Eurogentec

US FDA
inspected CDMO

GMP Manufacturing

Plasmid DNA | RNA | Recombinant proteins

Clinical trial & commercial biologics material

Eurogentec is a GMP accredited manufacturer of biologics. We produce clinical trial material for all major markets according to FDA and EMA requirements.

As experts in biologics manufacturing from bacterial and yeast sources, we provide tailored guidance and advice to support your projects, helping you anticipate and overcome industrial, regulatory, and economic challenges at every stage.

We bring extensive expertise in high cell density fermentation, protein purification, as well as plasmid DNA and RNA production. Our purification know-how covers refolding inclusion bodies, isolating periplasmic and extracellular proteins, and purifying intracellular soluble proteins.

Comprehensive GMP Experience

- GMP accredited since 1994
- FDA inspected since 2011
- >290 custom GMP processes developed
- >750 GMP batches released
- Manufacturing to FDA 21 CFR Part 210 & 211, EU 2003/94/EC and Eudralex Vol 4

Experience in All Clinical Phases & commercial

- Process development: USP, DSP, QC
- QC qualification and validation
- Process characterization
- Process validation
- In-house QA and QP release of DS

Product Experience

- RNA
- Plasmid DNA, API and critical starting material
- Recombinant proteins (*e.g.* enzymes, cytokines, antibody fragments)
- PEGylated proteins
- Peptide-protein conjugates

Multi-Product Manufacturing Facility

- 1 GMP IVT-RNA and purification suite (up to 50g)
- 4 GMP Fermentation suites (up to 2200 L)
- 3 GMP Purification suites
- 1 GMP 0.2 µm Filtration suite
- Plasmid and Protein manufacturing to 1kg scale

Host System Experience

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

Unique Advantages

- Planning reliability
- Scientific expertise with guidance
- Solid quality management
- Certified project management
- Cost effectiveness
- Short release time
- High yield design equipment

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

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

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