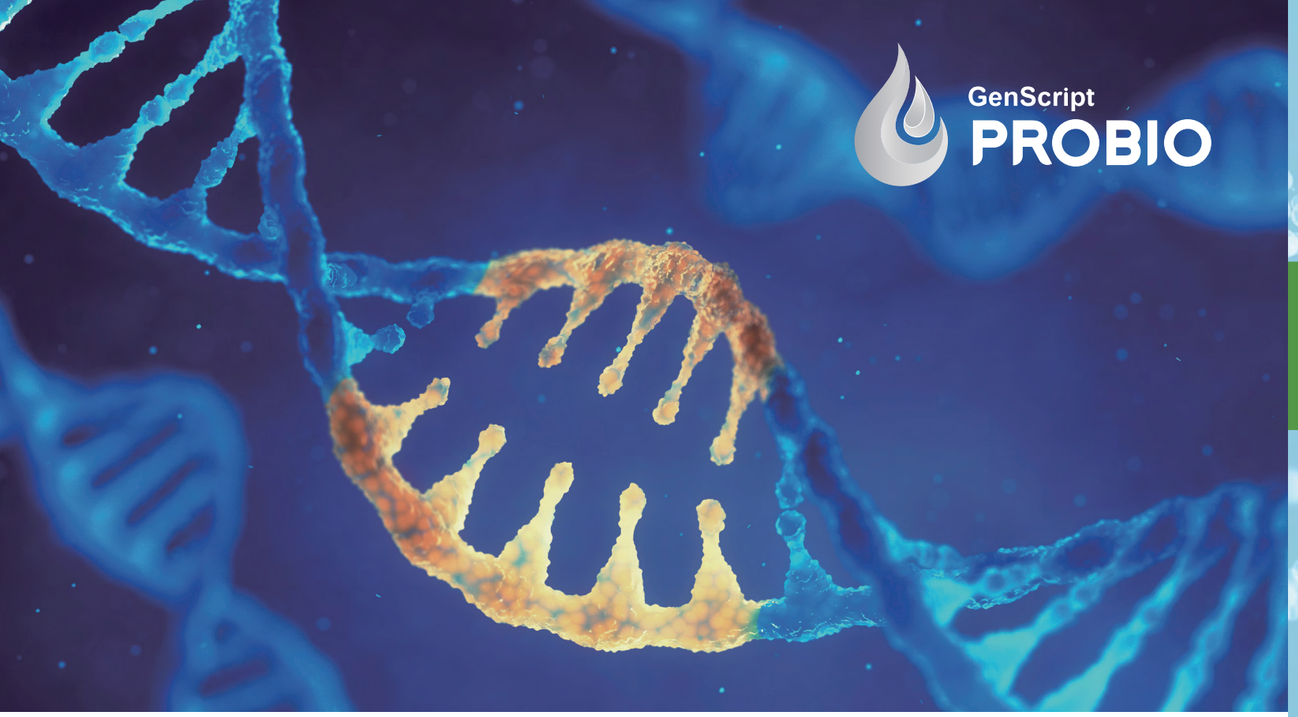
Making Cell and Gene Therapy Manufacturing Accessible

GenScript PROBIO



GenScript PROBIO

Solid Track Records with 30+ IND Approvals Globally, with Applications of Cell Therapy, Gene Therapy, mRNA Vaccine/Drug and DNA Vaccine/Drug

- **Custom Plasmid Manufacturing**
  GMP-Compliance

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

Fast lead time	Licensed strain	One-stop solution
GMPro™ Plasmid Manufacturing with 2~3 months fast delivery	Licensed strain with sub-license authority	One-stop solution, from cell banking to PD, AD, GMP MFG and stability study

- **Various Plasmid Applications**

Cell Therapy	Gene Therapy
Starting Material, Raw Material, Intermediate, DS	Raw Material, Intermediate
mRNA Vaccine/Drug	**DNA Vaccine/Drug**
Starting Material, Raw Material	DS, DP

- **LVV One-stop Solution**
  Adherent (HEK293T cell line)
  Suspension (PowerS™-293T cell line)

- **AAV One-stop Solution**
  Suspension (PowerS™-293 cell line)

Under the GMP regulatory condition, GenScript ProBio has established PCB (Primary cell bank), MCB (Master cell bank) and WCB (Working cell bank), and makes the fully research on the identification of cell banking and stability of cell generation, to compliant to application requirements of NMPA, FDA, and EMA.

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Innovation Through Collaboration

GenScript PROBIO

Making Cell and Gene Therapy Manufacturing Accessible

Introduction

Dr. Patrick Liu, Chairman and Acting CEO, GenScript ProBio

The COVID-19 pandemic has accelerated the adoption of some important new technologies, which have had a lasting impact on the global healthcare industry in recent years. At the same time, cell and gene therapies(CGT) technologies have brought hope to countless patients with rare diseases and cancers. However, large scale production of these new therapeutics remains a key challenge for the entire industry.

