

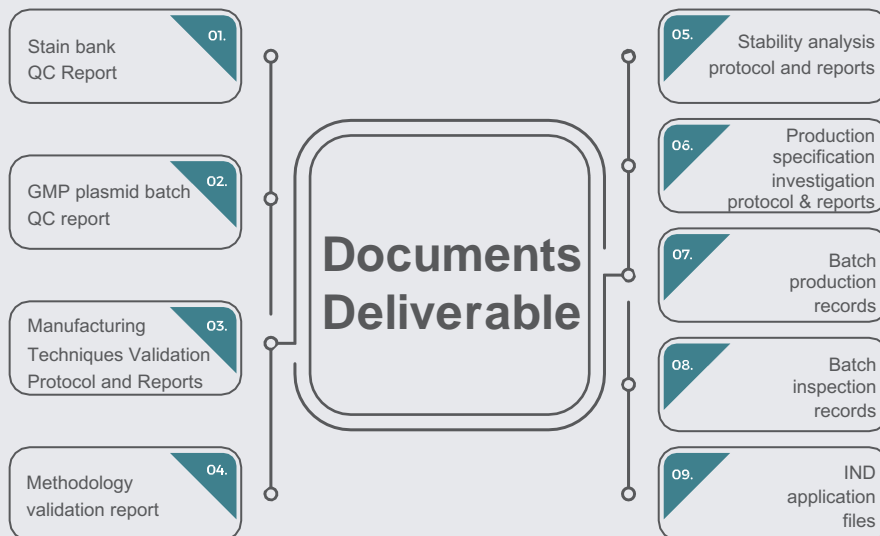




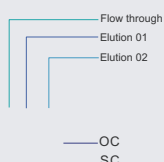
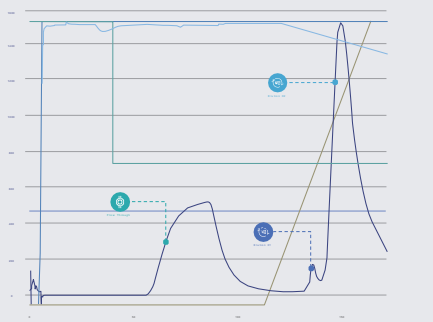
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**DNA 6 "Q1 , :\$. + = %9#\$R>\*+>" 1**

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.



**DNA 9\$ " \* . , , %T>G3'>G3: ,**

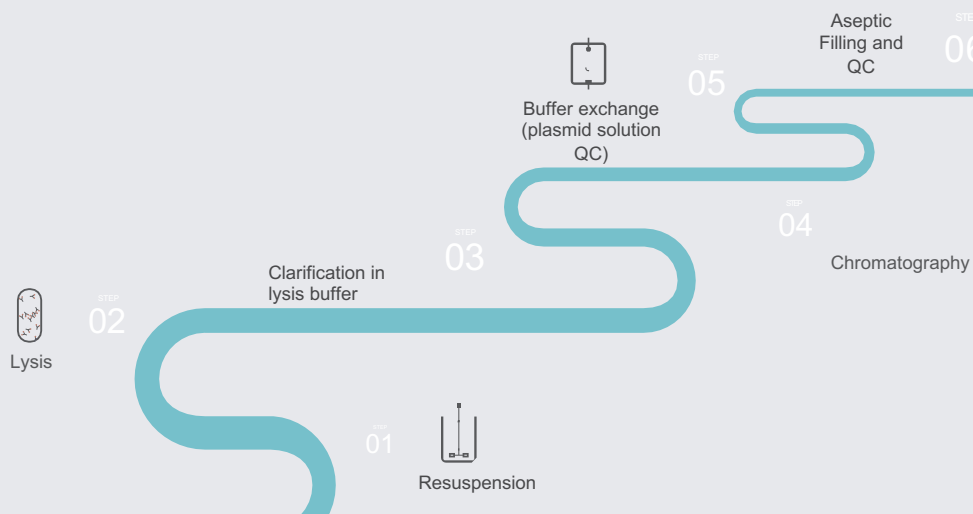


**Product Shipping**



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

**DNA 9#\$R>\*+>" 1%9\$ " \* . , , %<' " Q**



## GMP Plasmid Release Testing

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
	Host cell protein (HCP)
Host cell DNA (HCD)	ELISA
	qPCR
	Host cell RNA (HCR)
Endotoxin	Gel-electrophoresis
	Gel-clot method
Sterility	Direct-culture method
pH	pH meter



### Comprehensive Methodology Development

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.



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