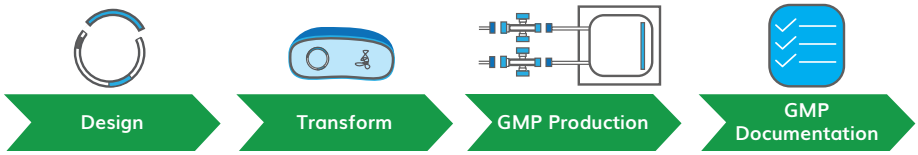
LakePharma
The Biologics Company

GMP-Grade Plasmid DNA microBiomanufacturing Services

End-to-end capabilities from vector design to GMP manufacturing

LakePharma offers vector construction, *E. coli* cell bank development, master and working cell bank generation, and two grades of GMP plasmid DNA manufacturing at its Hopkinton, MA facility, conveniently located near the Boston biotech hub.

Employing the microBiomanufacturing™ approach for plasmid production, LakePharma offers shorter queue times and quicker turnaround times. Plasmid DNA can be produced in batch sizes of milligram to multi-gram scale.



- Gene sequence
- Gene synthesis
- Clone gene into plasmid vector

- Transform plasmid into *E. coli* strain
- Generate cell bank

- Grow and purify
- In-process and release testing

- Batch records
- QC results
- QA release

LakePharma offers end-to-end plasmid production services from vector design to GMP manufacturing and documentation.

Highlights

- Two GMP grades of plasmid DNA to meet your needs
- Experienced, customer-focused teams to support your project
- Single-use technologies to reduce potential cross-contamination
- Integrated platform technologies to deliver best-in-class materials for your drug development needs

LakePharma Provides Two Grades of Plasmid DNA

	GMP-Ready (10 -500 mg/batch)	GMP (100 - 500 mg/batch)
Process Development: Transformation Assessment and Evaluation	✓	
ISO Cleanroom Manufacturing	✓	✓
Single-Use Equipment and Materials	✓	✓ (Aseptic Connections)
Approved Batch Record	✓	✓
Standardized In-Process Control Tests		✓
Chromatographic Purification	✓	✓
Raw Material Release	✓	✓
Manufacturing Summary Report		✓
Certificate of Analysis	✓	✓ (Full Panel Release Testing)
Client-Approved Change Control		✓

Additional Services Available Upon Request

- Development work and engineering run prior to GMP production
- Specific process control and analytical method development
- Formulation of concentration to client specification
- Client-specific Master Batch Records

For more information, visit lakepharma.com/GMP-plasmid-manufacturing.

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