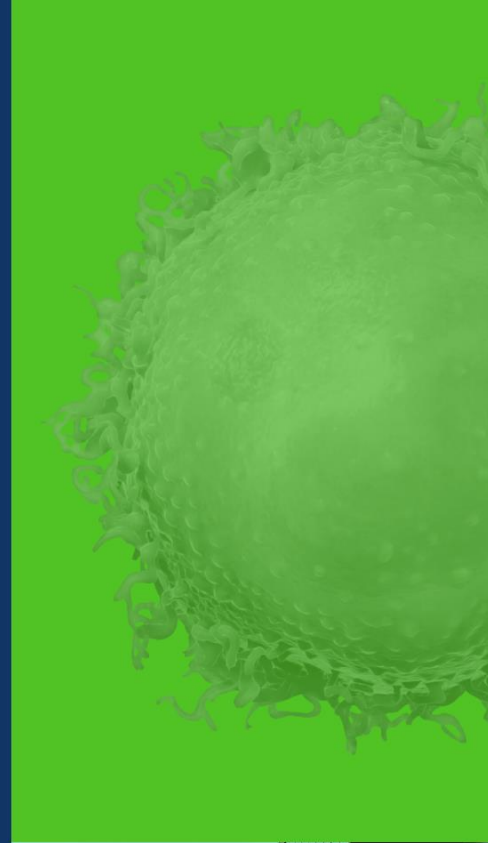
# LentiPeak™

Plug and Play Capabilities for a  
Lentiviral Vector Platform Process

**JIMMY XIN**

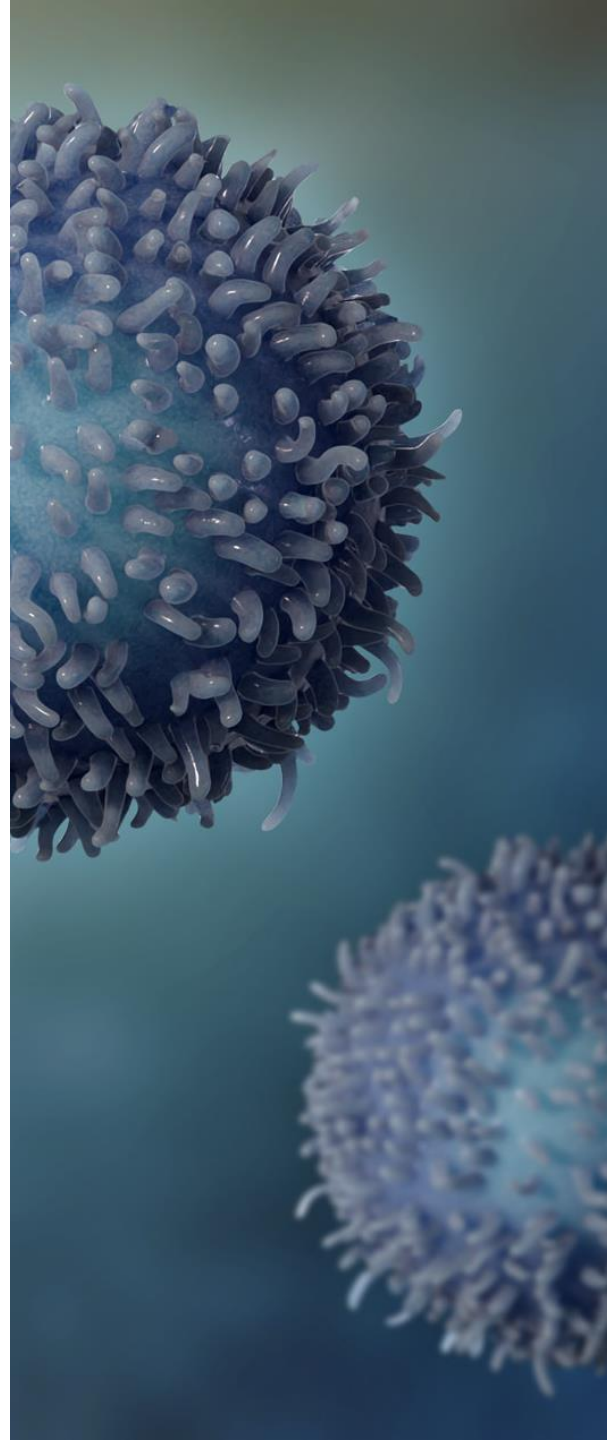
SCIENTIST, VECTOR PD

JULY 25<sup>TH</sup>, 2024



# ElevateBio

A TECHNOLOGY-DRIVEN COMPANY POWERING  
TRANSFORMATIVE CELL AND GENE THERAPIES



# Disrupting the Cell and Gene Therapy (CGT) Industry

.....

## OUR VISION

ElevateBio was **founded** in late 2017 to be the world's most indispensable cell and gene therapy technology company, changing how companies operate, how products are created, and how disease is treated.

## OUR MISSION

Our mission is to **power** the creation of life-transforming cell and gene therapies, at a speed the world deserves.

- Rewriting genes
- Regenerating cells
- Redefining manufacturing

*RIGHT FROM THE START*

# ElevateBio's integrated ecosystem provides biopharma companies a new approach to design, manufacture and develop genomic medicines

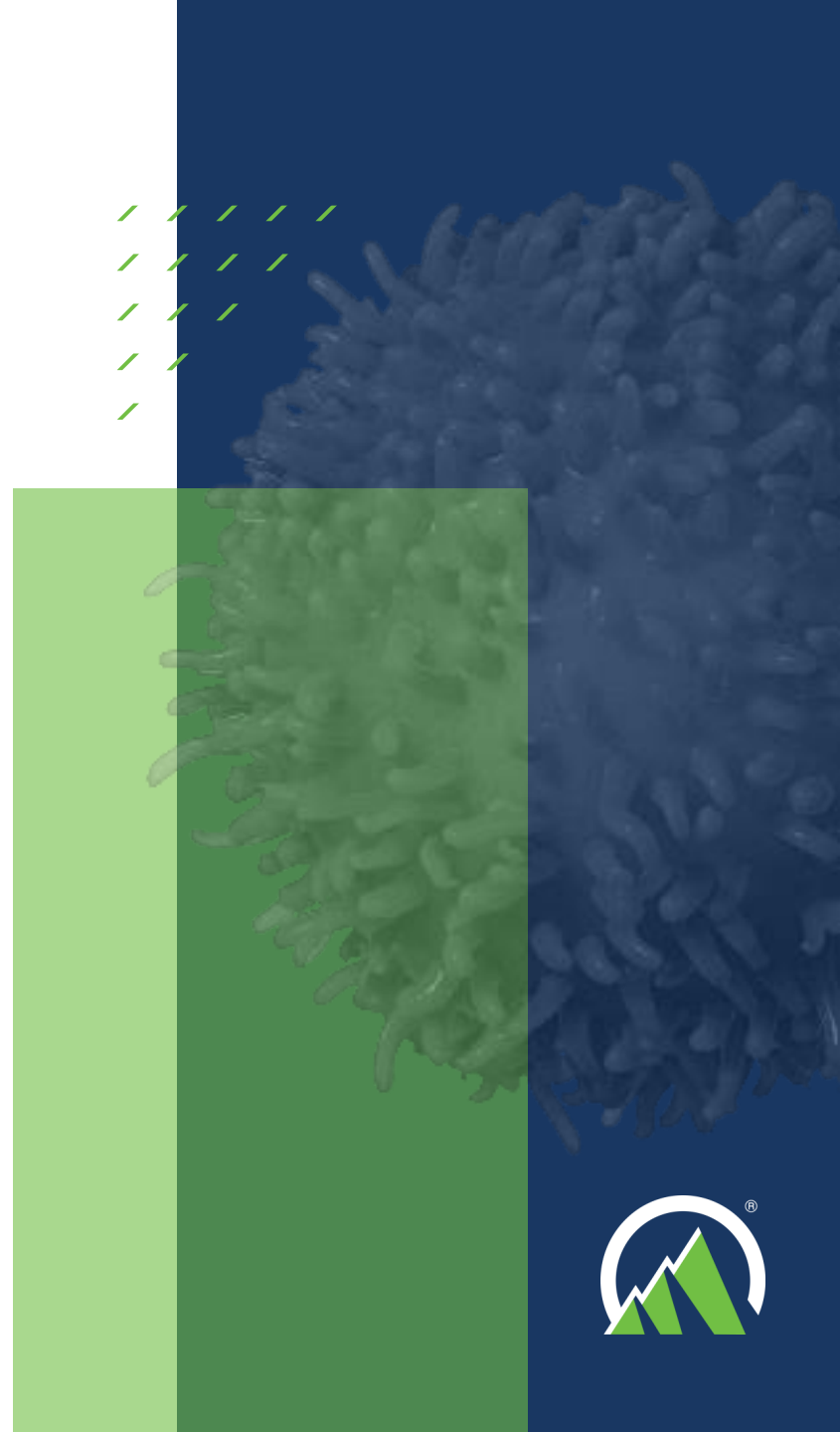


- ✓ Cutting-edge technology platforms
- ✓ End-to-end process development and cGMP manufacturing
- ✓ Industry-leading talent
- ✓ Integrated business model
- ✓ Next-generation cell and gene therapy programs

