GenScript ProBio

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

Improved Safety by Splitting Viral Genome into Separate Plasmids

November 2018

Opening ceremony of Plasmid Process Development Facility in ZJ, CN

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

March2019

3rd strategic collaboration

April 2019

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

August 2019

1st US Manufacturing Order

December 2019

Opening ceremony of GMP virus facility in ZJ, CN

January 2020

2nd US Order

January 2020

3rd US Order

January 2020

cGMP plasmid vendor collaboration in the US

2022

Opening of commercial manufacturing center in ZJ

2,500m^2

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

GMP virus manufacturing center

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

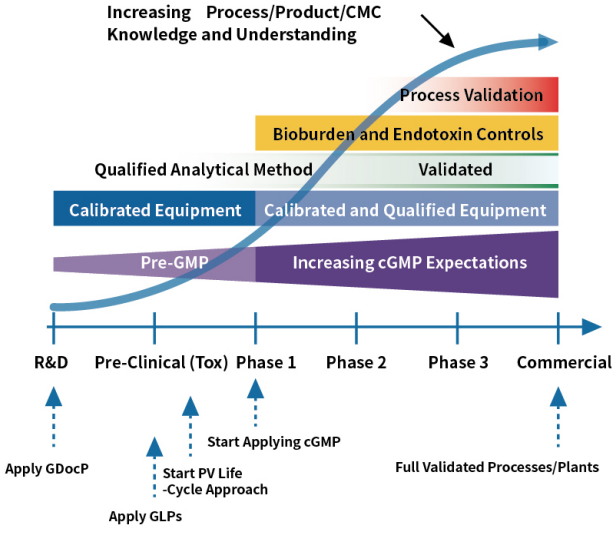
Process development and analytical laboratory

- 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



Lentivirus

AAV

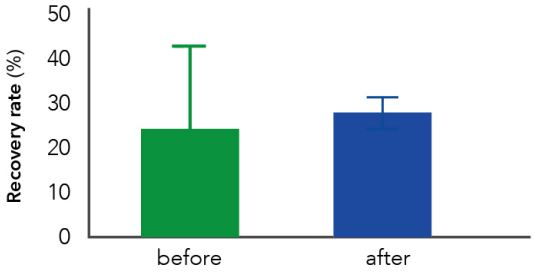
AdV

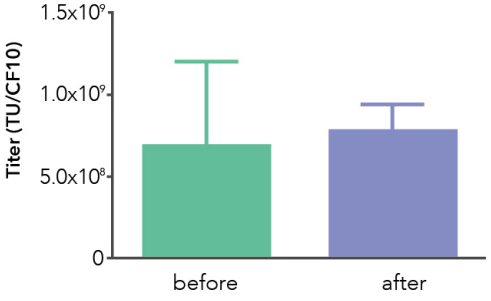
PROCESS DEVELOPMENT

Using cutting-edge technologies, GenScript ProBio keeps developing and optimizing lentivirus manufacturing process, to improve lentivirus efficiency in titer, residual impurities and stability. For every project, GenScript ProBio has the capability to develop manufacturing process for specific purposes.

What we can do:

- Upstream adherent culture process development
- Downstream purification process development
- Process scale-up
- Up to 50L adherent process optimization and qualification





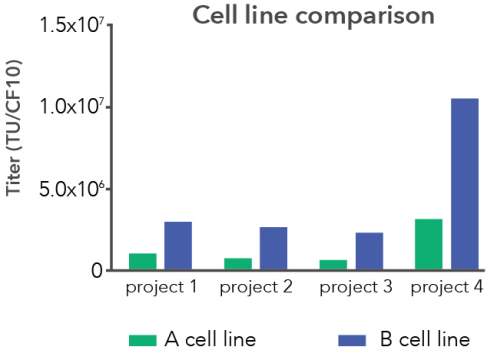
Stability of the titer and recovery rate of the virus improved after process development at GenScript ProBio

CELL BANKING

GenScript ProBio is ready to manufacture cell banks for customers under GMP requirements and comprehensive quality system. Besides, GenScript ProBio has selected IP-cleared cell lines from several and manufactured cell banks (PCB, MCB, WCB) for customers use.

