Biopharmaceuticals

Miltenyi Bioprocess, the contract manufacturing division of Miltenyi Biotec GmbH, has extensive experience in process development and production of monoclonal antibodies and cytokines under GMP conditions. Several of our standard procedures, e.g. our virus removal process for monoclonal antibody production, have been documented as US type II master files. At our sites in Teterow and Bergisch Gladbach, we have over to 5000 m² of laboratories and GMP production areas, ranging from class A to D. Our project teams combine the expertise of individuals with research, development, pharma production, regulatory and quality assurance backgrounds.

We offer the following integrated services for the biopharmaceutical industry:

Cell line selection, media adaptation and cell banking

- protein-free cultured hybridoma cells
- high-producer cell line development
- master cell bank (MCB), working cell bank (WCB) generation

Process development and production

- upstream process development (USP) for the production of recombinant proteins and monoclonal antibodies as active pharmaceutical ingredients (API)
- batch, fed-batch and continuous perfusion bioprocess development
- downstream process development (DSP)
- protein conjugation (GMP conditions)

Pharma production (injection vial filling)

- pharmaceutical production (formulation, lyophilization, fill/finish, labeling, packing)
- guidance in regulatory affairs and documentation

Bioreactor technology from B. Braun Biotech (up to 200 L working volume for mammalian cell culture, and up to 20 L working volume for *E. coli* fermentation) are installed in independent class C production areas for batch, fed-batch and continuous perfusion processes. Larger USP and DSP equipment can be installed on demand.

Our vial filling line, located in a class A area, has the capacity of several thousand vials per hour and can process vials from 2 mL up to 50 mL – with optional lyophilization. Standard operating procedures (SOPs) are in place and can be adapted to special requirements. Our documented processes are in accordance with the national and international regulatory guidelines of EMEA and FDA. All work at Miltenyi Bioprocess is performed according to the international guidelines, good development practices (GDP) and good manufacturing practices (GMP). We can produce cell culture media and buffers in-house. Our regulatory and QC groups are available to assist throughout.

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