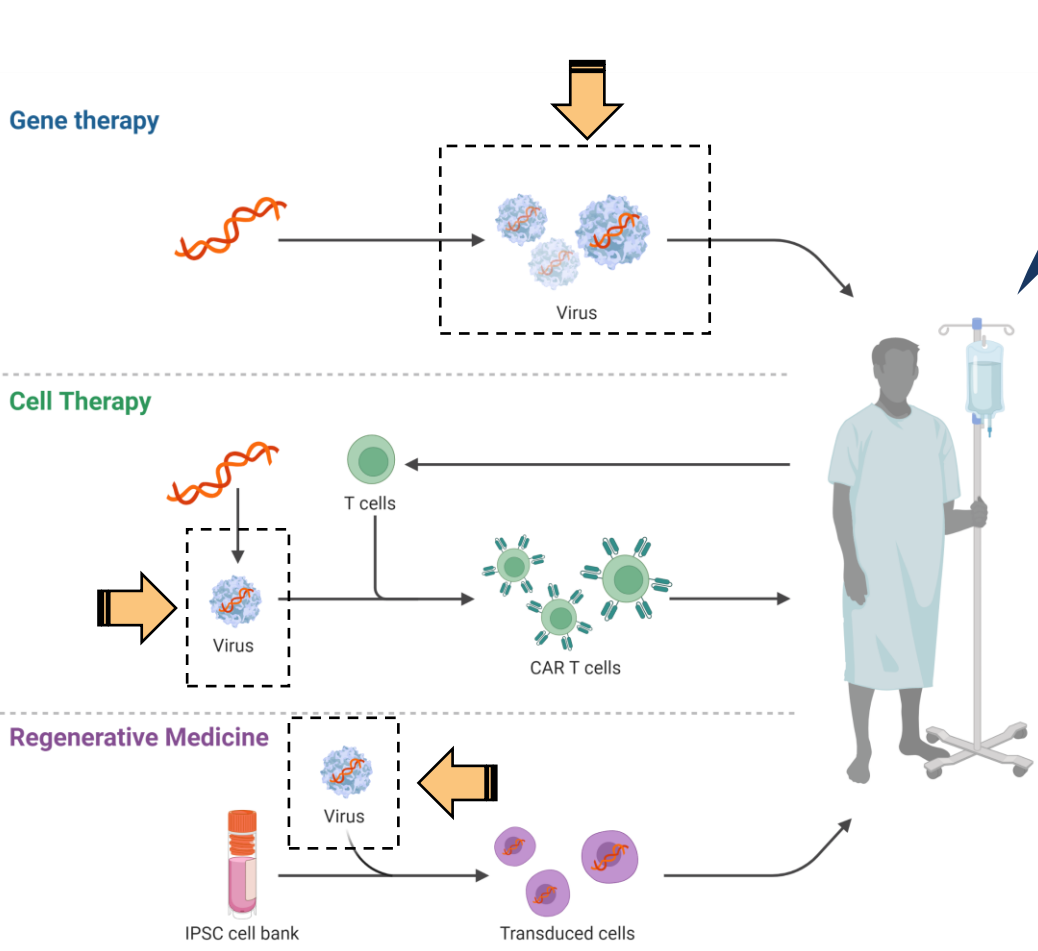




# Why Lentiviral Vectors?



# Application of Viral Vectors in C&GT



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Retrovirus



**FDA Approvals:**  
 Retroviruses account for 27% and Lentivirus account for 22% of the approved C&GT products.

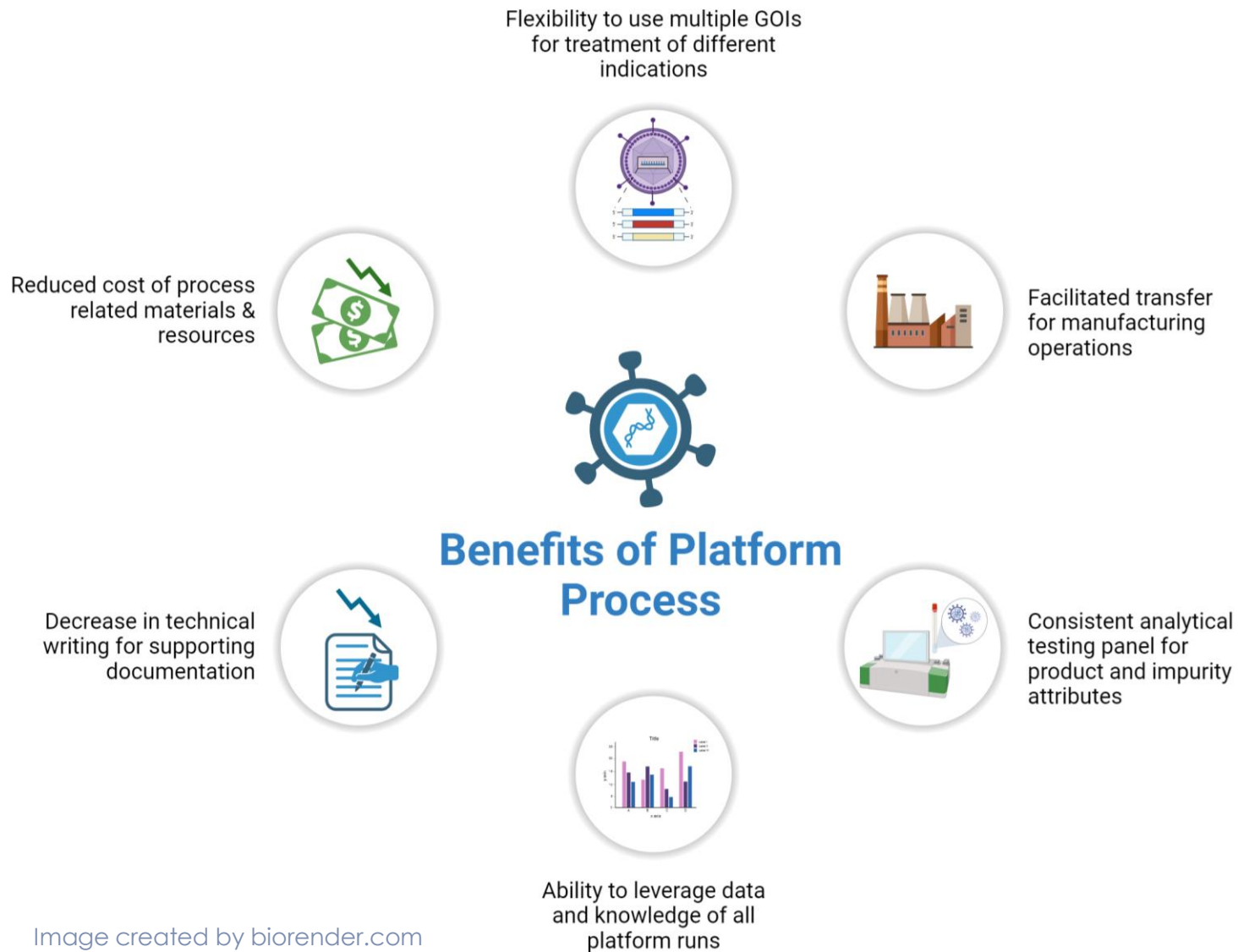
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Lentivirus