Already manufactured cell banks are:

- Selected a cell line with high expression level;
- Fully characterized;
- IP cleared with clear source and appropriate for regulatory use;
- Able to reduce turn-around-time (TAT).



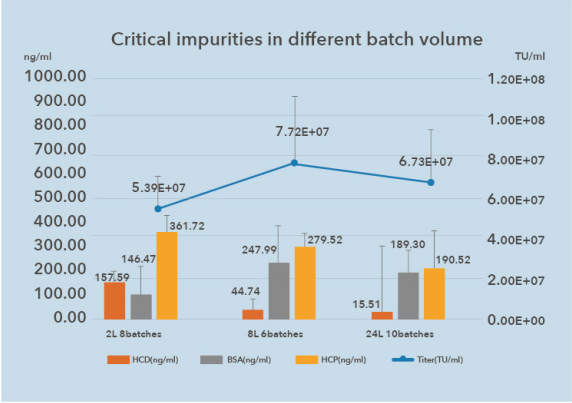
GenScript ProBio chose cell line B for manufacturing of lentivirus

Comparing the performance of cell line A and cell line B in 4 projects/batches of manufacturing, cell line B always led to a much higher titer than cell line A.

GMP LENTIVIRUS MANUFACTURING

Driven by comprehensive quality assurance process, GenScript ProBio is providing GMP lentivirus for customers strictly compliant to regulatory requirements. Currently adopting mature adherent culture platform and customer needs from pre-clinical to clinical supply can be satisfied.
GenScript ProBio's GMP lentivirus platform featured with:

- GMP manufacturing – 1,200 m^2 clean room with 4 segregated manufacturing suites;
- Manufacturing scales from lab-scale to 50L;
- Comprehensive quality assurance process, from materials, environment, to process control, documents and etc.;
- Quality control and release testing.



HIGH PURITY

- BSA remain between 150~300 ng/ml
- Endotoxin <10 EU/ml
- HCP between 200~400 ng/ml
- HCD <30 ng/ml in larger scale (24L)

HIGH TITER

- Titer >5x10^7 TU/ml

HIGH STABILITY: STABLE FROM BATCH TO BATCH SCALABILITY

- Performance remains stable during scaling up

ANALYTICAL DEVELOPMENT AND QUALITY CONTROL

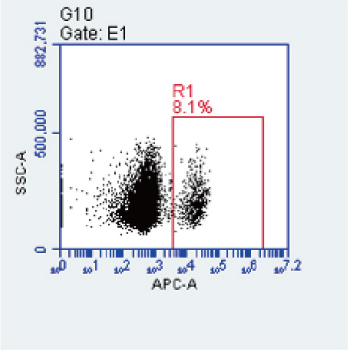
Analytical development, qualification and validation services, and stability tests are available according to clients' requirements, including preparation of regulatory filings.

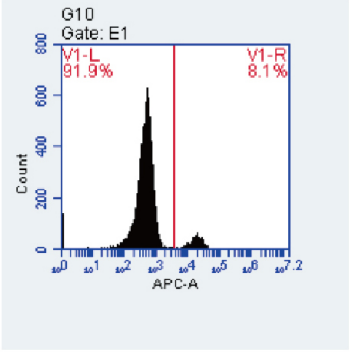
Assays:

- Benzonase
- SV40
- Residual plasmid
- Sterility
- Bioburden
- Endotoxin
- FACS
- P24 ELISA

What we can do:

- Analytical development and qualification
- Quality control and testing release
- Stability test
- Support for regulatory filing





Functional titer determination using FACS

- Clear distinction between negative cells and positive cells.
- Reasonable assays with the most appropriate specifications.

Milestones

in moving forward in GCT industry

2018

Enter into GCT CDMO

2019

Establishment of BDBU (Biologics Drug BU)

Introduction of top management (CEO, 5 VP)

2020

Officially named GenScript ProBio

Future

Developing with the industry and contributing to a healthier world

Company information

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