



## Live Cells 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' solid track record in manufacturing cGMP products helps to ensure programs are on time and to budget. Our goal is to accelerate our customers' programs in a cost effective and timely manner.

### Hosts

- *Listeria monocytogenes* (recombinant, attenuated)
- *Serratia marcescens* (non-recombinant, heat-killed at end of process)
- *Streptococcus pyogenes* (non-recombinant, heat-killed at end of process)
- *Salmonella typhimurium* (recombinant attenuated)

### Process Development & Scale Up

- Development of fully closed, sterile processes for whole cell products
- Development of robust and scaleable manufacturing processes
- Media development and optimisation (animal component free)
- Optimisation of harvest parameters to improve both quality and productivity
- Development of efficient extraction and primary recovery procedures
- Formulation
- Sterile harvest & cell washing facilities

### Analytical Development & Qualification

- Analytical method transfer, development, qualification & validation
- Analytical methods include: Identity by microbiological characterisation of the strain, purity (monosepsis), strength by determination of viability, development of cell based potency assays

### cGMP Manufacturing

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

### 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 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 and milestone tracking
- Program managed by single point of contact
- Regular process updates
- Risk management