



## Mammalian Cell Protein 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' mammalian cell protein development programs in a cost effective and timely manner.

### Experience

- CHO
- CHO-S
- Hybridomas
- Myelomas
- PER.C6

### Cell Line Development

- Cloning (any gene from any source)
- Expression vector development
- Technology services:
  - maxXpress: rapid mammalian protein production with UCOE
  - Cello™ robotic system for automated screening and expansion of large numbers of clones Stability

### Process Development & Scale Up

- Perfusion and fed-batch process development
- Media development and optimization (animal component free)
- Optimization of harvest parameters
- Development and optimization of purification process
- Formulation development

### cGMP Manufacturing

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

### Analytical Development & Qualification

- Assay transfer

- Product Characterization
  - Protein characterization for IND submissions
  - Analytical reference standards
- QC Release Testing
- QC testing: Drug Substance and Drug Product
- Cell based potency assays
- Stability Studies: Drug Substance & Drug Product
  - To ICH guidelines
  - Forced degradation studies
  - Pre-formulation studies
- Cleaning validation
- Raw material testing

### 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
- Licensed for cGMP manufacture in Sweden and the UK
- Support clients with their CMC filings
- Representation at MHRA and FDA meetings
- QP release & shipment to clinical trial sites