GMP BioManufacturing

US FDA inspected

GMP mRNA | GMP Plasmid DNA | GMP Recombinant proteins

Clinical trial and commercial biologics material

Eurogentec is a GMP accredited manufacturer of parenteral biologics. We produce clinical trial material for all major markets 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, purification of intracellular soluble proteins as well as production of plasmid DNA and mRNA.

Comprehensive GMP Experience

- GMP accredited since 1994
- US FDA inspected 2011, 2013, 2014, 2017
- >175 custom GMP processes developed, > 700 GMP batches released
- Manufacturing to FDA 21 CFR Part 210 & 211, EU 2003/94/EC and Eudralex Vol 4

Experience in All Clinical Phases

- Manufacturing for Phase I, II, III and commercial
- Process development: USP, DSP, QC
- QC qualification and validation
- Process characterization
- Process validation
- In-house QA and QP release of DS

Product Experience

- mRNA
- Plasmid DNA, API and critical starting material
- Recombinant proteins (eg enzymes, cytokines, antibody fragments)
- PEGylated proteins
- Peptide-protein conjugates

Multi-Product Manufacturing Facility

- 1 GMP IVT and purification suite (up to 30g)
- 4 GMP Fermentation suites (up to 2200 L)
- 3 GMP Purification suites
- 1 GMP 0.2 µm Filtration suite
- US FDA inspected 2011, 2013, 2014, 2017
- Plasmid and Protein manufacturing to 1kg scale

Comprehensive Service Offering

- GMP Cell banking
- USP, DSP and QC development
- Stress stability studies
- API Manufacturing
- Tox batch manufacturing
- GMP Clinical trial manufacturing
- Process characterization & validation
- GMP Commercial manufacturing
- ICH Stability studies on drug substance

Host System Experience

- Manufacturing with all the important microbial strains
- *E. coli*
- *P. pastoris*
- *H. polymorpha*
- *S. cerevisiae*
- Biosafety level 2 micro-organisms that are non-sporulating

Technical Expertise

- Fermentation development using a Design of Experiment approach with parallel 4x5 L fermentors
- Purification development by parallel screening of resins for multiple process
  performance properties
- In-house development of QC tests, IPC & release tests incl cell based potency assays
- Scale-down model validation
- Statistical approach to process analysis and specification setting
- IVT parallel reaction development

Comprehensive Experience

- In vitro transcription optimization and mRNA purification
- Plasmid fermentation and purification
- Protein purification from IB, periplasm, cytoplasm, secreted

BIO-GENERAL-0222-V9

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