



GenScript

PROBIO

Contract Manufacturing of
Plasmid DNA Under GMP-Compliance



Track Record

Plasmids are widely used vectors in gene and cell therapy. It can be served as a raw material for producing viral vectors, delivery vehicle to transfer gene of interest, or final drug product in the case of DNA vaccine. Appropriate quality of the plasmid is critical for cost effectiveness and to save time on your project.

Various Applications:

GenScript ProBio has accumulated experience in manufacturing plasmids as different use, such as raw material, drug substance or even drug product.

- ◆ Raw materials for producing viral vectors (LVV, AAV, etc.)
- ◆ Template for mRNA production
- ◆ Deliver vector to transfer gene of interest (GOI)
- ◆ DNA vaccine

GenScript ProBio Experiences

Largest and Best Plasmid CDMO

- ◆ Excellent track record:
 - 7 **IND approved** from NMPA&FDA
 - > 20 IND projects ongoing
 - > 30 GMPro batches for **clinical** phases
- ◆ For **viral vectors** production:
 - CAR-T, UCAR-T, TCR-T, Gene therapy**
- ◆ For **mRNA** production:
 - Assisting **plasmid manufacturing for COVID-19 vaccines**
 - CRISPR/Cas9 project
- ◆ For **DNA vaccine**
 - CMC study for plasmid as **drug substance**



Capabilities

1,200 m²

GenScript ProBio has a dedicated plasmid process development facility ready to provide pre-IND offerings and early stage clinical supplies that are appropriate for producing viral vectors.

- ◆ Two segregated manufacturing suites;
- ◆ Manufacturing scales from 5L to 100L.

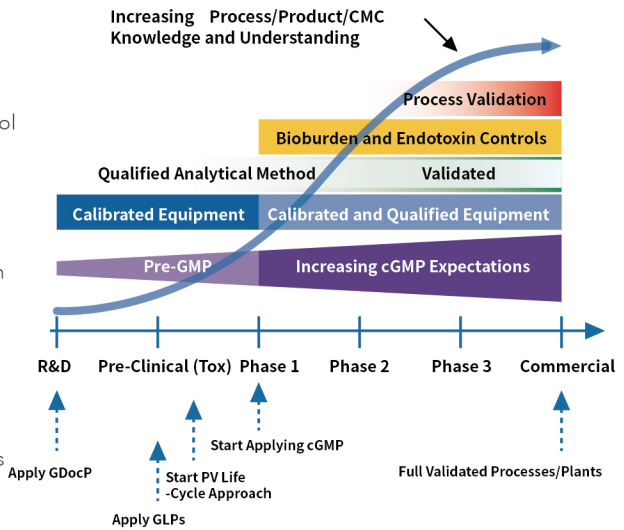
GenScript ProBio is expanding its capability and capacity at a new facility, which will more than double the footprint and capability of the current one. The new facility will be in full operation from 2021 Q3.



Appropriate COMPLIANCE

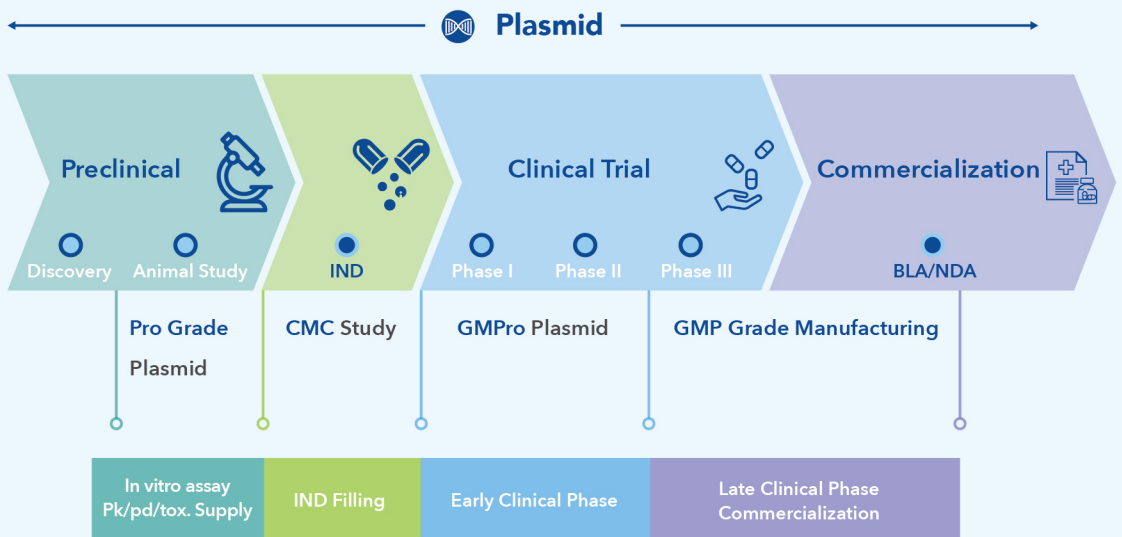
Integrated quality system with independent quality control and quality assurance department, to better manage the quality within each client's project.

- ◆ In line with ICH/GMP guidelines/regulatory
- ◆ 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.



