3PBIOVIAN

Plasmid DNA services

HQ and GMP grade

3PBIOVIAN manufactures plasmid DNA (pDNA) for a variety of client projects. Our high-quality (HQ) and GMP pDNA may be used in viral vector manufacturing for those gene therapies where pDNA constructs serve as raw material to develop novel DNA or mRNA vaccines and non-viral gene therapy applications.

Research and GMP grade cell banks

- DH5α, Stable, or 10β *E. coli* strains
- Starting from a sequence or a plasmid

Upstream processes

- HQ fermentation 20 – 40 L
- GMP fermentation up to 200 L
- Harvesting by centrifugation or TFF
- Alkaline lysis

Downstream processes

- In-house chromatographic purification platform
- Custom processes possible

Fill and finish

- Standard and custom formulations
- Fill and Finish
- Labelling

Quality control

- IPC and release testing
- HQ or GMP level certifications
- Analysis and TSE/BSE certificate
- Stability studies as requested and required

pDNA available off-the-shelf

- pHelper
- pRep/Cap (several wild types available)
- GoI

- Freedom to operate plasmids
- High quality, high yield
- Backbones suitable for clinical trials
- pHelper 100% free of fiber and hexon genes

3PBIOVIAN

+550 employees

Manufacturing sites located in Turku, Finland and Pamplona, Spain

Over 195 clients in 22 countries

EMA certified and FDA inspected for GMP production

+20 years of GMP experience

Plasmid DNA services

3PBIOVIAN

Plasmid DNA manufacturing at 3PBIOVIAN		HQ grade	GMP grade
Development	Plasmid construction	If agreed	If agreed
	Fermentation optimization / demonstration	If agreed	If agreed
Cell banks	RCB	Yes	If agreed
	MCB (GMP grade)	If agreed	Yes
Raw materials	GMP grade	Yes	Yes
	QA batch release	No	Yes
	Free of animal origin	Yes	Yes
	Qualified vendors	No	Yes
Facility	GMP EU classified clean room production suites	No	Yes
	Segregated production suites	Yes	Yes
	Line clearance protocol	Non-GMP	GMP
	Environmental control	No	Yes
Manufacturing	Batch records approved by	Production Manager	QA
	Standardized and scalable process	Yes	Yes
	In Process Control analysis	Yes	Yes
	Fermentation volumes	20 - 40 L	Up to 200 L
	Filling	Manual, non-GMP	GMP
Quality Management	Change control managed by	Production Manager	QA
	Deviations managed by	Production Manager	QA
	Raw material traceability	Non-GMP	GMP
	QA oversight	No	Yes
	Plasmid product specification	Yes	Yes
	QC testing	Yes (Non-qualified)	Yes (Qualified)
	Batch release by	QC and Production Manager	QA
Deliverables	Certificate of Analysis (CoA)	No	Yes
	Certificate of Testing (CoT)	Yes	No
	Certificate of Compliance (CoC GMP)	No	Yes
	Manufacturing summary report	Limited	Yes
	TSE/BSE-free statement by	Production Manager	QA
	Stability Studies	If agreed	If agreed

Plasmid DNA QC testing Key characteristics	HQ grade	GMP grade
Endotoxin	< 40 EU/mg	< 10 EU/mg
Residual host cell protein	< 2.0 %	< 1.0 %
Residual host cell gDNA	< 5.0 %	< 1.0 %
Residual host cell RNA	< 5.0 %	< 1.0 %
Identity and integrity	Sequencing, REA	Sequencing, REA
DNA purity	1.80-2.00	1.80-2.00
Homogeneity	> 80 % sc.	> 80 % sc.

MANUFACTURING TIMELINES

HQ pDNA | *3-4 months*

- Starting material for GMP grade viral vector production
- Drug substance or DNA vaccine for in vitro or in vivo applications

GMP pDNA | *6 months*

- Starting material for phase I, II, III, and commercial viral vector manufacturing
- pDNA vaccines and direct gene therapies