# Biggest Benefits for a Platform Lentiviral Production



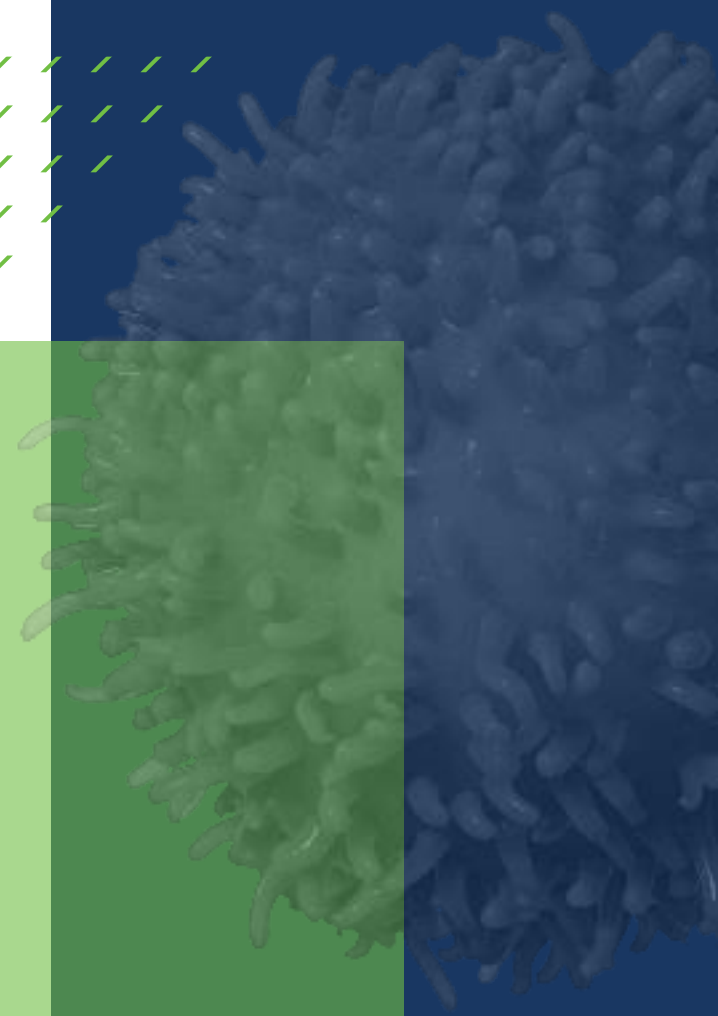
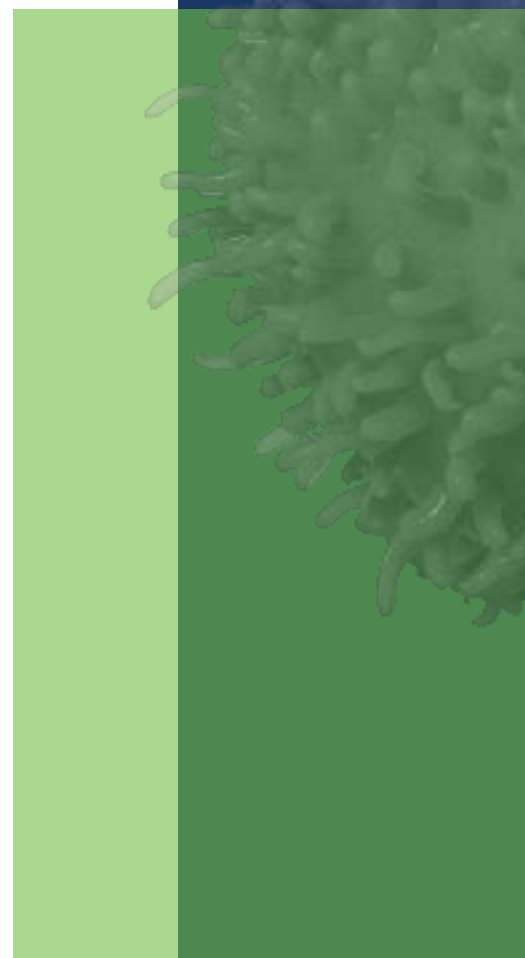
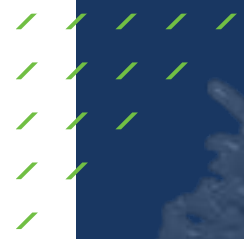


# LentiPeak™

THE LVV PLATFORM PROCESS FOR ONE SIZE FITS ALL



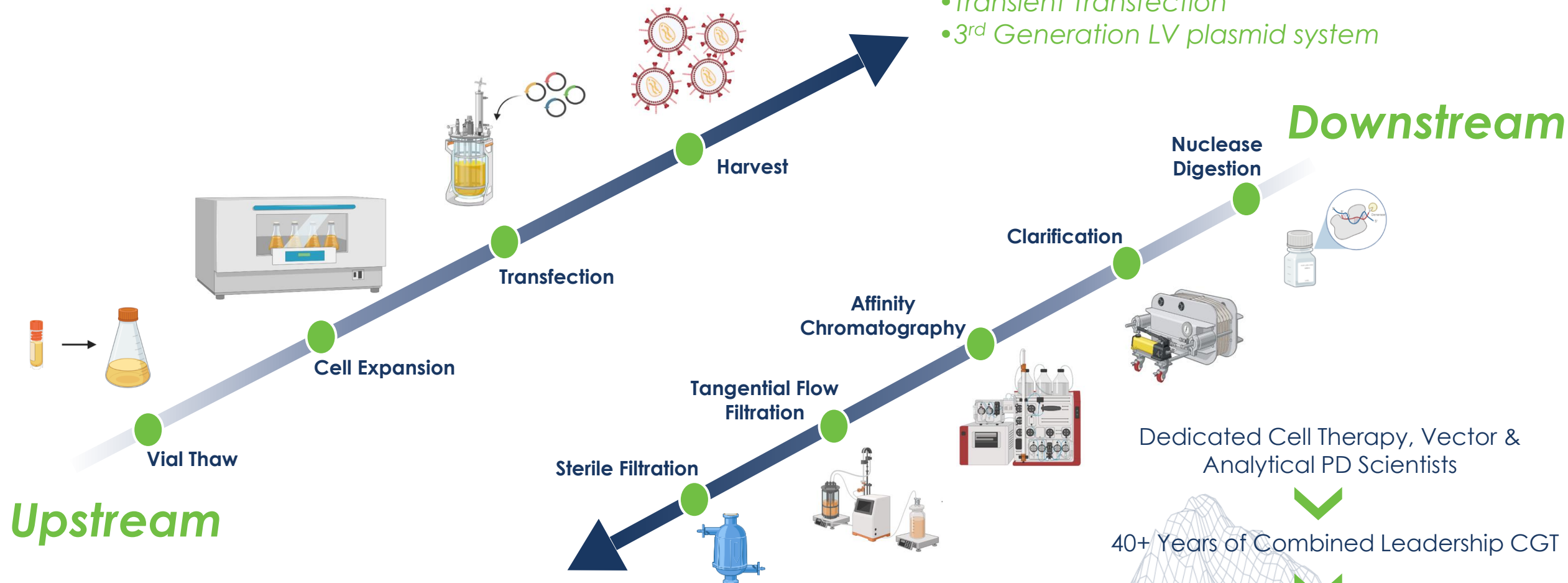
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# LentiPeak™ Platform: Process Overview

- HEK293 cell line
- Suspension based; serum free
- Transient Transfection
- 3<sup>rd</sup> Generation LV plasmid system



Upstream

Downstream

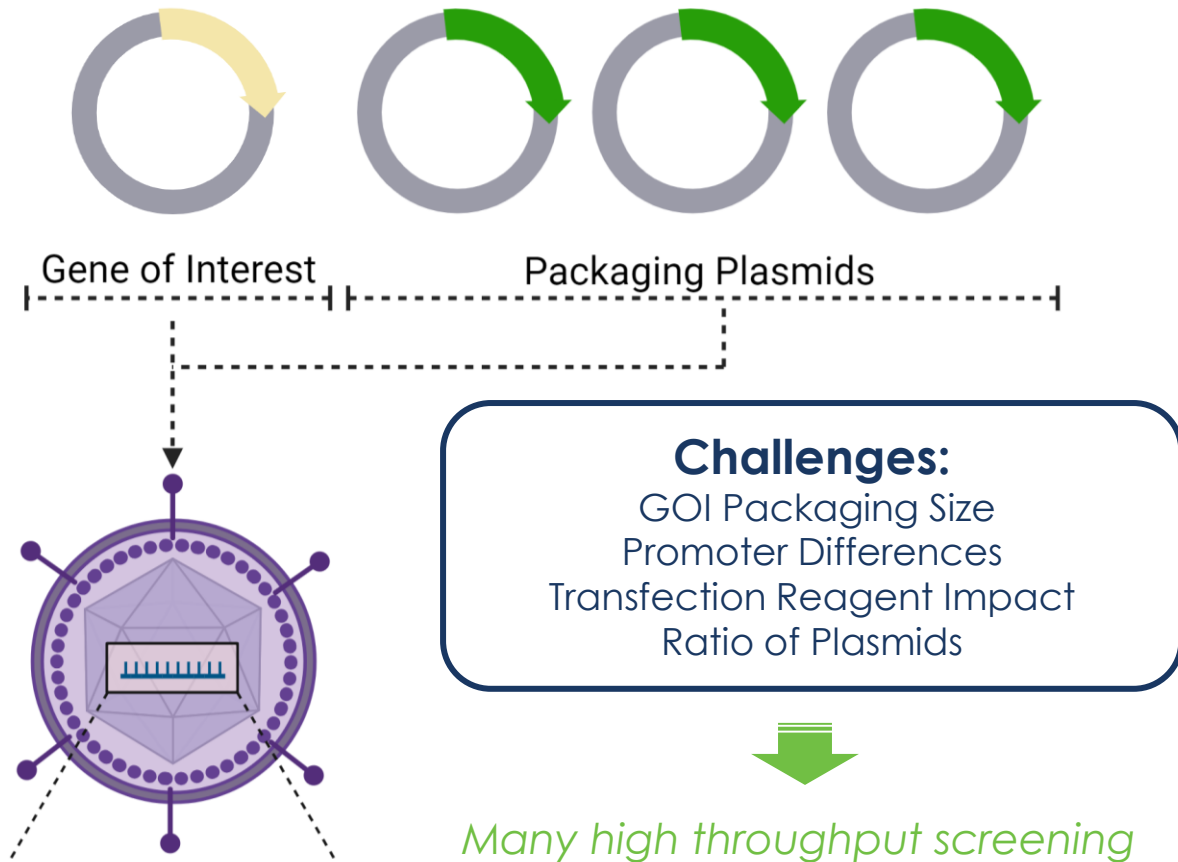
- Highly concentrated titer >1E+08 TU/mL
- Clearance of critical impurities
- Stable formulation for LVV and cell therapy application

