



CLINICAL TRIAL AND COMMERCIAL BIOLOGICS MATERIAL

EUROGENTEC BIOLOGICS

- GMP Recombinant proteins
 - GMP Plasmid DNA
 - GMP Protein conjugation

Eurogentec is a GMP accredited manufacturer of parenteral biologics. We produce clinical trial material for all major markets and produce according to FDA and EMA requirements. As experts in the manufacturing of biologics from bacterial and yeast sources, we offer significant know-how in high cell density fermentation, purification by refolding of inclusion bodies, isolation of periplasmic or extracellular secreted proteins as well as the purification of intracellular soluble proteins.

Comprehensive GMP Experience

- GMP accredited since 1994
- >80 custom GMP processes developed
- >400 GMP batches released

Experience in All Clinical Phases

- Manufacturing for Phase I, II and III
- Orphan drug commercial manufacturing
- QC qualification and validation plan
- Process characterization
- Process validation
- In-house QP release of DS and DP

Product Experience

- Recombinant proteins
- Plasmid DNA vaccines
- PEGylated proteins
- Peptide-protein couplings
- Biosafety level 2 microbial vaccines

Unique Manufacturing Platforms

- Strain specific high density fed-batch fermentation methods
- Continuous / non-batch based purification methods, highly scaleable
- Off-patent *Pichia pastoris* systems
- Plasmid manufacturing to 100g scale

Comprehensive Service Offering

- Cell line development
- GMP Cell banking
- USP, DSP and QC development
- Stress stability studies
- Preformulation development
- API Manufacturing
- Fill & Finish, Packaging, Labeling
- Tox batch manufacturing
- GMP Clinical trial manufacturing
- Process characterization & validation
- GMP Commercial manufacturing
- ICH Stability studies





Host System Experience

Manufacturing with all the important microbial strains

- *E. coli*
- *P. pastoris*
- *H. polymorpha*
- *S. cerevisiae*
- Biosafety level 2 organisms



Technical Expertise

- Fermentation development using a Design of Experiment approach with parallel 4x5L fermentors
- Purification development by parallel screening of resins for multiple process performance properties
- In-house development of QC tests
- Formulation by Design of Experiment based Stress stability studies
- Scale-down model validation
- Statistical approach to process analysis and specification setting



Comprehensive Expression Experience

- Refolding of inclusion bodies
- Periplasmic expression
- Soluble cytoplasmic expression
- Extracellular secretion

Multi-Product Manufacturing Facility

- 3 GMP Fermentation suites (up to 500L)
- 2 GMP Purification suites
- 1 GMP Sterile Filtration suite

→ FOR FURTHER INFORMATION, PLEASE CONTACT

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