This eBook aims to reveal the latest medical industry trends, challenges faced by the cell and gene therapy industry and most innovative solutions. In addition, Dr. Patrick Liu, Chairman and Acting CEO of GenScript ProBio, takes a look at the global biopharmaceutical development wave over the past 30 years and discusses his expectation of Chinese biopharmaceutical innovation, as well as shares his insights on the process challenges faced by the CGT industry.

At the end of this eBook, the challenges and solutions of cell and gene therapy in the applications of plasmids and viral vectors are shared from the technical aspect, and related cases and data are also shared.

A Look at Trends in the Global Biopharmaceutical Industry

[xijian, Getty Images]

Biopharma Demand of CGT Drives CDMO Industry

The pain points of R&D demand and application have jointly led to the prosperity of the cell and gene therapies CRO and CDMO industries. The clinical enthusiasm for cell and gene therapies continues, and the United States and China are the countries with the largest number of clinical trials. The high production cost limits the application of cell therapy, as it is a complex process, from separating and collecting T cells, to activation and motivation, to expanding cells and returning them to the patient. CDMO companies can reduce costs through automated production and standardized manufacturing of lentiviral vectors and plasmids.

Based on this trend, CDMO companies have risen rapidly. As a global CDMO company, GenScirpt ProBio has come along way in a few short years and has quickly became a first-tier CDMO company in the CGT field in China.

[gorodenkoff, Getty Images]

The World is Experiencing the Third Wave of Biotech Development

Since the 21st century, biological drugs have entered a period of rapid development, and the growth rate is much higher than that of small molecule drugs. Whether in terms of market share or new drug approval, biological drugs are exploding.

The continuous updating of Chinese policies is beneficial to biological drugs, and overseas biotech talents continue to return, making China a hot place for biological drugs.

"China's biotechnology market is booming, there is a lot of exciting research going on, and there is also a lot of funding from the government and private institutions." Dr. Liu believes that the support of private sector, as well as the Chinese government, has raised the hope and prospects of Chinese biopharmaceuticals development. "Innovation in Chinese biopharma is fast becoming a notable story. I hope the company can empower more innovative Chinese companies move forward on the world stage, and I hope to bring promising treatments worldwide to benefit patients in need,"said Dr. Liu.

Small and Medium Biotech Companies Lead Future Innovation

A new wave of biomedical technology innovation has arrived, and small biotechs are becoming a life saver for Big Pharma as they do not have enough in-house R&D to fill the void. The "chasm" is putting the Big Pharma in a perilous position. As a result, Big Pharma needs to make big bets before the patents on current "blockbuster" products expire. The share of FDA approvals for new molecular entities (NMEs) by Big Pharma decreased significantly in recent years, while approvals by smaller biotechs increased at a similar rate.

As of June 2023, GenScript ProBio helped its global clients develop 30+ investigational new drugs (INDs) in cell and gene therapies field, whichincludes customers in the U.S., Europe, Korea, Japan, and China, and other regions.

Among them are many innovative therapies that have been developed in China by small and medium-sized companies. GenScript ProBio has supported start-up biotech companies that have obtained China's first CAR-T, TCR-T, mRNA vaccine, as well as CRISPR programs to be approved for clinical trials by the National Medical Products Administration (NMPA) .

Challenges of CGT Startups

Complex technical mechanisms, high-threshold process development and large-scale production, strict regulatory requirements, and limited industrialization experience make CGT products more dependent on CDMOs than traditional pharmaceuticals.

The gap in production capacity cannot be met in a short period of time. In addition, if enterprises choose to build their own facilities for increasing production capacity, they will face huge financial pressure. In addition, in the context of the global economy, the price of raw materials at home and abroad has continued to rise. Dr. Liu said," The development of cell and gene therapies drugs is difficult, the control of process is complicated, and there is a shortage of compound talents with good technology, process background, and rich production management experience in the industry, and relatively mature CDMO companies often have explored and solved these problems in the early stage of establishment. For startups, the time cost is the biggest cost they face. "

In addition, global operations and application are also important considerations for many CGT companies when choosing a CDMO partner. Mature technology and experience

make CDMOs more proficient in quality control, which can help reduce R&D risks, open up the entire process efficiently and accurately, and quickly complete global application. Toward its mission of "Innovation through Collaboration," GenScript ProBio has a global vision based on a commitment to international biopharmaceutical R&D and biomanufacturing standards. It has established GMP capacity which meets FDA, EMA, and NMPA regulatory requirements.

The Importance of Quality Under Fierce Competition

The new generation of therapy has great potential in terms of efficacy; it is especially full of opportunities for diseases that have been difficult to break through in the past, but correspondingly, the manufacturing process is also several orders of magnitude more difficult than traditional therapy. Therefore, only by ensuring high-quality manufacturing can these therapies be better introduced to the market, bringing benefits to patients.

