



DNA Development & Manufacturing Services

Cobra Biologics, with locations in Matfors and Södertälje, Sweden and Keele, UK, provides a full range of services from gene cloning to cGMP manufacturing for pre-clinical through to Phase III clinical trials and commercial supply. Cobra Biologics' track record in manufacturing cGMP products helps to ensure programs are on time and to budget. Our goal is to deliver our customers' DNA development programs in a cost effective and timely manner.

Molecular Biology

- Proprietary technology:
 - Antibiotic free maintenance technology: ORT®
- Strains:
 - DH1
 - DH1-ORT
 - DH5α
- Plasmid stability testing
- Vector development: plasmid and strain construction
- Sequencing
 - Process Development & Scale Up
- Fermentation & media development
- Evaluation of productivity and optimization of harvest point
- Lysis optimization (primary recovery)
- Non-animal derived components
- Production for pre-clinical efficacy testing and pivotal preclinical safety testing
- Formulation

Analytical Development & Qualification

- Assay transfer
- Stability studies: Drug Substance and Drug Product
 - To ICH guidelines
 - Forced degradation studies
- Cleaning validation
- Raw material testing
- Shipping studies

- Product characterization
- QC release testing
 - QC testing of Drug Substance & Drug Product

cGMP Manufacturing

- Master Cell Bank & Working Cell Bank production
- Pre-clinical and clinical supply

Fill/ Finish

- Aseptic production
- Syringes and vials
- Freeze-drying/ lyophilisation
- Up to commercial scale

Quality Assurance & Regulatory Support

- 3 Qualified Persons (QP)
- Fully compliant with European Clinical trials Directive 2001/20/EC and FDA standards
- Authorized by UK MHRA for the cGMP production of Investigational Medicinal Products (IMPs)
- Support customers with their CMC filings
- Representation at MHRA and FDA meetings
- QP release
- Shipment to clinical trial sites

Project Management

- Dedicated Project Manager
- Cross-functional project teams
- Detailed timeline planning & milestone tracking
- Program managed by single point of contact
- Regular process updates & risk management