



Plasmid DNA Manufacturing - R&D and GMP

One-stop CDMO Service Platform
for Cell and Gene Therapy



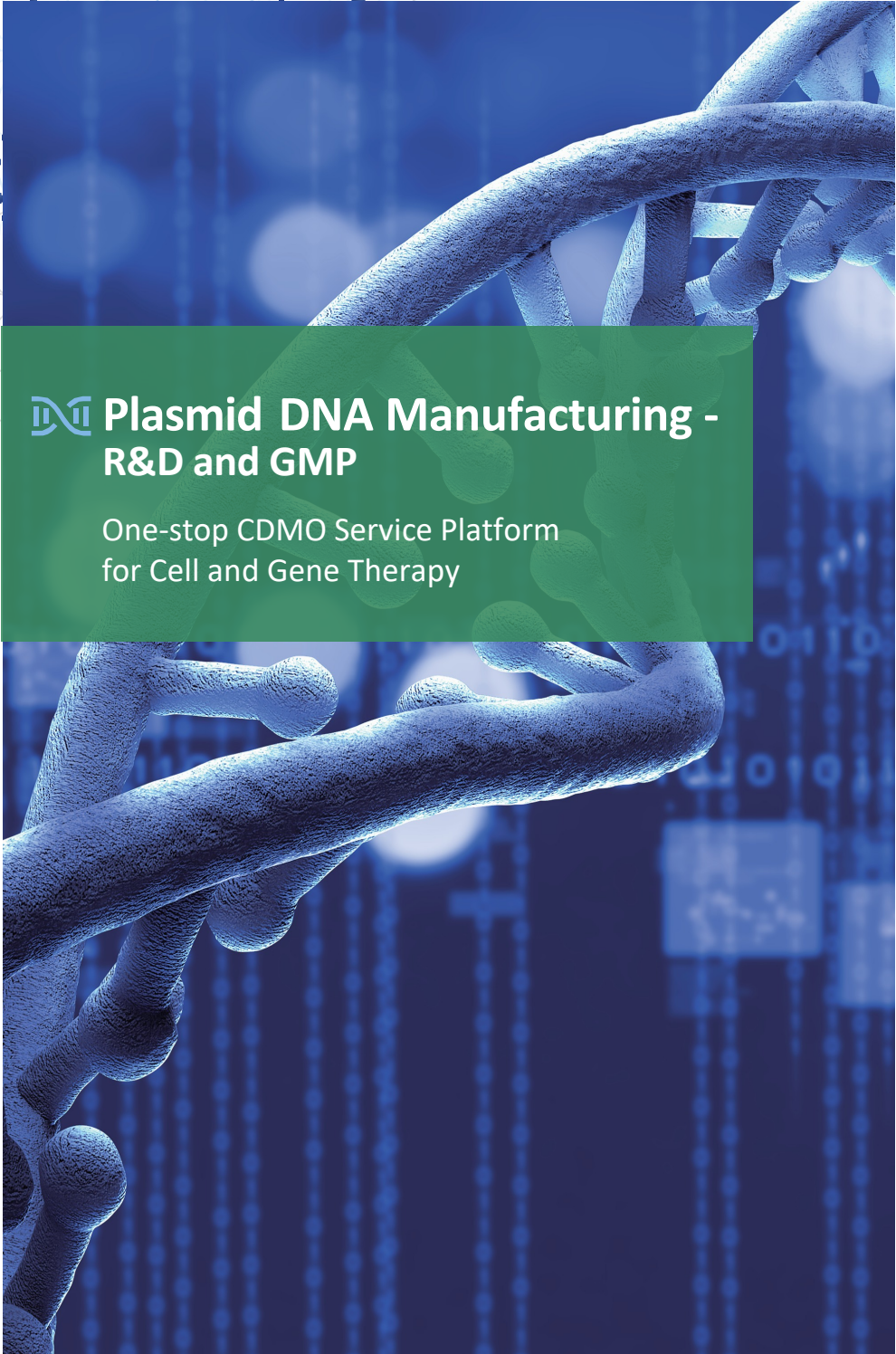
Single-use
fermentor



Two-step
chromatography
purification



Helper plasmids
in stock



Your bridge from ATMPs concept to commercialization

Canada

1208-13351 Commerce Parkway
Richmond, BC V6V 2X7 Canada

contact@ubrigene.com

www.ubrigene.com

+1 604 227 7066 / 1800 663 2528

United States

20400 Century Blvd, STE125
Germantown, MD 20874

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Biosciences International Co.