The strong combination model of cell and gene therapies companies with CDMOs enables R&D companies to focus more on the R&D and innovation of core products, while large-scale testing and some production can be handed over to more experienced CDMO partners to form industrialization advantages, improve efficiency, reduce costs, and improve patient accessibility.

Dr. Liu said, "In the process of cell and gene therapies, precise design is required at every step to ensure the safety and efficacy of the final product. Safety and efficacy are the core issues faced in the current development of cell and gene therapies, and the later process plan. The design of the product is a key factor in determining whether the product process can be scaled up and whether it can be rapidly commercialized."

For this reason, it is critical for the majority of cell and gene therapies companies to choose a highly professional and experienced CDMO partner. At present, the process control of cell and gene therapies adopts the concept of QbD (Quality by Design). Through the thorough cognition and research of the process in the early stage, it can accurately grasp the source and degree of risk in the process of quality control.

GenScript ProBio has implemented a system for Phase Appropriate Compliance. Depending on the stage of a project, different levels of quality oversight are applied. For example, clinical Phase III and commercial projects require more stringent levels of GMP production and oversight than clinical Phase I projects.

[Lane Oatey, Getty Images]

Currently, GenScript ProBio's Phase Appropriate Compliance (PAC) system can meet customer and regulatory requirements of countries such as China, the U.S., and Europe. In addition, GenScript ProBio has created a Customer Quality Verification (CQV) project management platform to provide customers with the highest quality efficiency. Based on its PAC system and CQV project management platform, GenScript ProBio's record of accomplishment is quickly gaining widespread recognition.

The Technological Innovations and Developments Brought by COVID-19

Since the spread of the COVID-19 epidemic in 2020, the fields related to the prevention and treatment of COVID-19 in the pharmaceutical industry have continued to benefit from the expansion of domestic and foreign demand, showing a high degree of prosperity. In the early days of the epidemic, the research and development of mRNA vaccines against COVID-19 was booming. In the early stages of the fight against the epidemic, GenScript ProBio played an active part in the field

[xijian, Getty Images]

of mRNA vaccines. It supported several mRNA vaccine enterprises to obtain clinical approval by NMPA in China, and helped mRNA vaccine projects of their customers in South Korea and the U.S. to successfully obtain clinical approval by the KFDA in Korea and PMDA in Japan.

The COVID-19 pandemic has brought mRNA vaccine technology to the public, making mRNA technology widely available for clinical research in multiple indications, including oncology, HIV, influenza, and genetic diseases. With strong plasmid process development and manufacturing capabilities and rich experience for global customers, GenScript ProBio has quickly established high-quality services in the mRNA field, providing customers in nucleic acid drug field with one-stop solutions from plasmids to mRNA, including plasmids, linearized DNA, mRNA in vitro transcription (IVT-mRNA), lipid nanoparticle (mRNA-LNP) formulation and (LNP) encapsulation.

Due to the characteristics of strong transmission, strong hiding ability, and many asymptomatic infections of the Omicron strain, the COVID-19 epidemic continued to have local recurrences in China in 2022. In September 2022, China's epidemic prevention measure was to administer heterologous vaccines strategy and GenScript ProBio's partner Livzon

Pharmaceutical Group's recombinant COVID-19 vaccine was approved in the heterologous vaccines strategy for emergency use.

In October 2022, a nasal spray device was approved by Thailand's FDA and was officially launched in the Thailand market. It was reportedly capable of preventing the COVID-19 virus from attaching to the internal surfaces of the nasal cavity, thus reducing the viral load in the cavity. GenScript ProBio's aseptic filling line was put into operation in February 2023. GenScript ProBio offers ORABs-based, fully-automated final drug product filling under Current Good Manufacturing Practice (cGMP) conditions and has capabilities for filling for multiple dosage forms such as nasal spray filling, vial liquid filling, vial lyophilized powder filling and pre-filled syringes filling.

The biotech industry is particularly vulnerable to the slowing of economic growth, rising inflation and rising interest rates. Unlike software companies, biotech companies require constant infusions of capital to develop drugs, which require a lot of time and money. Now that the epidemic has entered the late stage, some biotech companies whose INDs have not been approved have disappeared from view. Under the current situation of rapid changes, biotech companies can only survive by adjusting their pipelines in time.

The COVID-19 pandemic has driven the development of related biotechnologies, while at the same time, some companies have been phased out by the market.

CMC Challenges for Plasmids in Cell and Gene Therapies

A Brief Analysis of the Key Quality Control Elements for Naked Plasmid DNA Drugs *In Vivo* Gene Therapies

[Wladimir Bulgar, Getty Images]

In the field of gene and cell therapies, plasmids and viral products are often the basis of CMC development and are widely used as key raw materials or starting materials in cell therapies such as CAR-T, TCR-T, iPSC-derived, and mRNA products. Currently, there are 14 cell products and 3 mRNA vaccines on the market globally, and 13 viral vector gene therapy products have been approved for sales (As of May 2023). In contrast, there are only two plasmid-based gene therapy products approved so far, one in Russia (2011) and one in Japan (2019).

