GMP Plasmid Manufacturing

GenScript ProBio Provides High-quality Plasmid

Whether you're working on a gene therapy, cell therapy, DNA vaccine or mRNA vaccine, it starts with a high-quality DNA, GenScript ProBio will be your partner that supports you from small-scale, pre-clinical work through clinical trials, and eventually at commercial scale with phase-appropriate quality grades, analytics, and regulatory support.

Plasmid DNA

GenScript ProBio has proven experience from IND to BLA of plasmid DNA projects

- Viral Vector (LVV, AAV and RVV etc.)
- mRNA vaccine
- DNA vaccine
- CRISPR gene editing

Capability

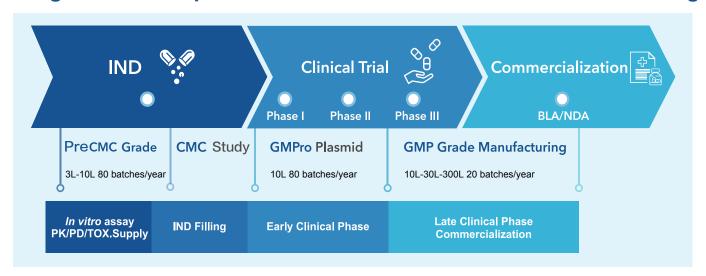
Regardless of the number of constructs, you can count on reliable plasmid DNA for pre-clinical, clinical and commercial uses. Our platform includes supercoiled and linearized DNA

Capacity

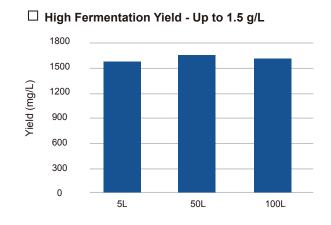
Our state-of-the-art, GMP, multi-production line facility is specially designed to enable your cell and gene therapy

- · 87,500 square feet GMP cleanroom suites at Grade B and C
- GMPro Grade: Up to 10L fermentation scale
- · GMP Grade: Up to 300L fermentation scale
- TFF Systems: Repligen KR2i for 10L scale; AKTA Readyflux and AKTA Readyflux XL for 30L/300L scales
- Chromatography Systems: AKTA Pilot 600R and AKTA Ready Gradient Extended
- Automated fill & finish capabilities; performed in Grade A qualified environments
- GMP suites specifically designed for maximum productivity and efficient production

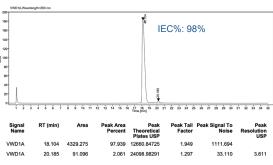
Integrated One-stop CDMO Solution: Preclinical to GMP Manufacturing



Off-the-shelf LentiHelper™ (MF25552) and AAssistV™ (MF29497) Plasmids with FDA DMF Registration









GLOBAL IND APPROVALS

300+ **CLINICAL MANUFACTURING**

BATCHES

IND APPROVALS FOR DNA **DRUG**

EMERGENCY USE AUTHORIZATION (EUA) ONGOING P&V CMC **PROJECTS**

ONGOING PROJECTS FOR **DNA DRUG**

New Jersey GMP Plasmid Facility (2024 Q3)