Dedicated Cell Therapy, Vector & Analytical PD Scientists

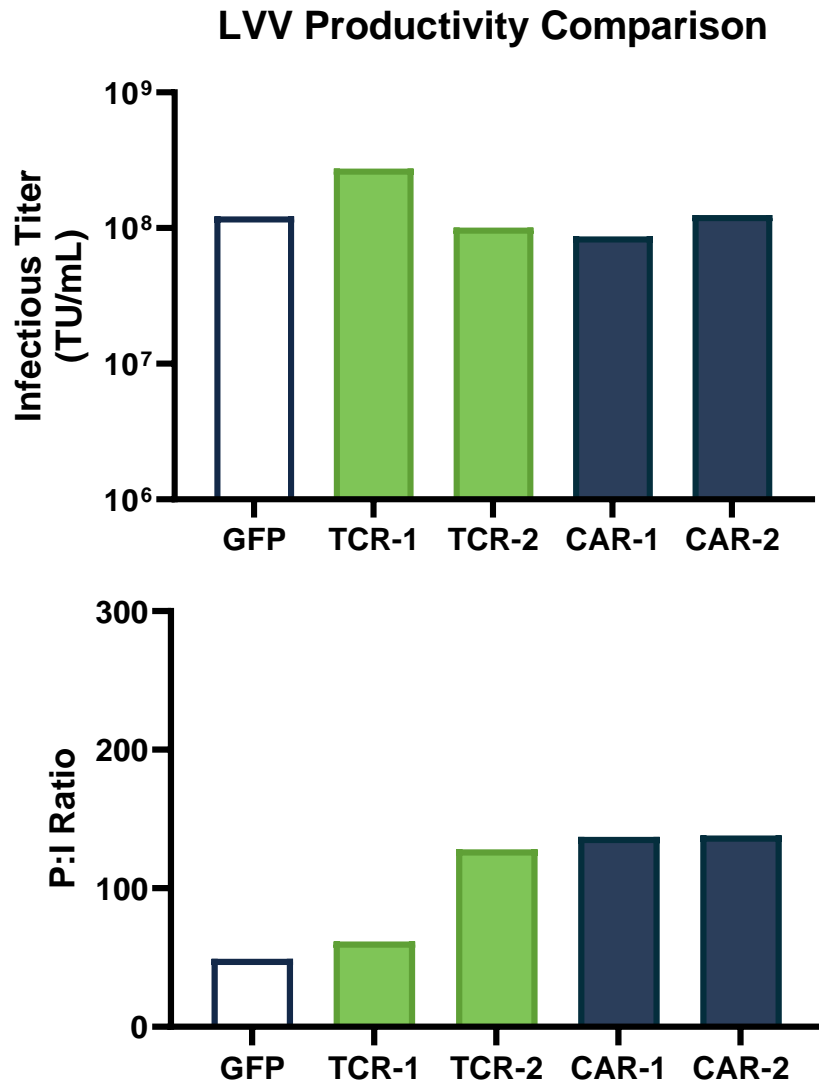
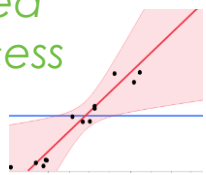
40+ Years of Combined Leadership CGT

140,000 ft<sup>2</sup> State of the Art Facility

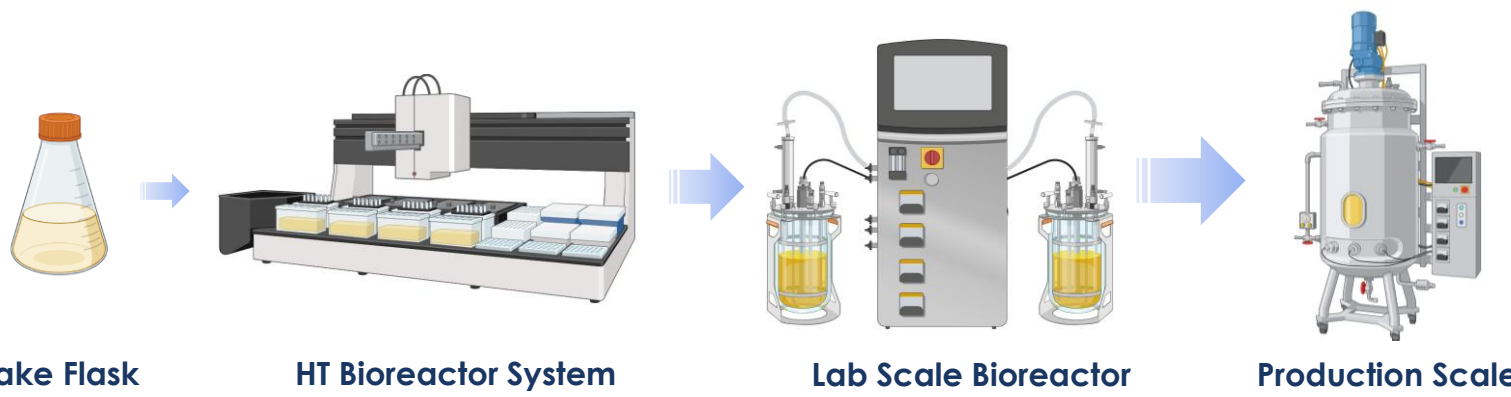
# LentiPeak™ LVV Production Developed for Multiple GOIs



*Many high throughput screening and DoE studies performed to develop the most optimized platform transfection process*



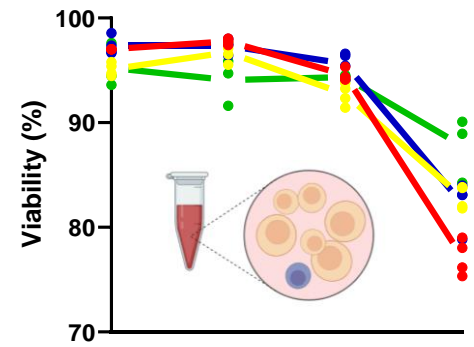
# LentiPeak™ Platform Upstream Development Scalability



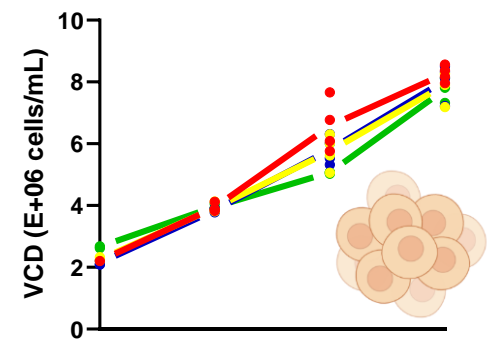
*Consistency is critical for upstream development and necessary to ensure a robust process for all scales.*