This article briefly discusses the pharmacological research of naked plasmid DNA drugs for *in vivo* gene therapy based on existing regulatory guidelines from NMPA, EMA, and FDA.

What Regulatory Requirements are Involved When Developing Plasmids as Therapeutic Products?

Current main reference regulatory guidelines for *in vivo* gene therapy product development both domestically and internationally are as listed in the following table:

Table 1: Guidelines for *In Vivo* Gene Therapy Product

Issued by	Guideline Name	Published Time
ChPC	人用基因治疗制品总论 Overview of Gene Therapy Products for Humans	2020
USPC	<1047> GENE THERAPY PRODUCTS	2021
EDQM	5.14. Gene transfer medicinal products for human use	2021
CDE	体内基因治疗产品药学研究与评价技术指导原则（试行） Guidance Principles for Pharmaceutical Research and Evaluation Techniques for *In Vivo* Gene Therapy Products (Draft)	May 2022
FDA	Human Gene Therapy Products Incorporating Human Genome Editing (Draft Guidance for Industry)	March 2022
FDA	Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)	January 2020
EMA	Guideline on the Quality, Non-clinical and Clinical Aspects of Gene Therapy Medicinal Products	March 2018
FDA	Guidance for Human Somatic Cell Therapy and Gene Therapy	March 1998

Note: ChPC: Chinese Pharmacopoeia Commission. USPC: United States Pharmacopieial Convention. EDQM: European Directorate for the Quality of Medicines & HealthCare.

The above listed regulatory guidelines all introduce the regulatory requirements for product cell bank, process control and quality standards to different degrees, and provide appropriate scientific explanations. Among them, USP <1047> provides a more detailed description of the control of the whole process of *in vivo* gene therapy products from cell bank construction to final product release, transportation to the clinical end.

GenScript ProBio, based on the above regulatory requirements, take the example of intravenously administered naked plasmid DNA therapeutic drugs, briefly analyze the specific requirements for non-viral vector gene therapy products.

Cell Banks

Cell banks are an important assurance of consistency in the quality between different batches of clinical samples and marketed products, usually referring to Master Cell Bank (MCB) and Working Cell Bank (WCB). They must be constructed under conditions that comply with cGMP and the raw materials used

must ensure no contamination from adventitious agents. Cell banks must be identified and purity tested, and the maximum number of passages must be tested. The above requirements are also mentioned in the EP 5.14 and ICH Q5D.

By interpreting relevant regulatory guidelines and based on scientific knowledge, at least MCB should be constructed in the IND stage. A well-characterized GMP level cell bank can effectively avoid cross-contamination, and the uniformity of the bank is the premise of the quality consistency of downstream products. By interpreting FDA, EMA, and ICH guidelines, MCB can be constructed from a single clone or primary cell bank (PCB), but it must be prepared under GMP management. In the stage of license application, to meet the needs of commercial manufacturing, if WCB needs to be constructed, it can be changed based on a well- characterized master cell bank (refer to the "Technical Guidance Principles for Post-Marketing Biopharmaceutical Change Research (Trial)" issued by CDE in June 2021). If the change does not have a significant impact on product quality after sufficient evaluation or comparability study, the change of this cell bank should be defined as minor or moderate.

Production Control and Quality Control

It is mentioned in USP <1047> that clear control indicators should be established for key intermediates during the production process to ensure that products with expected quality and yield are obtained. If the intermediates do not meet the control standards, rework can be carried out when there is a corresponding program control. For naked plasmid DNA therapeutic products, common intermediate control items include:

- Optical density or change in oxygen consumption during culture
- Amount and form of plasmid before culture harvesting and after extraction steps
- Amount of pyrogen or endotoxin after extraction steps in plasmid pool, etc.

It is also mentioned in USP <1047> that if sublots need to be pooled for further processing, attention should be paid to ensuring that each sublot meets the established quality standards. For example, if two or more sublots of fermented intermediate samples are pooled for purification, each sublot of fermented intermediate samples must be tested, and the test results must meet the process control requirements before pooling performed.

Clinical batch plasmids need to undergo characterization study, product- and process-related impurities need to be clearly identified, and the methods and control standards for purity and activity testing must be established. Specific testing items, analytical methods, and recommended acceptable standards are shown in the table at right and further explained.

