

One-stop GMP Contract Manufacturing of Biopharmaceuticals



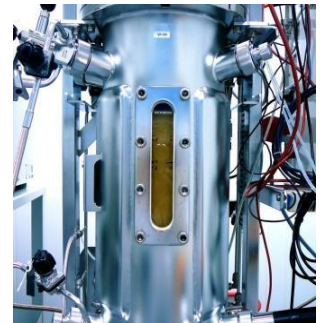
Biomay Offers Fully Integrated GMP Capacities for Contract Manufacturing of Recombinant Proteins and DNA Plasmids.

- Plasmid DNA, recombinant proteins, antibodies and allergens
- Contract development and tech-transfer of scalable and state-of-the-art bioprocesses
- cGMP manufacturing of mg to g lots (clinical phase I – III)
- One-stop-shop: from cell banking to aseptic filling of drug product
- Excellent price-performance ratio and minimal project lead time

Bioprocessing Expertise and GMP Capacities

Since more than 20 years, Biomay has gained expertise in manufacturing of recombinant biomolecules with microbial systems like *E. coli*. Biomay's product expertise comprises recombinant allergens, therapeutic proteins, antibodies and plasmids (DNA vaccines). Biomay performs state-of-the-art bioprocessing technologies like high-cell density fed-batch fermentation (25L), continuous centrifugation, homogenization, refolding, various chromatographies and ultra-filtration.

Biomay conducts a GMP quality management system in compliance with international standards and operates a fully integrated manufacturing facility certified according to EMA directives (2001/83/EC, 2001/20/EC). The facility is utilized for supplying Biomay's own clinical trials and for contract manufacturing services. In two independent GMP suites, three controlled clean room classes are available: class D for upstream and recovery, C for downstream and A for aseptic formulation and filling.



Scope of Contract Manufacturing Services

As a contract manufacturing organization (CMO), Biomay is addressing clients who require mg to g quantities of active pharmaceutical ingredients (APIs) and drug products for clinical phases I – III. Biomay has positioned itself as a one-stop CMO that offers a highly attractive price-performance ratio at a short project lead time.

The scope of Biomay's CMO services comprises:

- Vector and host development
- cGMP cell banking
- Tech-transfer and contract process development
- cGMP manufacturing of API (drug substance)
- cGMP manual aseptic filling of drug product
- QC with a comprehensive set of validated assays
- In-house QP batch release
- Assay / process / cleaning validation
- Long-term storage and stability testing
- Regulatory support (CMC part of IMPD / IND)

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