**Viability Across LVV Production**

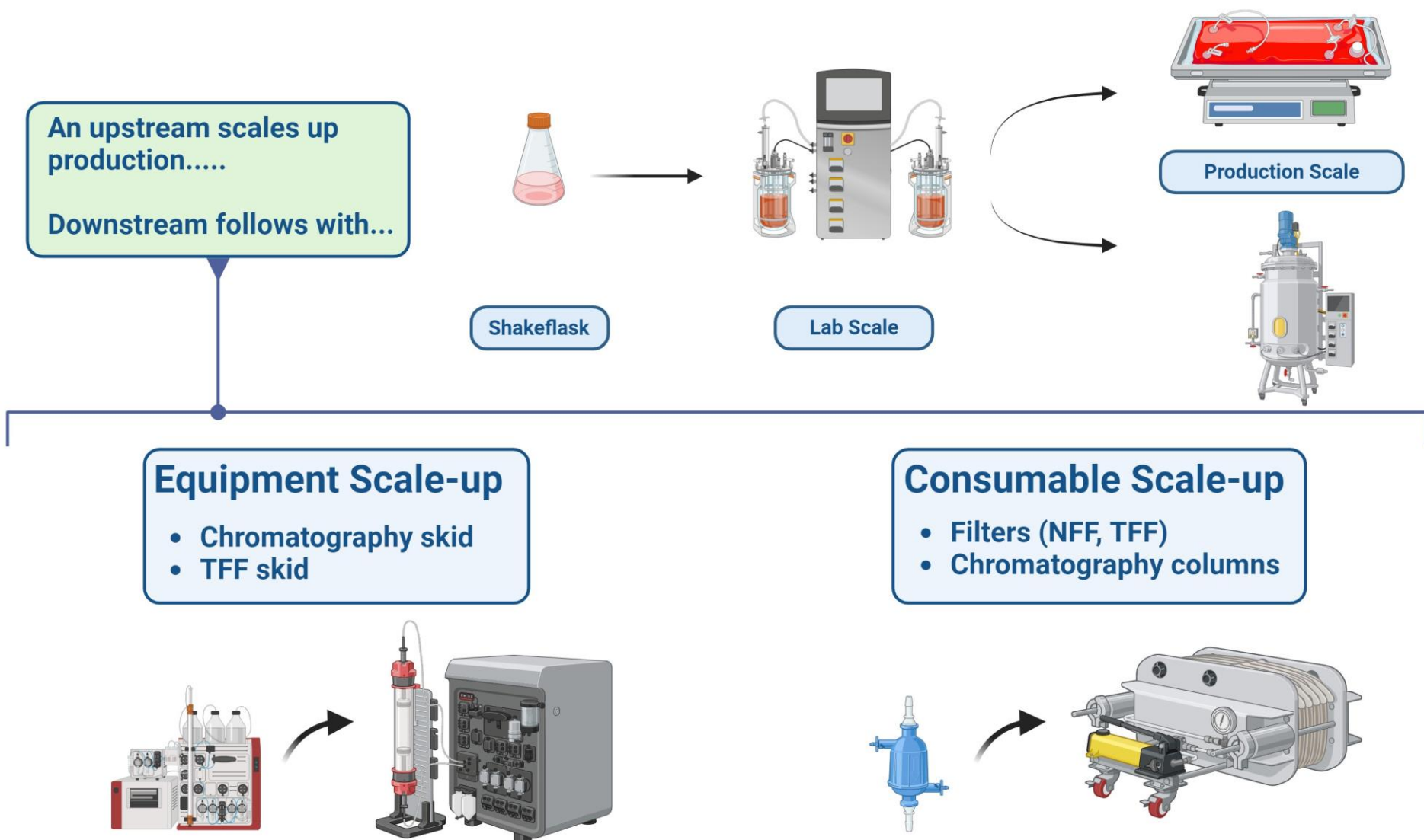


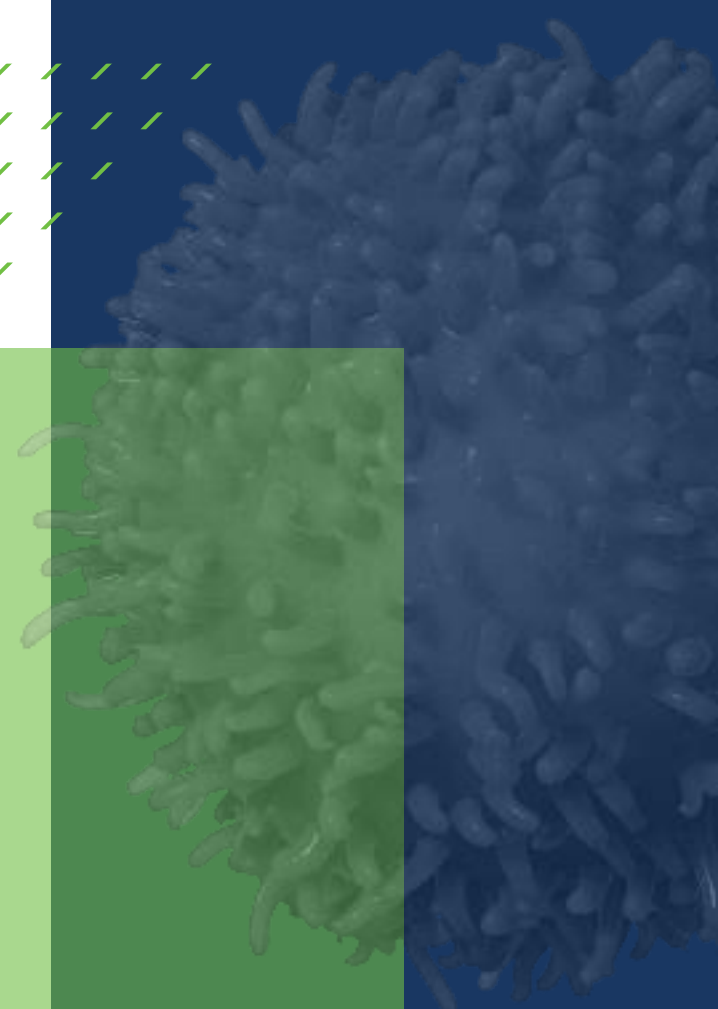
**Viable Cell Density Across LVV Production**



- Shakeflask
- HT Bioreactor System
- Lab Scale Bioreactor
- Production Scale

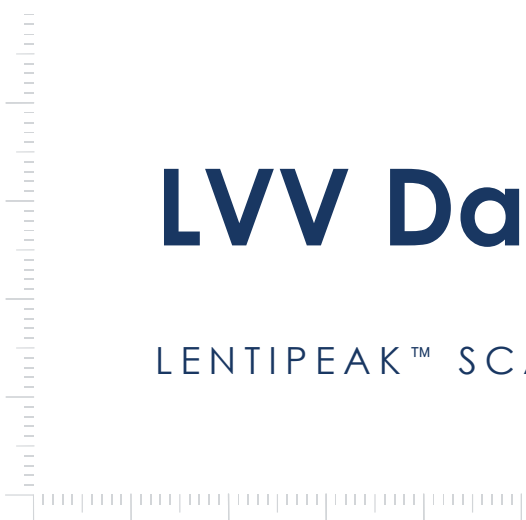
# LentiPeak™ Platform Scalability from Bench to Production