Table 2 : Testing and Specifications for Plasmids Intended for Clinical Use

Assay Type	Issue	Determined By	Acceptable Level in Final Product
Identity	Cross-contamination with other products	Restriction digest/gel electrophoresis	N/A
Purity	Residual bacterial chromosomal DNA	Real-time polymerase chain reaction (PCR)	< 2 µg/mg DNA
	Residual RNA	Analytical HPLC	< 0.2 µg/mg DNA
	Residual bacterial protein	Bicinchoninic acid (BCA) protein assay	< 3 µg/mg DNA
	Endotoxin	Limulus amebocyte lysate (LAL) assay	Suitable criteria based on the final manufacturing process
	Sterility (bacterial and fungal)	Method outlined in 21 CFR 610.12	No growth
	Appearance	Visual inspection	Clear solution free of particulates
	pH	pH meter	Physiologic (7.0-7.4) but may be product-specific
	Plasmid confirmation (ccc vs oc)	HPLC or capillary gel electrophoresis (CGE)	> 97% ccc
Potency	Labeled dose	*In vitro* Enzyme-linked immunosorbent assay (ELISA) Fluorescence-activated cell sorter (FACS) Reverse transcription (RT)-PCR Light absorbance (A_{260})	Transgene/plasmid specific

Note: 1'ccc: covalently closed circular; oc: open circular. The table is taken from USP <1047>.

Identification: The most commonly used method for identifying plasmid products is restriction enzyme digestion mapping, i.e., gel electrophoresis after restriction enzyme digestion, where the correct plasmid is determined by comparing the size of the digested fragments to the theoretical molecular weight, and whether cross-contamination exists.

Purity: When plasmids are used as drugs, characterization is relatively simple, and key process-related impurities are also relatively clear, usually including residual host cell DNA, RNA, and protein. In addition, residual organic solvents (such as phenol and ethanol), salts and antibiotics (such as kanamycin) added during production should also be tested for residue or proven to be

effectively removed in subsequent processes. It is mentioned in USP<1047> that plasmid DNA may be produced in large-scale fermentation processes in the form of single supercoiled, relaxed single and linear structures. At the same time, *in vivo* activity data is so limited that it is impossible to prove the effectiveness of different plasmid structures, which requires monitoring of the content of different plasmid structures during production to prove batch-to-batch consistency of quality.

Safety: Safety tests, such as endotoxins and sterilization, need to be performed on naked plasmid DNA therapeutic products. In addition, the safety issue of unexpected genetic mutations during production needs to be considered.

Potency: Potency can be evaluated through *in vitro* or *in vivo* biological testing. Despite stringent design of analytical methods, the variability of potency assays may still range from 30% to 50%. Potency assays require a representative positive reference, which can be used for calculation of relative potency of test samples. Potency should be tested during stability studies of the product for the determination of shelf-life.

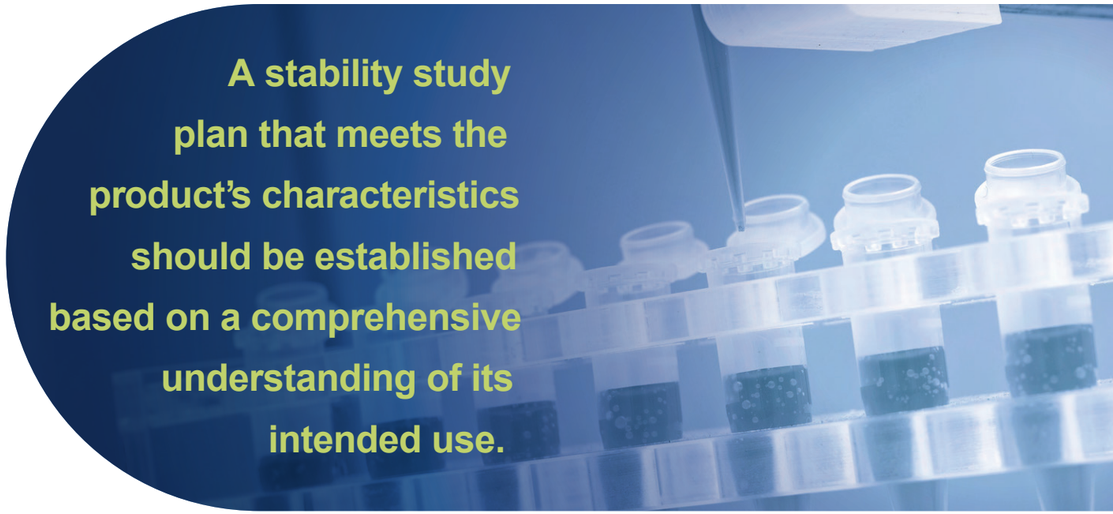
For naked plasmid DNA therapeutic products used as injectable agents, in addition to the aforementioned identification, purity, safety, and potency indicators, routine tests of the formulation product such as osmotic pressure, visible impurities, and insoluble particles of the plasmid final product should also be in accordance with pharmacopeia requirements to ensure the safety of the subject. For control of visible impurities, visible impurities should be checked individually for each bottle after filling of the product, and unqualified products should be removed. In the release test, re-inspection should be carried out according to the sampling requirements of the pharmacopeia.

Finally, to prevent safety and quality issues, a certain number of samples should be retained for each batch of product.

