





SAFE DELIVERY OF VIRAL VECTORS IN GENE AND CELL THERAPY (GCT)

Accelerate Your Project with One-stop Solution



November 2018

1st CMC Order & 1st strategic collaboration

January 2019

2nd CMC Order & 2nd strategic collaboration

March 2019

Strategic collaboration with Merck for GCT platform construction

March 2019

3rd strategic collaboration

April 2019

Ground-breaking ceremony of commercial manufacturing center in ZJ, CN

August 2019

1st US collaboration

December 2019

Opening ceremony of GMP Viral vector facility in ZJ, CN

April 2020

1st Korea strategic collaboration

September 2020

1st IND approval from FDA TCR-T project

January 2021

1st IND approval from NMPA UCAR-T project

2022

Opening of commercial manufacturing center in ZJ

2,500m²

Our 2,500 m² state-of-the-art facility is dedicated for viral vectors production in gene and cell therapy.

GMP viral vector manufacturing center

- Four segregated manufacturing suites
- ♦ Clean room with Grade A in C environment

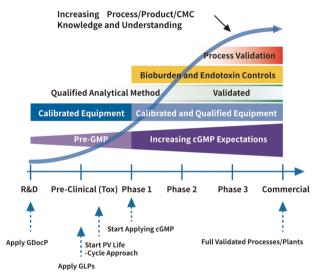
Process development and analytical laboratory

- Independent microbial, physical and chemical, instrumental, and functional titer testing laboratories
- Testing and control of viral products, intermediate, materials, water systems, etc.
- Equipment: MD SpectraMax-M2, BMG CLARIOstar, Sterile Isolator, Thermo Fisher ABI 7500, BD FACSCelesta and Agilent 1260
- 120 batches of analytical assays for CMC projects per year

Appropriate COMPLIANCE

Integrated quality systems with independent quality control and quality assurance department, to better manage the quality of each client's project.

- ♦ In line with ICH/GMP guidelines/regulatory compliance
- Use PAC (Phase-Appropriate Compliance) to perform quality assurance process specifically in each period of drug development phases;
- One-to-one QA for each project to ensure quality assurance all along the project;
- Quality control from environment, materials, in-process control to final product;

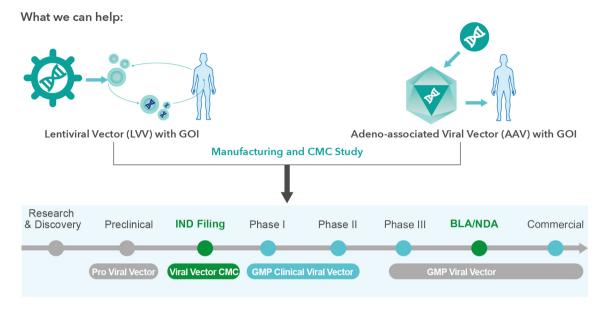




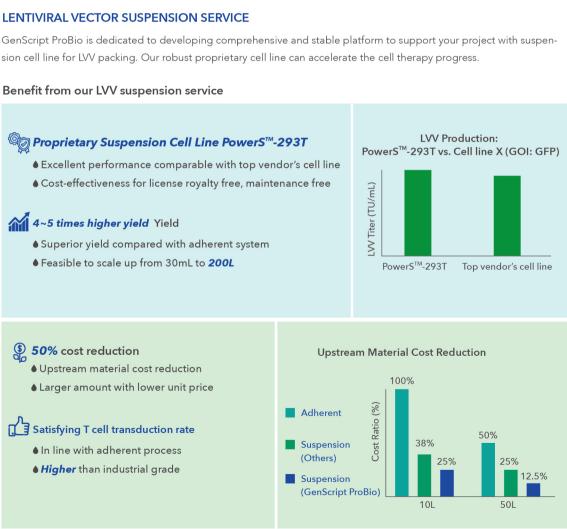
Lentiviral Vector



Using cutting-edge technologies, GenScript ProBio keeps developing and optimizing viral vector manufacturing process, to deliver breakthrough to the Gene and Cell Therapy.



sion cell line for LVV packing. Our robust proprietary cell line can accelerate the cell therapy progress.





LENTIVIRAL VECTOR ADHERENT SERVICE

Driven by comprehensive quality assurance process, GenScript ProBio also establishes matured adherent platform to meet your various needs.



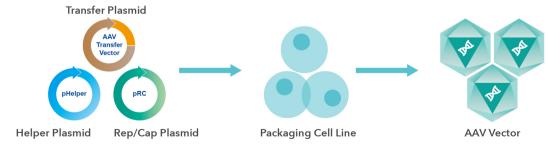
Adherent platform featured with:

- Closed culture system:
 avoid contamination, full-automatic operation, feasible to scale up
- Well-developed manufacturing. process:
 specifically optimized cell density, harvest time, transfection system
- ♠ Above-industrial LVV titer: high titer >5X10^7 TU/mL, high stability, high quality

ADENO-ASSOCIATED VIRAL VECTOR SERVICE

GenScript ProBio helps solve the challenge of scalable and reliable manufacturing for AAV from preclinical through IND application to clinical phase, and brings excellent solution for gene therapy.

• Using mature and versatile triple transient transfection system to promise safety



- ◆ Crude titer above industrial grade ◆ Professional and experienced production team
- State-of-the-art facility ready for AAV manufacturing
- ddPCR for AAV titer measurement, AUC for AAV full ratio detection

