BIOMEVA
MANUFACTURING

YOUR GOOD MANUFACTURING PARTNER

CONTRACT MANUFACTURING

active pharmaceutical ingredients
microbial fermentation
process development
bioanalytical services
cell banking

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Company Profile

BIOMEVA GmbH is dedicated to the current Good Manufacturing Practice (cGMP) production of biologics and therapeutic proteins for the biopharmaceutical industry. Our production facility and extensive technical expertise meet the quality requirements for manufacturing active pharmaceutical ingredients (APIs) and assure regulatory approval.

BIOMEVA Services and Expertise

- cGMP production of APIs using microbial fermentation up to 1000 L
- Process development and up-scaling
- Cell banking
- Cell bank storage
- Sophisticated quality system
- cGMP manufacturing experience since 1993

Microbial Cell Banking and Storage

BIOMEVA manufactures master and working cell banks in state-of-the-art class A/C laboratories according to FDA and ICH requirements. BIOMEVA offers full cell bank testing (identity, purity and stability). Cell Banks are stored in a dedicated storage room in the gas phase of liquid nitrogen and are continuously monitored at the highest security level.

Process Development

BIOMEVA operates a fully equipped process development laboratory to establish optimal processes for the cGMP production of APIs. BIOMEVA's processes are developed in a time- and resource-efficient manner and can be directly transferred and up-scaled into BIOMEVA's cGMP production facility.
BIOMEVA's experience in process development is built on its strong expertise in technology transfer and the production of more than 350 batches of cGMP-compliant material over the past 20 years.

microbial fermentation process development cell bank storage

Large-scale production of Active Pharmaceutical Ingredients

BIOMEVA's facility is dedicated to the large-scale manufacturing of APIs expressed in microbial systems. Recombinant material on a clinical and commercial scale can be produced in batches up to 1000 L working volume.

Production and purification systems include:

- Fermenters with working volumes of 10 L, 100 L and 1000 L
- Batch and fed-batch fermentation
- Continuous centrifugation
- High-pressure homogenization
- Protein micro-filtration and ultra-filtration
- Sterile filtration
- Column chromatography
- Bulk drug substance filling

Bioanalytical Services

BIOMEVA's analytical service department provides full services for batch release testing and stability testing of APIs. Analytical Services assist clients in determining which assays are best suited for their biological drug substance, as well as in developing new methods. BIOMEVA's analytical laboratories are fully compliant with cGMP regulations.

Batch Release Testing
BIOMEVA's API batch release testing programs emphasize the importance of timely and accurate analysis by providing clients with validated assays performed in compliance with cGMP. These assays can also be used for drug product testing.

Stability Testing
BIOMEVA's stability testing protocols of biological drug substances meet the requirements as outlined by ICH. In addition, BIOMEVA can provide custom stability testing protocols to fulfill the specific requirements of individual clients. These stability testing protocols provide real-time stability data as well as accelerated or stress data.

All relevant documents are subject to the BIOMEVA document control system administered by Quality Assurance (QA).

We care about your project – as much as you do!

Why BIOMEVA?

- Experience of 20+ years
- 350+ production batches at 1000 L scale
- 80+ master and working cell banks
- APIs for preclinical and clinical studies, medical devices and the market
- State of the art production rooms (class A, B, C, D)
- Fully cGMP compliant
- Customer focus
- Fast and direct communication
- Long term customer binding, many recurring clients
- Experienced employees, minimal employee turn over
- German quality
- Best references
- Excellent price/performance ratio

- **BIOMEVA: A successful, reliable and experienced partner for your project!**

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Quality Control and Assurance

BIOMEVA's Quality Control (QC) and Quality Assurance (QA) departments ensure that facilities, equipment, critical materials, API and cell bank manufacturing are fully cGMP-compliant. The QC group is responsible for testing and release of raw materials to the manufacturing group, sample testing during the manufacturing process and environmental monitoring of the production suites during manufacturing campaigns.
The Quality Assurance (QA) group guarantees the cGMP-compliant API and cell bank manufacturing. BIOMEVA's QA auditors provide auditing and monitoring of all production activities.

Product types

- Antibody fragments
- Therapeutic proteins
- PEGylated proteins
- Recombinant Vaccines
- Cytokines
- Plasmid DNA

History

- 2006 Privately owned after management buy-out and renamed BIOMEVA
- 2004 Takeover by Invitrogen
- 1997 BioReliance Manufacturing
- 1993 BIOMEVA (Beginning of cGMP-compliant API manufacturing - CMO)
- 1987 RCC Genbiotec (Contract fermentation)
- 1983 Foundation of Genbiotec (R&D company)

References

GENE TECHNO SCIENCE

ucb

Takeda

DELENEX Therapeutics

BAYER

Bayer HealthCare

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