Stability

The shelf life of gene therapy products is closely related to the product's properties, prescription composition, storage conditions, clinical demand, etc. Therefore, a stability study plan that meets the product's characteristics should be established based on a comprehensive understanding of the product and its intended use, combined with scientific principles. In addition, stability studies must also be conducted on the strain library, intermediate samples, key raw materials, and reference standards during the license application.

The shelf life quality standard may differ from the release quality standard but should be supported by clinical data and there should be a planned collection and analysis of stability data during the early clinical stage.



Adequate stability studies should also be conducted on naked plasmid DNA as a drug, with long-term stability studies supporting the shelf life setting and stress studies providing supportive data for product manufacturing, transportation, and use environments. Additionally, transportation conditions should also be studied to ensure that temperature and agitation do not affect product quality during transportation to clinical institutions. If the drug substance needs to be transported to the filling manufacturer for filling, the stability of the drug substance during transportation should also be studied. Compatibility between plasmids, reagents and diluents, and administration devices should also be studied for diluted products in line with clinical application needs.

Currently, as knowledge and experience of gene therapy products accumulate, regulatory agencies in various countries are continuously supplementing and refining their regulatory guidelines, providing guidance for researchers during product development and ensuring the safety, efficacy, and quality control of the product.

Plasmid Solutions to Accelerate R&D and Manufacturing for Cell and Gene Therapies

[kasto80, Getty Images]

Plasmids are widely used in cell and gene therapies. They can be served as rawmaterials for viral vector production, the delivery vehicle to transfer the gene of interest, or the final drug product in the case of DNA vaccine.

GenScript ProBio is dedicated to producing plasmid DNA in high yields and high recovery rate with advanced technologies and can provide CDMO services from the preclinical preparation, IND-enabling CMC studies, all the way through until commercialization.

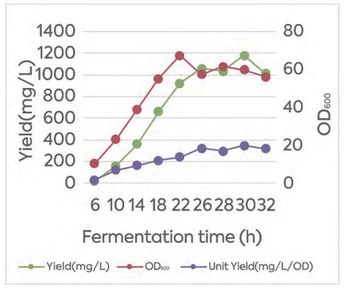
GenScript ProBio is dedicated to producing plasmid DNA in high yields and high recovery rate with advanced technologies.

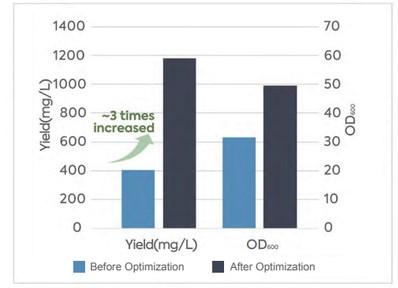
Case Study: Plasmid for Lentiviral Vector in Cell Therapy

During the manufacturing of a LVV plasmid, both upstream and downstream processes will affect the manufacturing efficiency. This case study shows how these two processes can be optimized.

During the upstream process, the medium will be optimized. The key parameters include pH, component, and temperature. The results show approximately 3 times increase of fermentation yield after optimization.

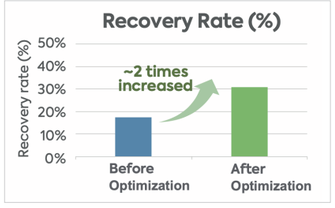
Fermentation Yield Comparison Between Before Optimization and After Optimization



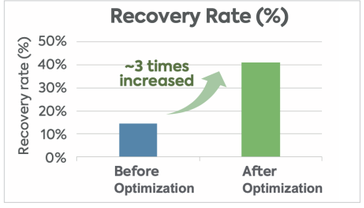


In the downstream process, key steps include lysis, clarification and GF, HIC and AEX. The data in two cases shows a range of 2-3 times increase in recovery rate after the optimization.

Range of Recovery Rate after Optimization



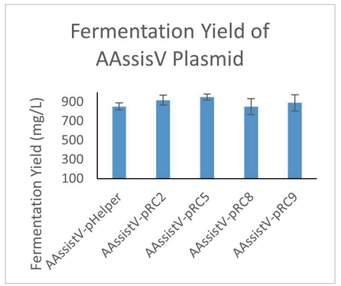
Case 1

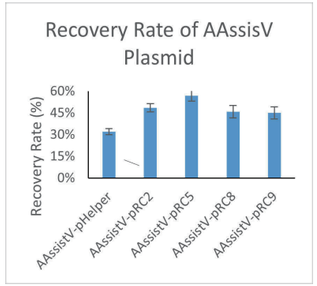


Case 2

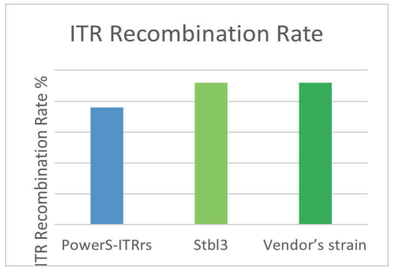
Case Study: Plasmid for AAV in Gene Therapy

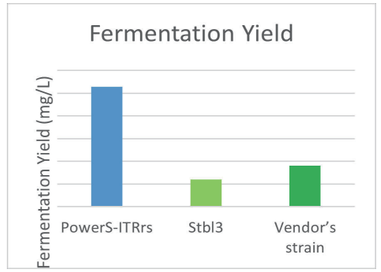
AAV vectors are produced from the triple transient transfection system, with one helper plasmid (AAssistV-pHelper), one Rep/Cap plasmid (AAssistV-pRC), and one transfer plasmid. Through the high density fermentation and chromatographic purification process, the fermentation yield of AAssistV plasmid is larger than 850mg/L with the recovery rate ranges from 30-60%.





