



BIOLOGICS SOLUTIONS

Plasmid DNA (Research, High Quality, and GMP) Contract Development and Manufacturing Services and Products

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Questions for our specialists?

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Related Services

- [Viral Vector CDMO Services](#)
- [Viral Vector Packaging Services](#)
- [Plasmid and Viral Vector Products](#)
- [Molecular Cloning Services](#)
- [Cell Therapy CDMO Services](#)

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We offer plasmid DNA CDMO solutions with centers of excellence in the UK, providing a variety of products and services from early discovery through commercialization including off-the-shelf to custom plasmid products and manufacturing services comprised of three grades – Research, High Quality (HQ), and GMP, with off-the-shelf timelines from 48 hours and custom production from five weeks.

Available Services and Products

Molecular Biology

- Plasmid synthesis
- Custom construction and engineering
- Clone screening

Process Development and Scale Up

- Fermentation and media development (animal component free)
- Evaluation of productivity and optimisation of harvest point
- Lysis optimisation (primary recovery)
- Purification development and optimization
- DoE (Upstream and Downstream)

Analytical Development and Qualification

- Assay transfer, development and validation
- QC release testing (BDS/DP)
- Product characterisation
- Stability studies: drug substance and drug product

Quality Assurance and Regulatory Support

- Three Qualified Persons (QP) (Keele, UK)
- Fully compliant with European Clinical Trials Directive 2001/20/EC and FDA standards (Keele, UK)
- Authorised by UK MHRA for the GMP production of Investigational Medicinal Products (Keele, UK)
- Support for CMC filings
- QP release (Keele, UK)
- Shipment to clinical trial sites

Project Management

- Dedicated project manager
- Cross-functional project teams
- Detailed timeline planning and milestone tracking

Off-the-Shelf HQ Viral Vector Packaging Plasmids

- Premanufactured - 48 hour turnaround
- High Quality grade for viral vector GMP production
- GMP quality control (QC) testing
- Kan^r resistance
- Animal component free production

EVERY STEP OF THE WAY

Plasmid DNA Manufacturing Comparison

Plasmid DNA Production Conditions and Options	Research Grade	High Quality (HQ)	GMP
Cloning/Synthesis/Mutagenesis of plasmid (optional)	✓	✓	✓
Scale-up and manufacturing of existing plasmid constructs	✓	✓	✓
Proven manufacturing and purification processes for high yield and recovery	✓	✓	✓
Standardized manufacturing platform processes (optional for Research Grade)*	✓	✓	✓
Establishment of E. coli master and working cell banks (optional)		✓	✓
Upstream PD (optimization of transformation and culture conditions, strain, etc.)		✓	✓
Downstream PD (optimization of purification and formulation conditions)		✓	✓
Full traceability of materials		✓	✓
Full room changeover prior to each production		✓	✓
Production in segregated and dedicated space		✓	✓
Process and change control		✓	✓
Aseptic fill and finish**		✓	✓
Document support for IND and IMPD filing		✓	✓
Master Batch Records		✓	✓
Stability studies (optional)		✓	✓
Certificate of Analysis		✓	✓
Manufacturing in GMP suite with graded air			✓
Environmental monitoring throughout production process			✓
QA oversight for production			✓

*RNase A and RNase A free processes available.

**High Quality plasmid is vialled in an ISO 5 BSC non-controlled room. GMP plasmid is vialled in an ISO 5 environment.