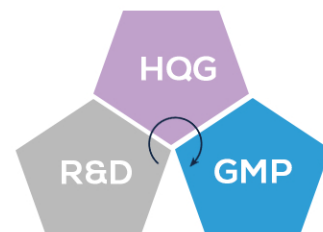


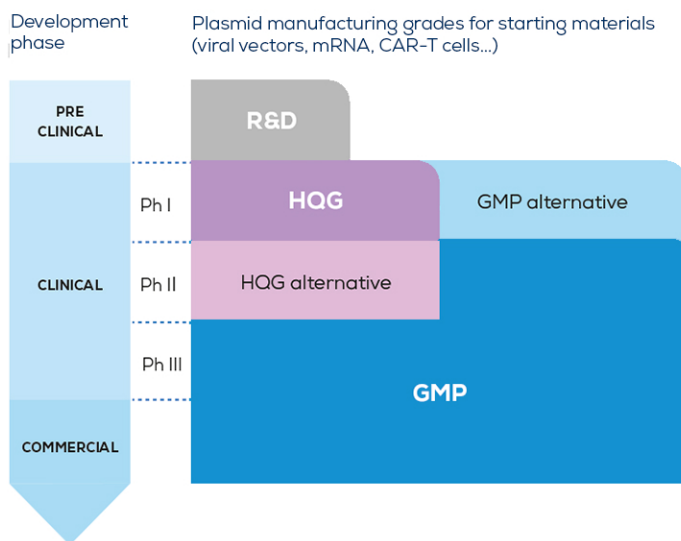


CUSTOM PLASMID DNA MANUFACTURING SERVICES



WHY CHOOSE RD-BIOTECH?

- ✓ **One stop shop partner** for your discovery & manufacturing needs
- ✓ **Over 20 years of experience** in molecular biology & biomanufacturing
- ✓ Complete offer from **early discovery** (pDNA cloning) to **commercial manufacturing** (GMP grade)
- ✓ **Three quality grades** to meet each phases of your development
- ✓ **Scalable process** of pDNA production **from several mg up to 20 g**, for R&D, High Quality & GMP grades
- ✓ **Cost effective & adaptable process** to **meet your requirements**



PLASMID BIOMANUFACTURING SERVICE

Description	Research	High Quality	GMP
Screening / feasibility steps for optimal conditions	●	●	● **
Upstream: Shaker flasks production	●	● *	
Upstream: Fermenter production	●	●	●
Downstream: Giga prep column purification	●	● *	
Downstream: Double process purification (Chromatography)		●	●
Downstream: Industrial purification process		●	●
<i>E.coli</i> master cell bank		●	●
Single use materials		●	●
Animal free, RNase free, Alcohol free process		●	●
Certificate of analysis (CoA)	●	●	●
Manufacturing batch record		●	●
Change control management	●	●	●
Dedicated production room		●	●
Classified GMP production suites			●
Aseptic fill & finish under isolator (Class A) in class C room		●	●
Master batch records		●	●
Full digital batch record			●
Environmental monitoring			●
QA release			●

* Competitive process for small scale HQG production

** Adaptability phase / Process development

Customize and produce your plasmid with RD-Biotech, a full integrated expertise

QUALITY CONTROLS

Test	Method	Specification	Research	High Quality	GMP
All QC are performed in independent lab					●
Appearance	Visual inspection	Clear and colorless Particles free	●	●	●
Plasmid concentration	Spectrometry UV	To be defined	●	●	●
Plasmid purity	Spectrometry UV 260/280 nm	Ratio between 1.8-2.0	●	●	●
Plasmid identity	Restriction enzyme & AGE	Conform to expected band patterns	●	●	●
Plasmid conformation	AGE	Mostly supercoiled	●		
Plasmid conformation	Affinity chromatography	Supercoiled rate >80%		●	●
Poly A tail integrity	Acrylamide gel electrophoresis & Sequencing	Conform to expected data	●	●	●
Residual RNA	AGE	Not visible	●	●	●
Mycoplasma	qPCR	Absence		●	●
Residual bacterial genomic DNA	AGE	Not visible	●		
Residual bacterial genomic DNA	qPCR	<50 µg/ml (<5%)		●	●
Endotoxins content	Quantitative LAL assay	<100 EU/mg	●		
Endotoxins content	Quantitative LAL assay	<10 EU/mg		●	●
Plasmid sequence	Sanger sequencing	100% homology with reference sequence	On request	●	●
Residual host cell proteins	µBCA	<10 µg/ml (<5%)		●	●
Bioburden µorganisms determination (TAMC, TAnMC, TYMC)	Membrane filtration	<1CFU/mg		●	●
Sterility	Direct inoculation	No growth in 5% of production		●	●
pH	Physical measurement	6≤pH≤8.5		●	●
Stability study			On request	On request	On request



**THE RD-BIOTECH
ONE STOP SOLUTION**



pDNA Design & Engineering
Cloning / Subcloning



Screening



pDNA manufacturing
3 quality grades

*Customize and produce your plasmid with RD-Biotech, a full integrated expertise
and a scalable production process from discovery to commercial phases*