The major challenge for AAV plasmid manufacturing is ITR structure, a special structure in AAV transfer plasmid. The ITR regions in AAV transfer plasmids are notoriously unstable, which is easy to recombine during the manufacturing process. Disruption of ITR reduces plasmid integrity, and increases variability in downstream studies. In order to solve the issue, PowerS-ITRrs strain is developed by GenScript ProBio. The newly developed strain presents a low ITR recombination rate with a high fermentation yield.

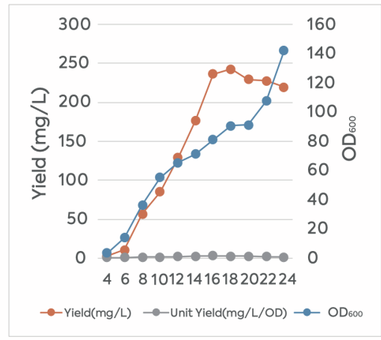


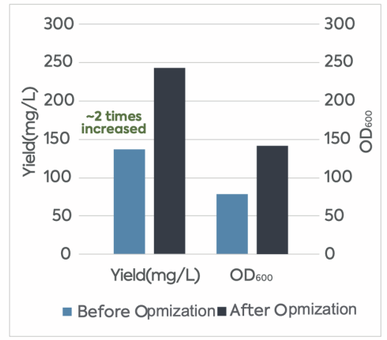


Case Study: Plasmid and Linearized DNA in mRNA Vaccine/Drug

Plasmid: In order to control and prevent COVID-19, mRNA vaccination has been shown to be an effective and economical intervention. However, during manufacturing, the low plasmid yield is still a big concern. Through controlling the key parameters including pH, component, and temperature, the fermentation yield has doubled for the plasmid that has 151 bp poly (A) length.

Fermentation Yield Comparison Between Before Optimization and After Optimization





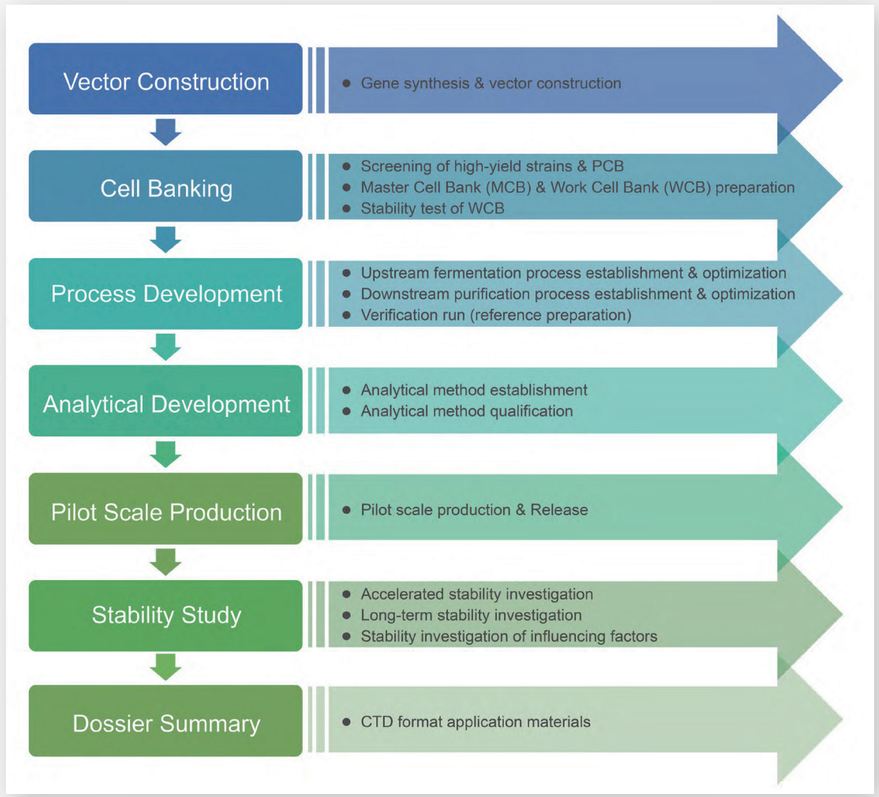
Linearized DNA: During the process of plasmid linearization, the recovery rate is the main concern during the manufacturing process. With over 30 batches of experience, GenScript ProBio's Linearized DNA has maintained a high recovery rate, which can be up to 80% and with an average from 30% to 60%.