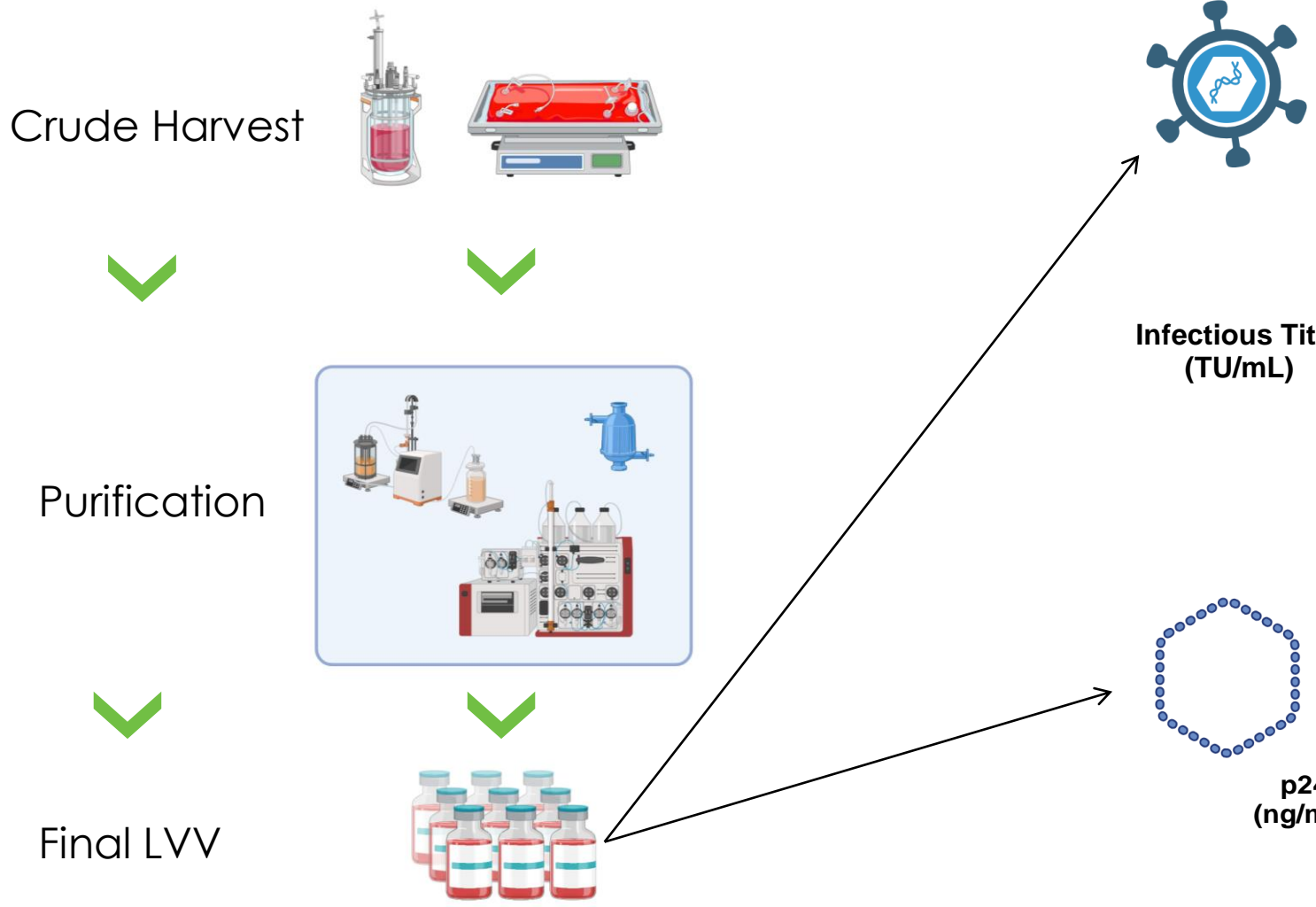


# LVV Dataset with LentiPeak™

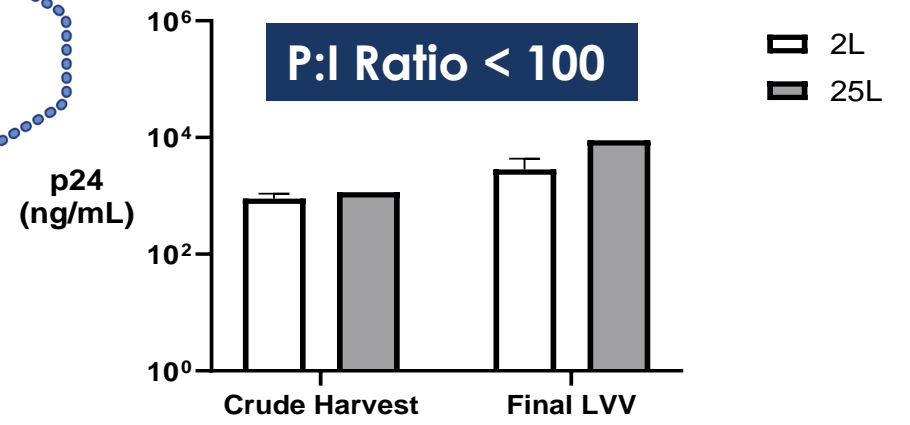
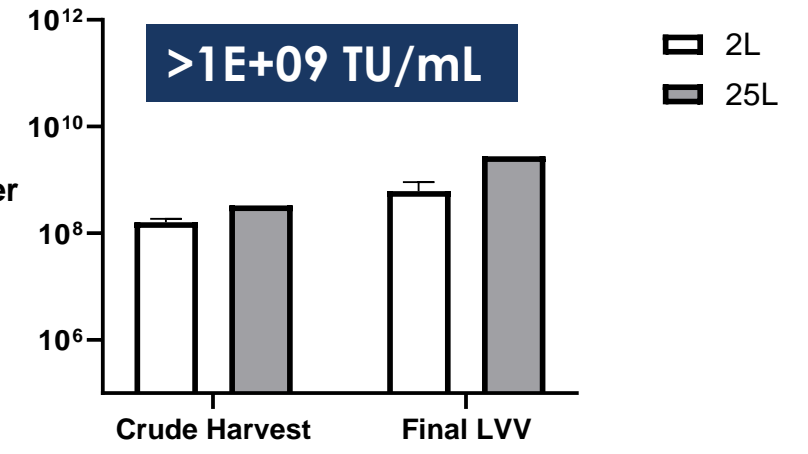
LENTIPEAK™ SCALE UP COMPARISON 2L VS. 25L TO FINAL LVV



