

Biopharmaceuticals, development to the market

Biopharmaceuticals

Cell line development

- protein-free cultured hybridoma cells
- mammalian cell lines
- development of high-producer cell lines
- *E. coli* strain development
- Master Cell Bank/Working Cell Bank (MCB/WCB) generation

Process development and production of API

- process development (USP/DSP)
- production of recombinant proteins and mABs as active pharmaceutical ingredients (API)
- batch, fed-batch and continuous bioprocesses
- release of purified drug substances

Pharma production

- pharmaceutical production of clinical trial material
- market supply
- formulation, fill, finishing
- lyophilization
- labeling, packing, logistics for clinical trials

Affinity chromatography/adsorbers/magnetic beads

- custom-made aseptic mAB/peptide-based affinity resins produced under GMP conditions for DSP and process optimization for pilot and industrial scale
- development of chromatography media/adsorber media and aseptic production
- aseptic filling into custom-made housings
- manufacturing (GMP) of magnetic beads with functional proteins

Medical devices

- manufacturing (GMP) and aseptic packaging of adsorber casings, complex tubing systems, and bags

Cell culture media and solutions

- protein-free and serum-free cell culture media for GMP processes
- chromatography solutions for GMP-DSP
- custom-made, sterile solutions for intravenous applications

Quality control, quality assurance and regulatory support

- method development and validation
- raw material control
- in-process control
- API control
- release of dry substance
- release of formulated, filled and finished drug
- release of clinical devices for human use
- regulatory support during product development and market authorization
- contacts with authorities like EMEA and FDA
- advice in biological/virological safety questions



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