China

B16, 2nd Floor
Ai North Tower
No.218 Xinghu Street
Suzhou Industrial Park
Jiangsu Province 210000

GMP Plasmid Production



Reliable Quality

High yield, high purity, no antibiotics, no animal-derived components



Established Process

Two-step chromatography purification
Shortened project cycle
Linearly scalable



Extensive Experience

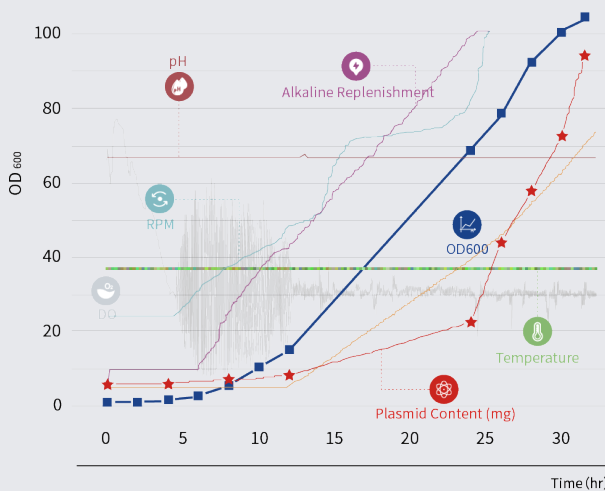
300+ batches of GMP plasmid production experience
Well-established process using 10L, 50L, and 200L single use fermenters

uBriGene is dedicated to large-scale PD and production of GMP plasmids. Our comprehensive platform for PD, QC, and QA fully meets large-scale production needs of CGT plasmids.

Upstream Fermentation

At uBriGene, the PD of upstream plasmid production involves optimizing pH, temperature, dissolved oxygen, feed rate, and fermentation time during pilot batch and engineering runs. Bacterial growth and metabolism, fermentation density, and plasmid yield are closely monitored to obtain a stable and efficient fermentation process. uBriGene's established high-yield GMP plasmid fermentation process is scalable for manufacturing volumes ranging from 2L to 200L.

Fermentation Optimization



Single-use fermenter



Fermentation yield >1g/L

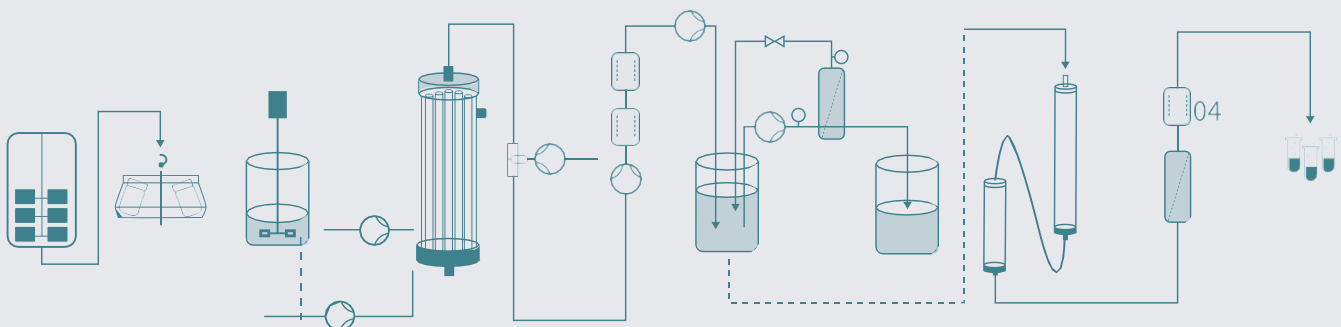


Antibiotics-free fermentation



No animal-derived components

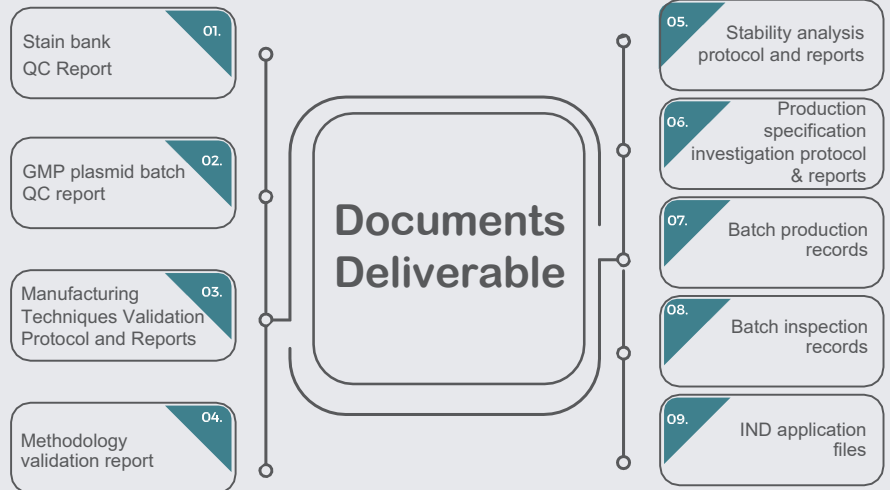
Fermentation Harvest Suspension Lysis Clarification Concentration by Diafiltration Chromatography Concentration/Sterilization Fill & Finish