# LVV Product Attributes Shows Consistent High Titer

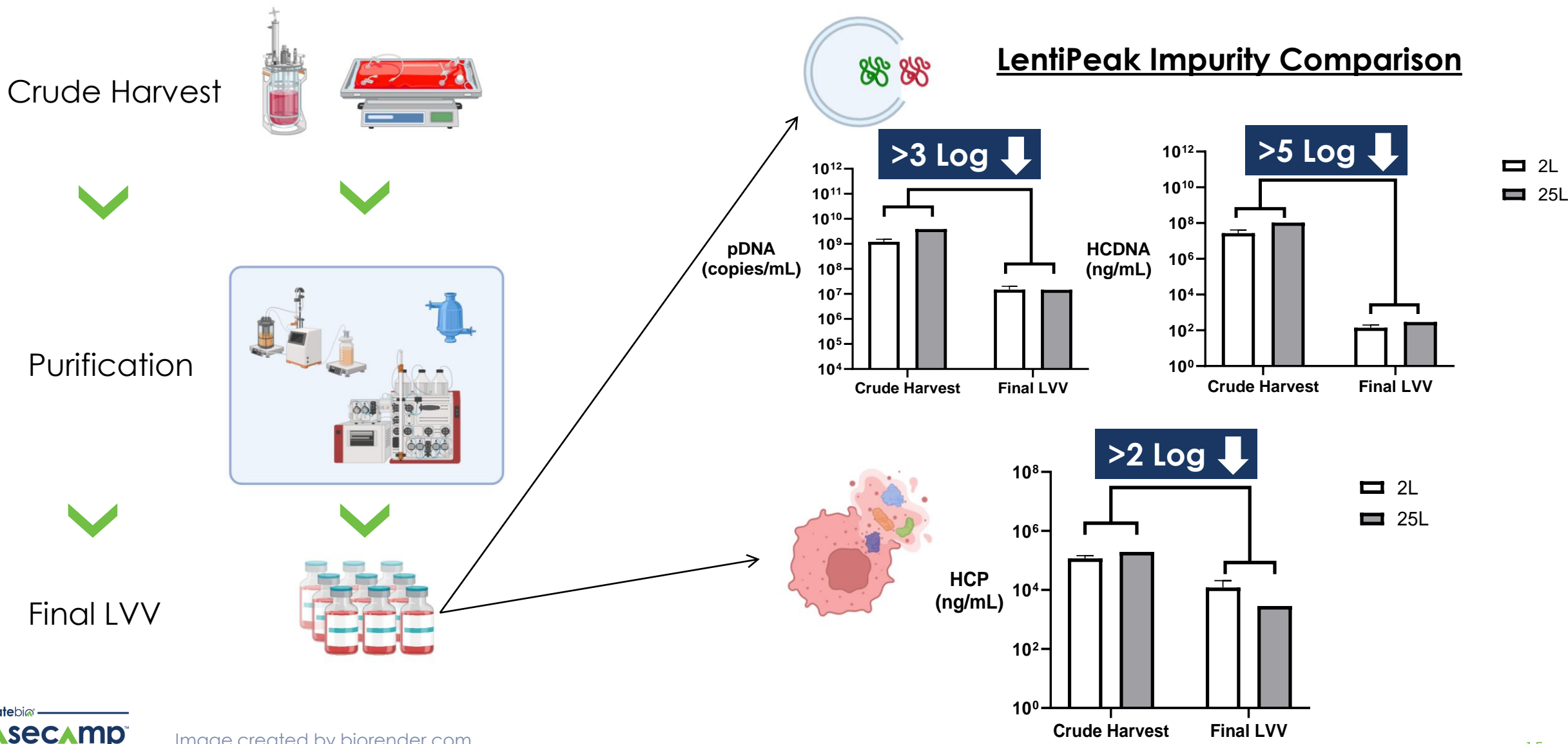


## LentiPeak Product Comparison

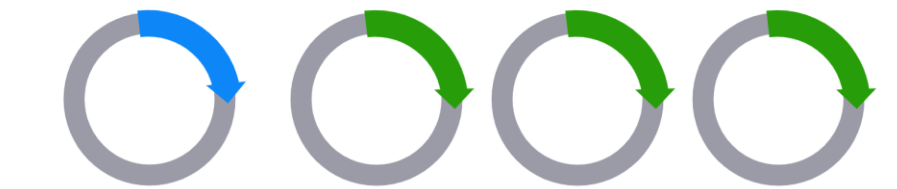




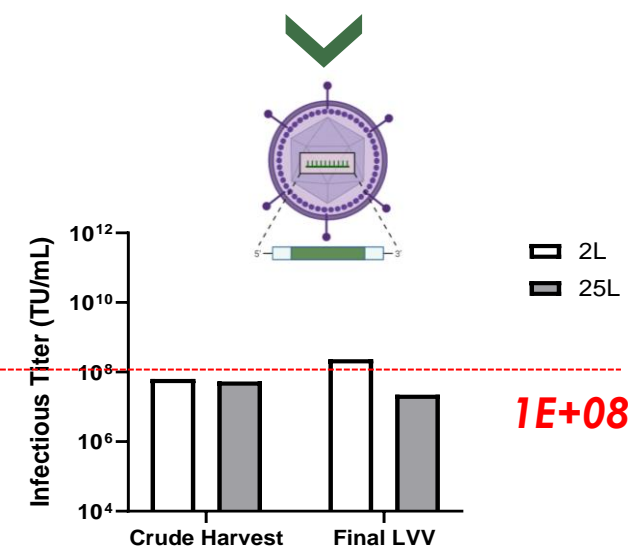
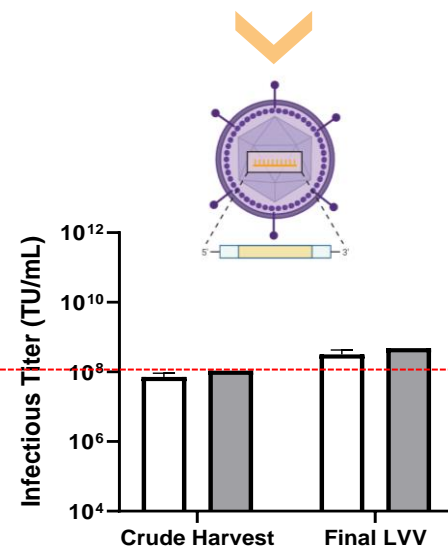
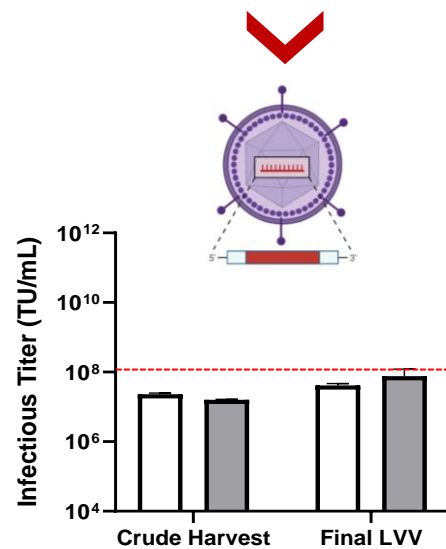
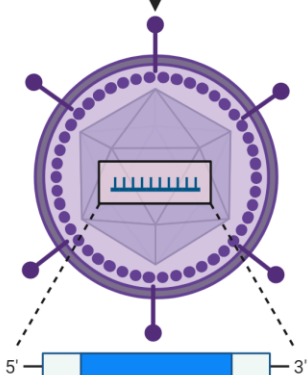
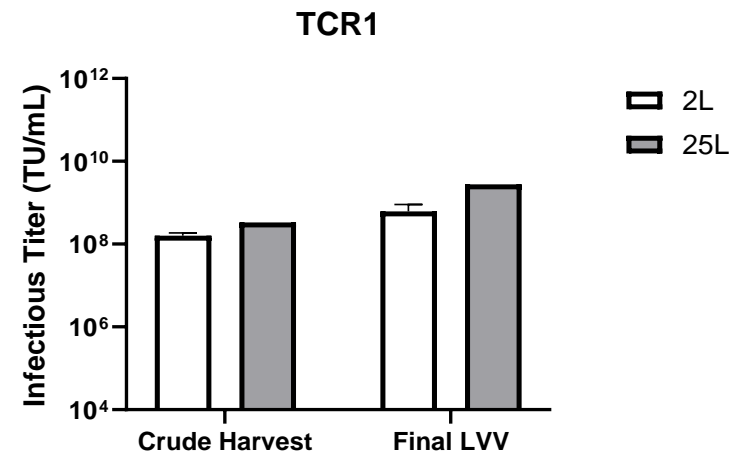
# DNA and Protein Impurity Attributes Show Consistent Clearance



# Platform Capabilities from Infectious Titer Comparison

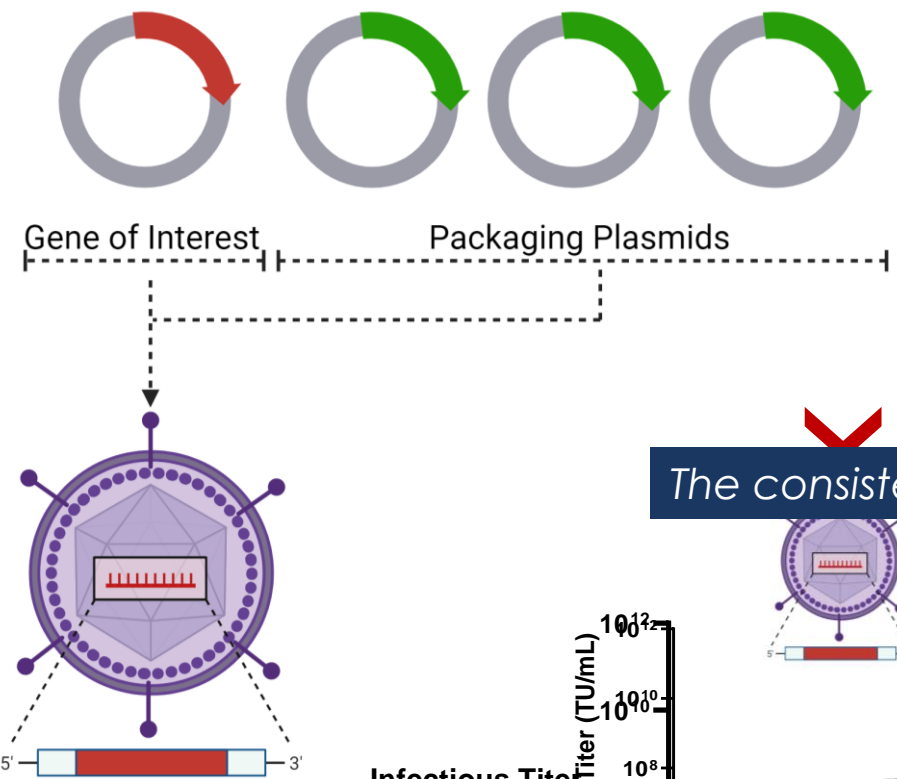


The LentiPeak process developed with TCR1 tested with other GOIs to show **platform** capabilities.



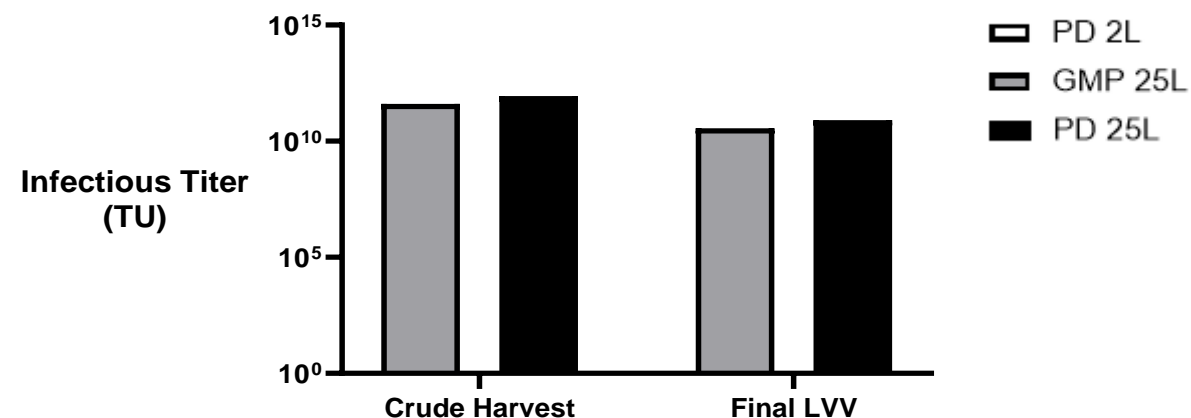
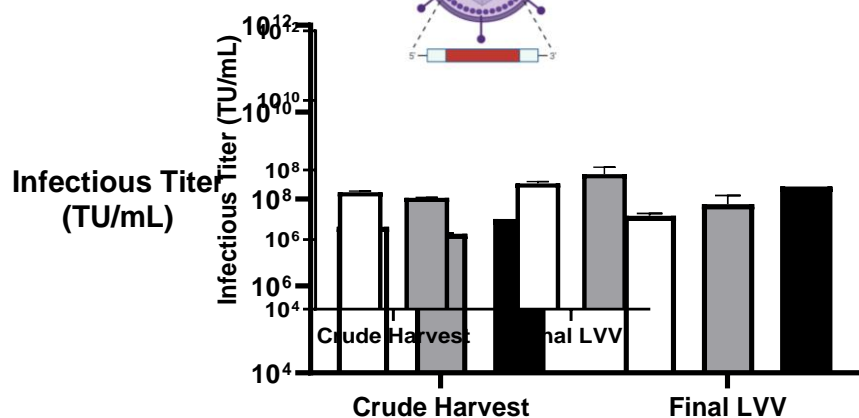
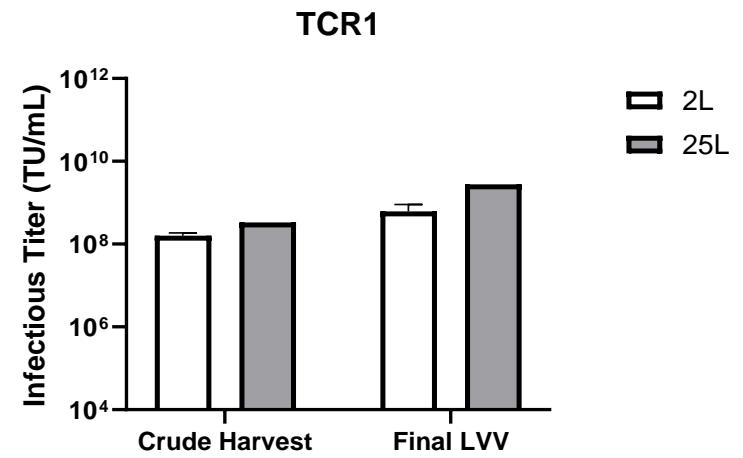
While variation is observed, LentiPeak's **platform capability** is still consistent within industry standard for LVV production.

