

## GMP antibody manufacturing

### Our service for your antibody

In recent years, the increasing number of therapeutic monoclonal antibody candidates under preclinical and clinical development require new flexible, efficient and economic opportunities for GMP production of therapeutic antibody candidates. Small-scale batch production of test samples for late preclinical GLP animal studies or for phase-1

and phase-2 clinical studies is often not appropriate for large-scale manufacturing facilities in the industry.

The Fraunhofer IZI, founded in 2005, investigates and develops solutions to such specific problems at the interfaces of medicine, life sciences and engineering.

## State-of-the-art equipment

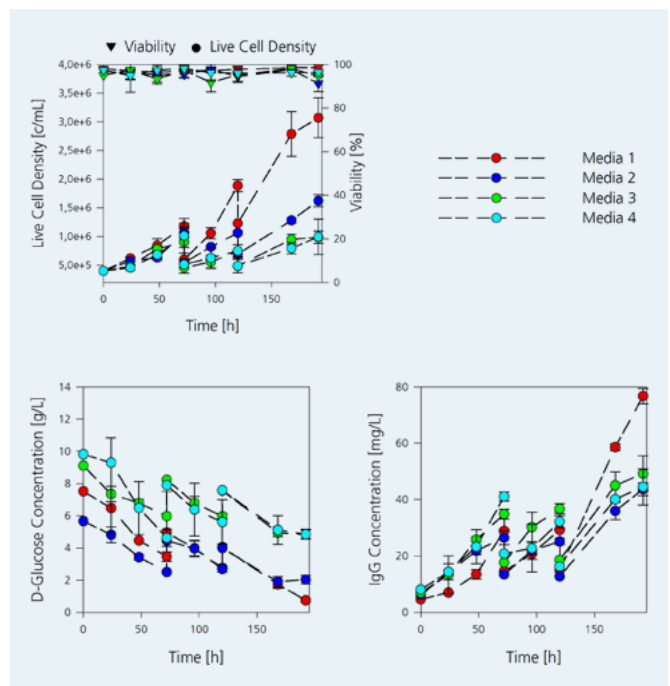
- Isolator / Incubators for inoculation from the master cell bank
- Sartorius Biostat® STRplus 200 L for production
- Sartorius Biostat® RM20 & RM50 for seeding
- Sartorius FlexAct® Controlling systems for media preparation, cell harvest and virus removal
- GE Healthcare ÄKTA Pilot chromatography system for protein purification
- Sartorius Sartoflow® Advanced for ultra- and diafiltration
- Colanar semiautomatic filling machine for product formulation

## Process development

- Transfer of your Research Cell Bank into a GMP Master Cell Bank with strategic partners for characterization
- Customized design for all parts of the manufacturing process
- Establishment of a lab scale process and process optimization e.g. expression media screening, fed-batch development
- Identification of critical process parameters for cell growth and protein production
- Establishment and validation of product QC

## Upstream

- Transfer to production scale up to 200 L of total cultivation volume
- Based on single-use bag assemblies
- Equipment for aseptic liquid transfer e. g. Biowelder® TC, Biosealer® and Biosafe® Transfer Ports





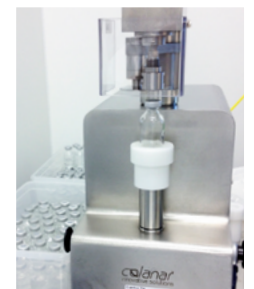
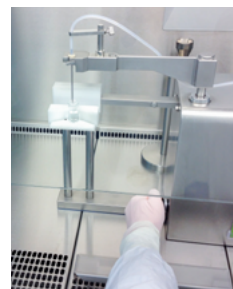
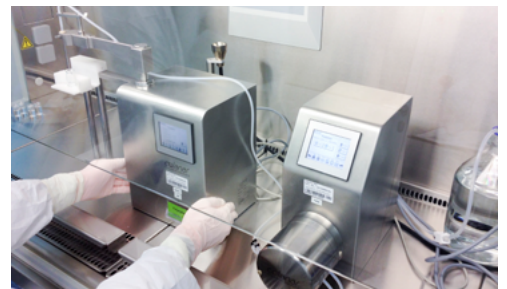


