

Plasmid DNA



BioCina
YOUR MICROBIAL EXPERTS

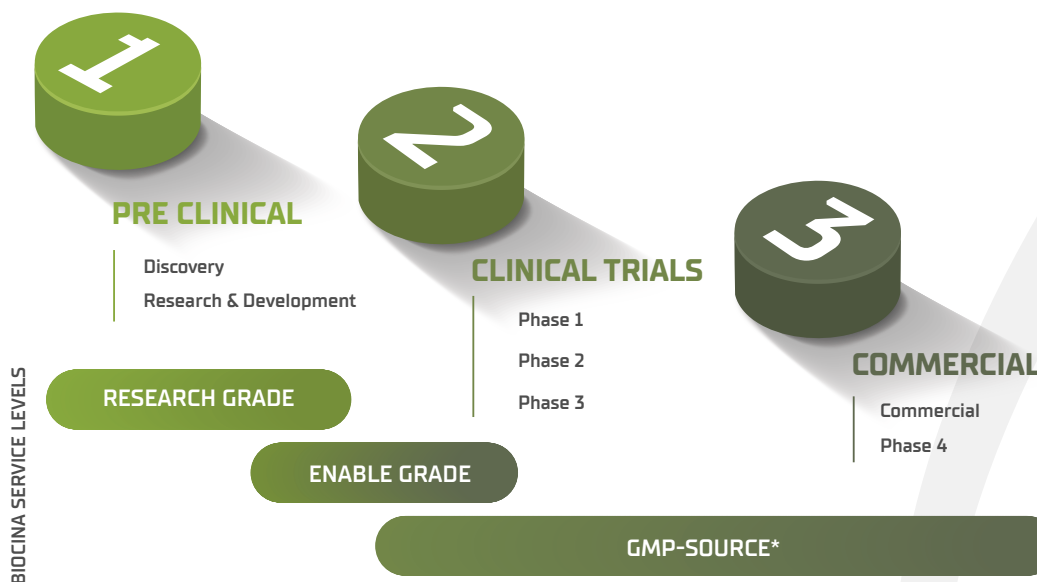
BioCina is your partner for high-quality, cost-effective microbial process development and cGMP manufacturing solutions for recombinant proteins and GMP plasmid DNA. Our professional and experienced project management team will guide the efficient development, delivery, and supply of all your contract development and cGMP manufacturing requirements.

BioCina supplies bulk plasmid DNA in three grades:

- Research
- Highly Documented
- GMP-grade plasmid DNA for pre-clinical to commercial use.

All three grades are supplied as non-sterile bulk (DS or API). Our capabilities include host/plasmid selection from an in-house host library, cell banking and testing.

GRADES OF PLASMIDS FOR DIFFERENT STAGES OF PRODUCT LIFECYCLE



NOTE: The services outlined above are a visual representation of possible client selections.

R&D manufacturing typically consists of a 1-20L scale fermentation with matching scaled lysis and downstream purification. GMP plasmid manufacturing follows Good Manufacturing Practices for production and release testing of bulk product for clinical trials through to commercial supply. Our GMP manufacturing fermentation capabilities include 20 and 500 L (wv) Stainless Steel fermenters and a 300 L (wv) single use fermenter. Lysis and downstream processing equipment are scaled to match.

pDNA manufacturing capability			
Instrument	Working Volume	Scale	Plasmid Yield
2L Fermenter x8	400 mL-1L	Small	50-200mg
30L Fermenter	6-20L	Small/Medium	50-1000mg
435L S.U.B Fermenter	60-300L	Medium/Large	>10g

BioCina Plasmid DNA Offerings

		PLASMID DNA PRODUCTION		
		Research Grade	Highly Documented	GMP
MANUFACTURING	Manufacturing Documentation	✓ R&D Controlled	✓ R&D Batch record	✓ GMP Batch Record
	Process Development or Optimization	✓	✓	✓
	ISO Classified Suite		✓	✓
	Cell Banking (WCB)		✓	✓
	Bill of Materials and Lot traceability		✓ R&D Controlled	✓
	TSE/BSE Statement		✓	✓
	Raw material / Excipients Release		✓ CoA release	✓ QA release
QUALITY CONTROL	Product Final Testing	✓ R&D	✓ R&D / QC	✓ QC
	Product In-Process Testing		✓ R&D / QC	✓ QC
	Test Method Validation		✓	✓
QUALITY ASSURANCE	Certification of Test / Analysis		✓	✓
	Product specific investigations		✓	✓
	QA Oversight			✓
	Certificate of Manufacture			✓

All manufacturing processes are defined and controlled to ensure compliance. BioCina's intermediate grade of highly documented plasmid bridges the gap between R&D and GMP and was designed to provide plasmid for use as a raw material in a GMP process, such as for GMP virus production or toxicology studies.