# Platform Capabilities from Infectious Titer Comparison



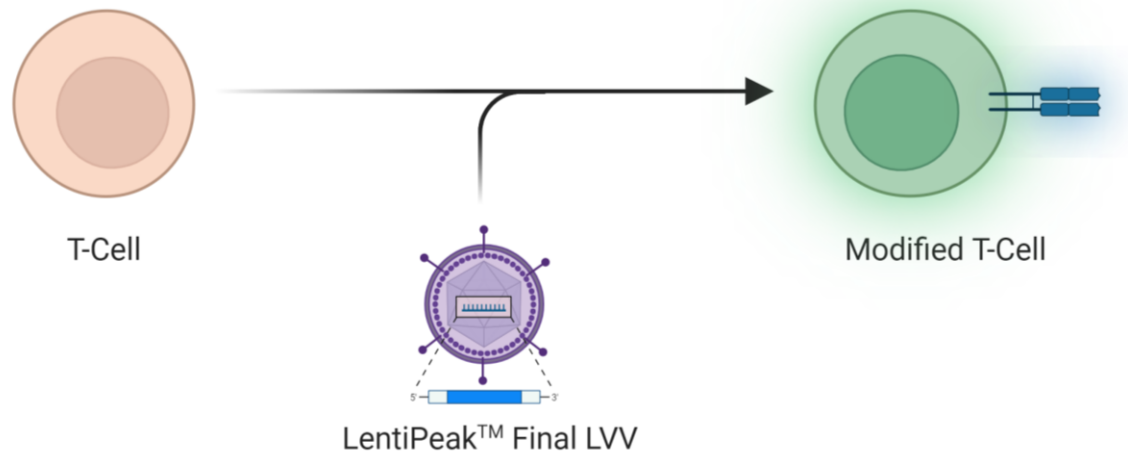
The LentiPeak process developed with TCR and stem cell consistency in GMP manufacturing capabilities.

The consistency in the LentiPeak platform process translates to the GMP suite



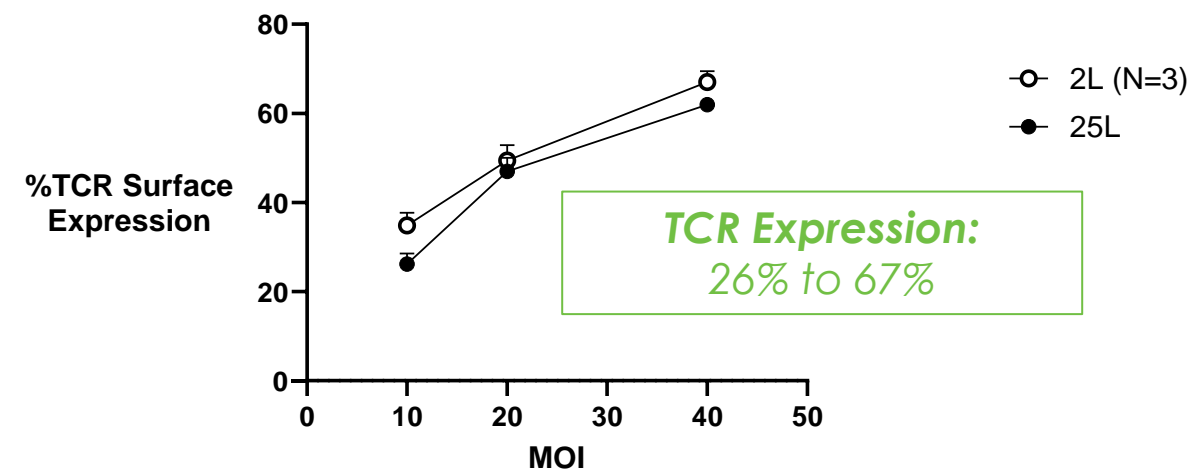
# Potency Evaluation with LentiPeak™ Generated LVV

## Modified T-Cell with LentiPeak™ LVV Material

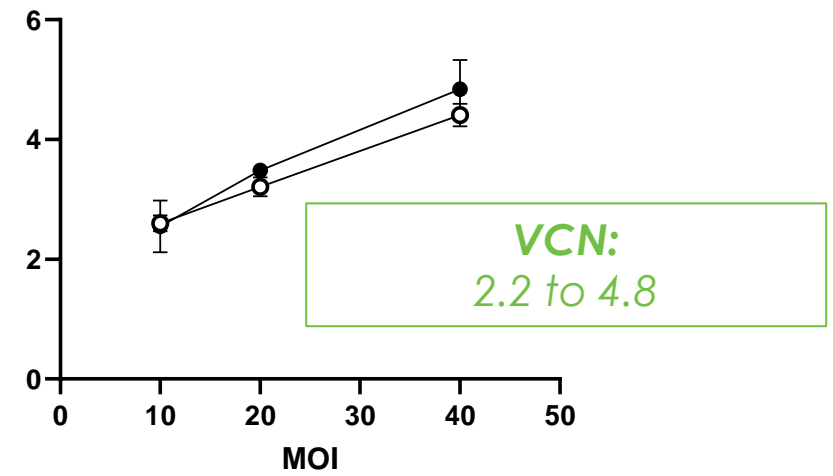


The **LentiPeak™ Platform** process has capability of creating **highly consistent** and **potent LVV** for use in many **cell and gene therapy** applications.

### Expression and VCN Between Production Scales

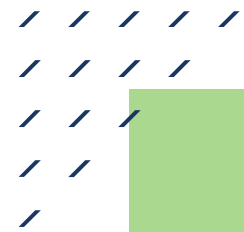


### Vector Copy Number (VCN/Transduced Cell)





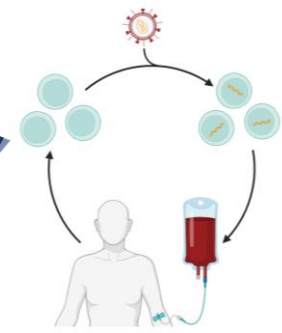
# ElevateBio BaseCamp Development Pathway



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# Redefining Success: LentiPeak™ Platform Speedway to Clinic



## Upstream

## Downstream



**Partnership**

- Side-by-side client on site
- Dedicated project manager
- Regulatory Support

**Technology**

- Expertise on innovated technologies to streamline
- Ensure equipment & materials will support product through pivotal & beyond

**Unit Op Optimization**

- Starting Material
- High throughput screening and DOE for further characterization
- Early initiation of an analytical development plan

**Tech Transfer Success**

- Clinical scale data
- Early integration & training of Tech Ops and Manufacturing personnel
- Highly collaborative QA and QC personnel

**Process Dev SME Support**

- Process development scientific knowledge and data
- Continuous process characterization for the product lifecycle

**Training & Engineering Runs**

- Integrated Process Development SMEs
- Highly qualified trainers and support teams



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