



**Enabling Advanced** Gene and mRNA Therapies with Plasmid DNA.

BioCina is your partner of choice for costeffective development and manufacturing solutions for highquality cGMP plasmid DNA.

## **Plasmid DNA Offerings**

We provide large-scale high quality cGMP manufacture of complex plasmids for the production of mRNA and viral vector-based gene therapies.

We provide the know-how and the resources for large-scale and challenging projects. We pay attention to every detail and ensure excellence at all stages of development and plasmid manufacturing.

We offer optimal plasmid host cell line selection from an in-house cell line library, cell banking and extensive testing. Our manufacturing processes employ the leading-edge technologies as well as fully enclosed, single-use systems to ensure a sanitary environment throughout manufacturing.

BioCina partners with clients from pre-clinical development through commercial production. We fully leverage our team's exceptional knowledge and experience to guide your journey to product approval with success and confidence.

## Large-Scale Plasmid DNA and mcDNA Manufacturing Process\*

Fermentation	Cell Concentration	Continuous Cell Lysis	Primary & Secondary Clarification	Concentration / Buffer Exchange	Chromatographic Separation	Concentration / Formulation	Final Filtration
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## Development and Manufacturing Scales

Stage	Equipment	Working Volume	Yield
Process Development	2 L Fermenter	Up to 1 L	50 — 200 mg
cGMP Manufacturing	435 L SUB Fermenter 750 L SS Fermenter	65 — 500 L	5+ g

## Typical Plasmid DNA Development and Manufacturing Timelines

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3 Months →	6 Months →	9 Months →	
Cell Line Development, Cell Banking	3 months to MCB release for use		
	Technology and Analytical Verification 5 months to Process Transfer / Scale-Up		
	8 months to cGMP Batch Disposition Process Scale-	Up, ENG, cGMP Batch Manufacturing	