Custom Plasmid Manufacturing

Different degree of plasmids are available in GenScript ProBio to meet your different needs during gene and cell therapy development cycle.



BENEFITS

- Ready-to-use **Helper Plasmids** for LVV packaging **DMF** registered at FDA CBER, **IP free**
- **Licensed strains** for commercial use, with **sub-license authority**
- Animal free and antibiotic free
- High density fermentation: **600–800 mg/L**
- High supercoiled plasmid content: **>90%**

HIGH DENSITY FERMENTATION: HIGH YIELD, HIGH STABILITY, EASILY SCALE-UP

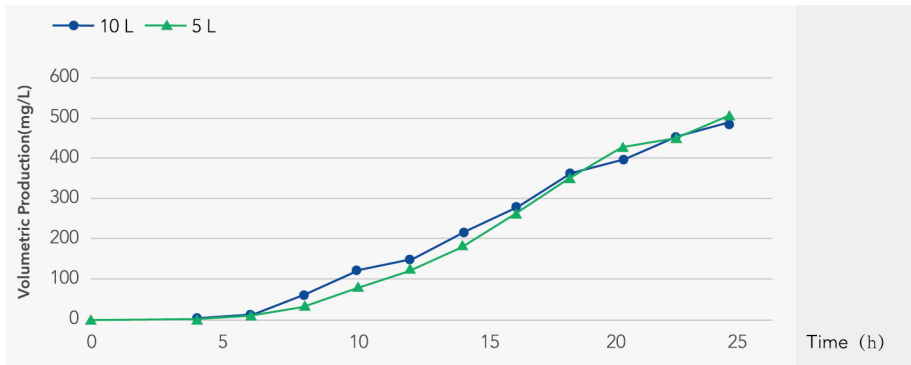


Figure 1 Volumetric production of 3 batches at 5 L scale and 3 batches at 10 L scale during the whole fermentation period.

EXPERT PURIFICATION PLATFORM: UP TO 50% RECOVERY RATE, LOW IMPURITY CONTENT

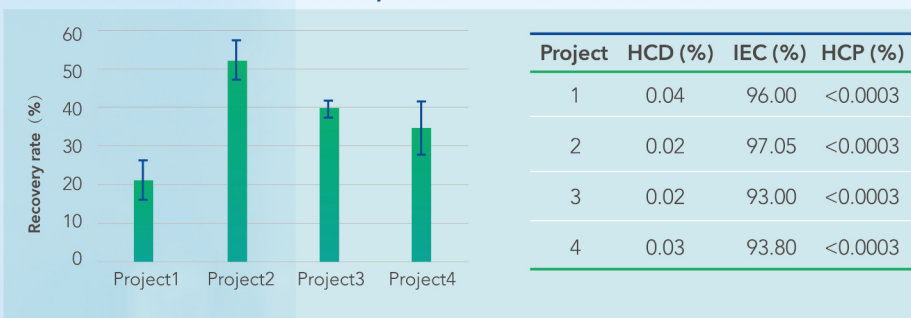
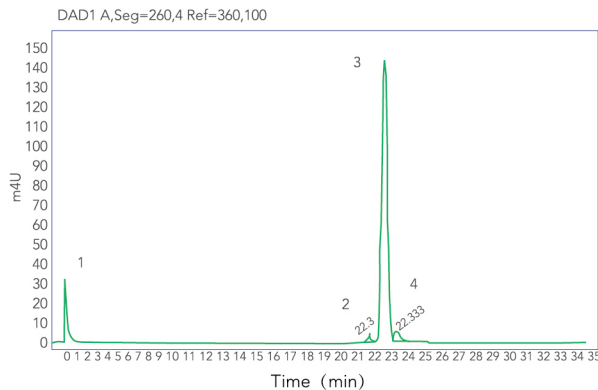


Figure 2 Data of 4 projects, all including 3 batches of production. Left: recovery rate of 4 projects. The highest one achieved over 50%. Right: critical quality attributes. Host cell DNA as low as 0.02%; host cell protein lower than the minimum detection value 0.0003%; Supercoil content exceeds 93%.

HIGH-SENSITIVITY QC METHODS FOR CRITICAL QUALITY ATTRIBUTES CONTROL



1: Solvent; 2: Open circular plasmid;
3: Supercoiled plasmid; 4: Dimer plasmid.

Sample	Time	Area(%)
OC-Plasmid	20.800	1.62
SC-Plasmid	21.790	94.07
dimer-Plasmid	22.533	4.31

Figure 3 High Performance Liquid Chromatography (HPLC) of the purified samples after step 1 and step 2 to detect the content of supercoiled plasmid.

Milestones

in moving forward in
GCT industry



2018

Enter into GCT CDMO

2019

Establishment of BDBU
(Biologics Drug BU)

2020

Officially named
GenScript ProBio

Future

Developing
with the industry and
contributing to a healthier
world

Company information

www.genscriptprobio.com

Address:

GenScript USA Inc.
860 Centennial Ave.
Piscataway, NJ 08854 USA

Phone: 1-732-885-9188
Toll-Free: 1-877-436-7274
Fax: 1-732-885-5878