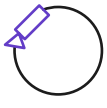
Biopharmaceutical manufacturing

GMP Plasmid DNA

From Tox studies to clinical phases up to commercialization

With over 20 years of expertise in Plasmid DNA (pDNA) manufacturing, Eurogentec is a trusted CDMO. Operating from FDA-inspected facilities, we leverage an optimized high-yield process and certified project management to drive the success of your therapeutic programs.

20+ years of experience



For APIs & Starting Materials

Small & large scale

Certified project management

From Starting Material to API

Our GMP manufacturing capabilities support the production of plasmid DNA for a wide range of applications. Whether as a **Starting Material** for **mRNA synthesis** and **viral vector** manufacturing, or as an Active Pharmaceutical Ingredient (API) for **DNA vaccines** and **non-viral gene therapies**.

pDNA MANUFACTURING LEADER

Over 1 kg of pDNA per batch
Provider of Starting Material for FDA-approved drugs

Optimized GMP process designed for success

Our GMP-compliant process, built on **Quality by Design** (QbD) principles, includes our proprietary lysis method and a single chromatography step. It ensures **high yields, consistent batch** performance, and **scalable** production, all while meeting stringent regulatory requirements.

Its inherent **flexibility** enables a seamless transition from clinical phases to Process Performance Qualification (PPQ) and full commercial manufacturing.

PROCESS DEVELOPMENT

- **Non-animal origin materials**
- **Plasmid sizes from 1.5 - 20.0 kbp**
- **High-yield**
- **Cost-effective GMP plasmid DNA production**

1. Master cell bank

- Use of the cell bank provided by the client
- Or manufacturing of an *E. coli* master cell bank, and its characterization and stability testing

2. Fed-batch fermentation

- High-yield proprietary HyperGro® technology
- Scale-up from 80 L to 2,200 L
- Batch sizes from 1 g to kilo scale

3. Lysis

- Optimized scalable proprietary process

4. Purification

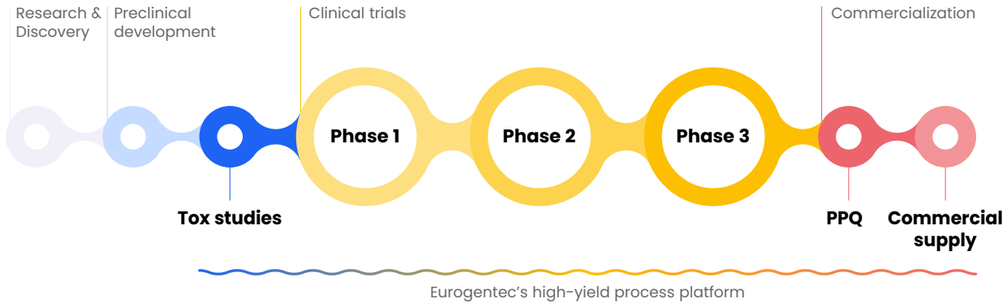
- Proprietary one-chromatography-step purification technology
- High yield
- High purity
- Above FDA quality requirements

5. GMP product release

- Quality review
- Manufacturing report
- CoA
- TSE/BSE-free statement
- GMP statement
- Client-specific batch record
- Formal stability studies (ICH)

Expert GMP pDNA production at every scale

With a strong track record in microbial fermentation, we manufacture GMP plasmid DNA **in gram to kilo-scale** quantities. Our flexible manufacturing supports a wide range of therapeutic applications from **preclinical** tox studies to **clinical** trials and **commercial** supply. Production is carried out in **dedicated GMP suites** equipped with fermenters ranging **from 80 to 2,200 liters**.



GMP QC package

Our GMP QC package **includes all the required release testing** to ensure the identity, purity, safety, and compliance of each plasmid batch. All methods are validated or qualified according to GMP standards.

** on demand*

Attributes	Testing
Identity	Restriction mapping
	DNA sequencing
Purity	Plasmid topology by HPLC or CGE
	UV Ratio 260/280
Physico-chemical	Visible particles*
	Appearance (instrumental methods or visual inspection)
	pH
	Osmolality*
Residuals	Host Cell Proteins by ELISA
	Residual Host Cell genomic DNA
	Host cell RNA by HPLC (limit test)
	Host cell genomic DNA by qPCR
	Antifoam by ICP/MS
	Antibiotic by RP-HPLC-MS*
Safety	Bioburden
	Endotoxin content by LAL kinetic method
	Mycoplasma detection*
Content	DNA concentration by UV (A260)

Certified project management

Our certified project managers provide **end-to-end support** with **transparent communication** at every stage. Working closely with your team, we **anticipate challenges** and drive project execution to deliver your product within the defined timeline. Supported by extensive regulatory experience, we also assist in preparing your submission files to keep your development on track.

State-of-the-art facilities

All GMP material is produced in our **GMP certified facilities in Belgium** in accordance to FDA 21 CFR Part 210 & 211, EU 2003/94/EC, Eudralex Vol 4, and relevant ICH.

Scan this code and

Discuss your project with us!

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