



## Virus Development and 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. 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' virus development programs in a cost effective and timely manner.

### Experience

- Adenovirus (Human, ovine, and primate)
- Herpes simplex virus
- Lentivirus
- Reovirus

### Cell Line & Virus Vector Development

- Cloning (any gene from any source)
- Cell lines: HEK 293, PER.C6, HEK 911, Vero, CSL503, A549, HeLa
- Vector development: plasmid and cell line construction
- Virus rescue
- Characterisation & plaque purification
- Genetic stability testing

### Process Development & Scale Up

- Development of robust and scalable process strategies
- Media development and optimization (animal component free)
- Adaptation to suspension-based growth
- Development of closed processing systems
- Transfection efficiency optimization
- Optimization of harvest parameters to improve quality and productivity
- Optimization of multiplicity and point of infection (MOI & POI)
- Development of efficient extraction and primary recovery procedures
- Purification by low pressure chromatography
- Formulation

### cGMP Manufacturing

- Master Cell Bank and Working Cell Bank production
- Master Viral Seed Stock and Working Viral Seed Stock production
- Clinical manufacture, including disposable systems

### Analytical Development & Qualification

- Analytical method transfer, development, qualification & validation:
  - Reverse phase chromatography; Ion exchange chromatography; PCR; SDS-PAGE; ELISA; LAL; Bioburden; Spectrophotometry (UV/visible); Fluorimetry; Capillary electrophoresis; Mass spectrometry; Picogreen particle assays; Electron microscopy; Development of cell based potency assays; Plaque assays; TCID50 assays

### Fill/ Finish

- Audited filling houses
- Project managed
- Detailed timeline planning & milestone tracking

### 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 clients 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