XbaI Enzyme

Plasmid Length	4.7 K bp
Poly A	95 bp
Fermentation Scale	5 L
Service	PreCMC
Recovery Rate	39.87%

GenScript ProBio plasmid platform:

- ✓ Internal & compliance gene synthesis for plasmid construction, clear traceability
- ✓ LentiHelper and AAssistV plasmid are DMF ready, saving time and cost
- ✓ FDA*Ready*/EMA*Ready* CMC: 4-month support for IND filing
- ✓ Strong track record: Over 35 IND cases approved from NMPA to FDA, from cell therapy to gene therapy and mRNA vaccine/drugs
- ✓ Various applications: CAR-T, TCR-T, CAR-NK, CRISPR editing cell therapy, gene therapy, mRNA vaccine, DNA vaccine, etc.
- ✓ Plasmid facility from IND to commercialization (5-300L) in the US and China



GenScript ProBio develops and manufactures plasmid for a wide range of applications, designed to meet all requirements, with rapid turn-around time and 100% on-time delivery rate.

Learn More Here

Solid Track Records

Biologics

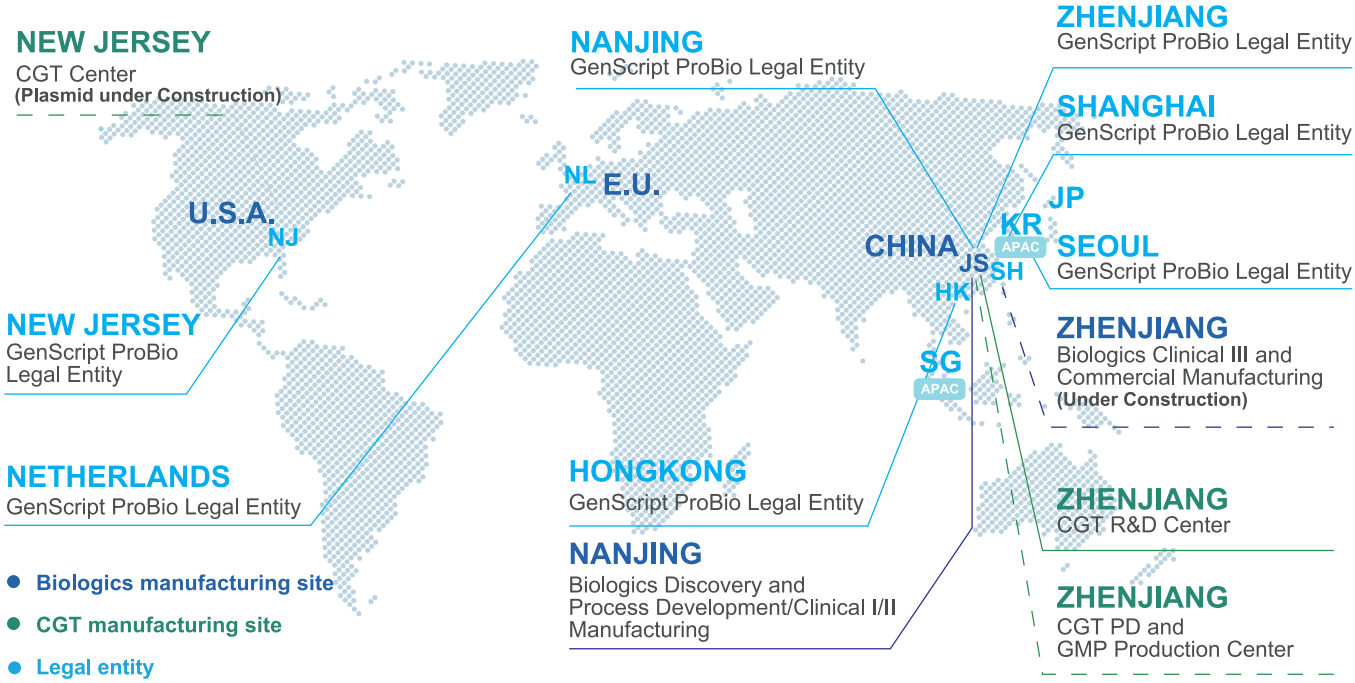
- **14** International License-out projects
- **90+** CMC & CMO projects
- **30+** IND approvals from NMPA and FDA
- **110+** GMP batches completed

CGT

- **60+** Global CMC projects
- **40+** IND approvals from NMPA, FDA and PMDA, MFDS: CAR-T, TCR-T, mRNA vaccine and CRISPR related cell therapy
- **400+** Global Clinical mfg. batches

*By Oct 2023

Global Footprint



GenScript PROBIO

Innovation Through Collaboration