



active pharmaceutical ingredients  
bioanalytical services  
cell banking



Your **G**ood **M**anufacturing **P**artner.

- Contract manufacturing
- Microbial fermentation
- 1,000 L production scale
- cGMP-compliant
- Manufacturing experience since 1993
- Sophisticated quality system



## Company Profile

BIOMEVA GmbH, a leading provider of contract services in the biopharmaceutical industry, is dedicated to meeting the manufacturing needs for the production of microbially expressed protein products. Our current Good Manufacturing Practices (cGMP) production facility and extensive technical expertise provide the support to obtain regulatory approval.

Since 1993, BIOMEVA has produced cGMP-compliant material for biopharmaceutical clients worldwide. Our scientific knowledge and operational expertise in the transfer, scale-up and validation of cGMP processes are recognized globally.

## Large-scale production of Active Pharmaceutical Ingredients

Our Heidelberg, Germany, facility specializes in the manufacture of Active Pharmaceutical Ingredients expressed in microbial systems. Recombinant material on a clinical and commercial scale can be produced in lots of up to 1,000 L. This facility houses laboratories for E.coli cell bank production, characterization and storage, classified rooms for fermentation, chromatography, bulk filling and QC laboratories. A Class 100/1,000 filling suite is maintained for bulk product filling.

Production and purification systems include the following:

- Fermenters with working volumes of 10 L, 100 L, and 1,000 L
- Continuous centrifugation
- High-pressure homogenizer
- Protein micro-filtration and ultra-filtration
- Sterile filtration
- Column chromatography
- Bulk substance filling

## Microbial Cell Banking

Master and working cell banks are manufactured, characterized and tested in state-of-the-art laboratories according to FDA and ICH requirements.

## Quality Control

To support cGMP production activities, the Quality Control (QC) group ensures that all facilities, equipment and critical materials are under control and cGMP-compliant. Our QC group is responsible for supporting manufacturing in the following activities:

- Testing and release of raw materials to the manufacturing group
- Sample testing during the manufacturing process
- Environmental monitoring of the production facilities during and between manufacturing campaigns
- Release testing of the Active Pharmaceutical Ingredient

## Quality Assurance

The mission of the Quality Assurance (QA) Department is to ensure that all manufacturing at BIOMEVA fulfills cGMP requirements, and that we exceed clients' quality expectations. Our QA auditors provide inspection, auditing and monitoring of all production activities including:

- Working with clients and regulatory agencies during audits
- Performing in-process and system inspections
- Reviewing products' Certificate of Analysis and approving release of products to the client
- Auditing Master Production Records
- Confirming that Standard Operating Procedures are followed
- Inspecting all cleaning and change-over activities



Your **Good Manufacturing Partner.**

BIOMEVA GmbH  
Czernyring 22  
69115 Heidelberg  
Germany

**Phone** +49 (0) 6221 - 9026-0  
**Fax** +49 (0) 6221 - 9026-00  
**E-Mail** info@biomeva.com  
**Internet** www.biomeva.com

www.biomeva.com