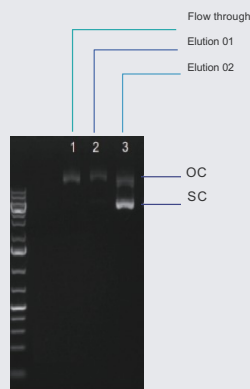
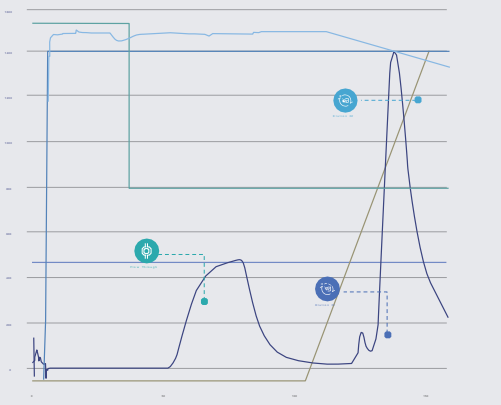
Comprehensive CMC development data for IND applications

Downstream Purification

uBriGene's downstream purification of plasmids involves well-established continuous alkaline lysis and two-step column chromatography purification. This process removes impurities effectively and remains reliable after scale-up, allowing high-yield and high-purity plasmid production to meet clinical trial and commercialization needs.

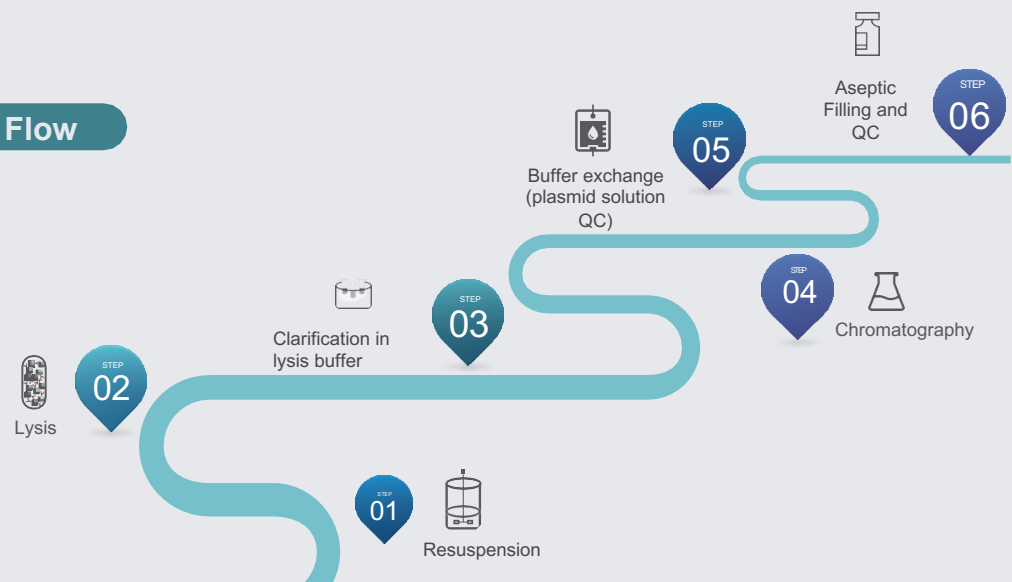


Process Highlights



- Two-step chromatography
- Effective removal of impurities
- Supercoil ratio >95%
- High recovery rate

Purification Process Flow



GMP Plasmid Release Testing

Your bridge from ATMPs
concept to commercialization

04/04

Rigorous product release
quality standards



Comprehensive methodology
development documentation

QC Categories	QC Method
Plasmid concentration	UV-Vis spectrophotometry
Appearance	Visual inspection
Plasmid identity	Restriction enzyme digestion
	Sanger sequencing
Plasmid purity	A260/A280
	UV-Vis spectrophotometry
	Supercoil ratio
	Gel-electrophoresis/HPLC
Endotoxin	Host cell protein (HCP)
	ELISA
	Host cell DNA (HCD)
Sterility	qPCR
	Host cell RNA (HCR)
pH	Gel-electrophoresis
	Direct-clot method
	Direct-culture method
	pH meter



Service Highlights

uBriGene specializes in the development of large-scale GMP plasmid production processes. Through continuous innovation and optimization, a comprehensive platform of production process, QC, and QA has been established, fully meeting large-scale production needs of clinical CGT plasmids. uBriGene has completed the development and validation of 300+ GMP plasmid products and provided related development data for clients' IND applications. The project timeline can be greatly shortened when collaborating with our clients, as only the confirmation of methodology is necessary.

Comprehensive Methodology Development



Knowledgeable international technical team with 10+ years of viral vector industrial experience. An international CDMO service provider:

- [Suzhou GMP facility](#): almost 100,000 sq ft
- [Jinan GMP facility](#): 54,000 sq ft
- [Canada CMC center](#)
- [U.S. CMC center](#)

Filing services for both FDA and CFDA

- Grade A isolator with Grade C background
- Independent HVACs for each suite
- Fully enclosed Grade A production system

Diversified upstream fermentation/cell culture platform.

- Single-use Bacteria fermentation scales: 10L, 50L, 200L
- Single-use cell culture bioreactor scales: 50L, 200L, 500L, 2000L

Highly effective downstream purification with two-step chromatography technique

Guaranteed high purity, reduced cost, and increased recovery.

Complete life-cycle quality management

QC platforms for chemistry, microbiology, and biochemistry

Comprehensive, fully compliant QA system