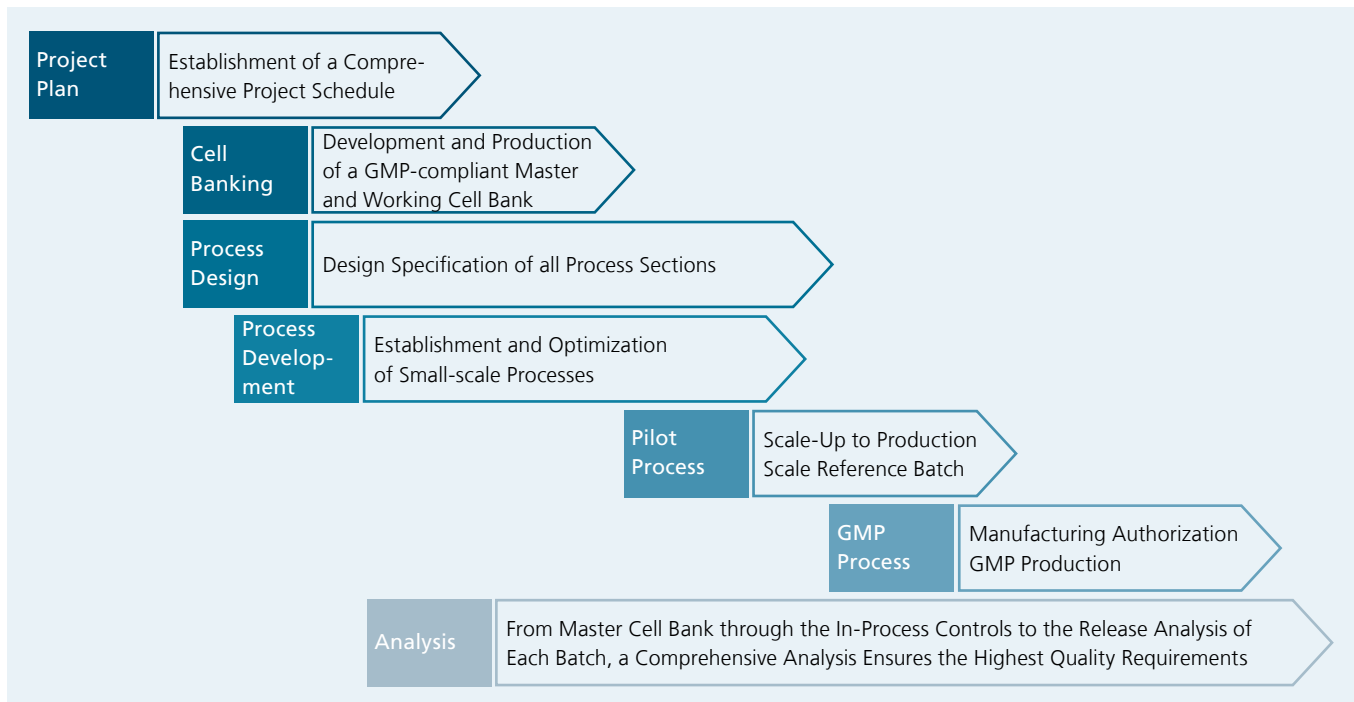
### Downstream

- Cell removal via depth filtration
- Capture, purification and polishing with three step affinity and ion exchange chromatography
- virus inactivation and removal
- Setting the final buffer for the product
- End up with a minimal volume of 200 mL

### Aseptic filling

- Final product as bulk ware or in glass vials
- Filling in clean-room class A in class B environment
- Available glass vials in different sizes





## Advantages & services

### Advantages over traditional technologies

- High flexibility
- Easy change-over to different products
- Fast implementation of technology changes
- Customized production
- Ideal for preclinical and early clinical trials
- Ready-to-use GMP compliant products by integrated sample filling

### Our service for your ideas

- Transfer of your promising biopharmaceutical candidate from research to clinical development
- Manufacturing of Master and Working Cell Banks
- Process development from Upstream to Downstream
- Design of your user-specific process by single-use materials
- GMP-compliant production of e. g. human monoclonal antibodies in 200 L-scale

### Contact

PD Dr. Stephan Fricke  
 Head of Department  
 of GMP Process Development / ATMP Design  
 Tel. +49 341 35536-2205  
 stephan.fricke@izi.fraunhofer.de

Fraunhofer Institute  
 for Cell Therapy and Immunology  
 Perlickstraße 1  
 04103 Leipzig  
 Germany  
 www.izi.fraunhofer.de