

BioCina provides pharmaceutical grade GMP microbial fermentation manufacturing of various proteins and GMP plasmid DNA. A science driven CDMO that is agile, accessible and has proven ability.

Isn't it time your CDMO is as invested in your success as you are?

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# Plasmid DNA

High Quality, Cost-Effective Microbial Process Development and cGMP Manufacturing Solutions for recombinant proteins and GMP Plasmid DNA.





**BioCina is a science driven CDMO, providing pharmaceutical grade GMP Microbial fermentation manufacturing of various proteins and GMP plasmid DNA.**

**We are an agile and trusted CDMO with access to capacity and with proven ability to execute through to commercial phase.**

BioCina supplies bulk plasmid DNA in three grades:

- R&D
- 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.

R&D manufacturing typically consists of a 1-20L scale fermentation with matching scaled lysis and downstream purification.

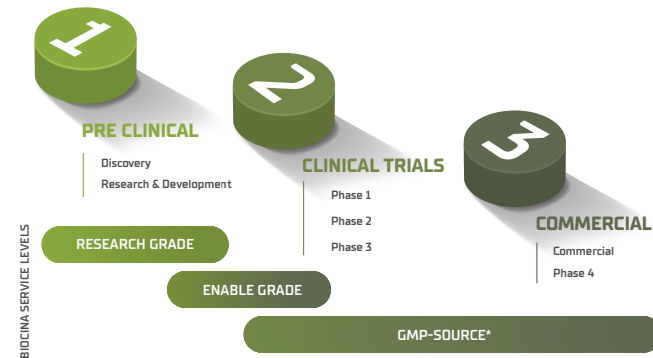
**Your cGMP Partner bridging the gap from laboratory bench to first-in human trials and beyond.**

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. All manufacturing processes are defined and controlled to ensure compliance.

BioCina's intermediate grade of non-GMP/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.

## GRADES OF PLASMIDS FOR DIFFERENT STAGES OF PRODUCT LIFECYCLE



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

## BioCina Plasmid DNA Offerings

		PLASMID DNA PRODUCTION		
		Research Grade	GMP-Like	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	Certificate of Test / Analysis		✓	✓
	Product specific investigations		✓	✓
	QA Oversight			✓
	Certificate of Manufacture			✓