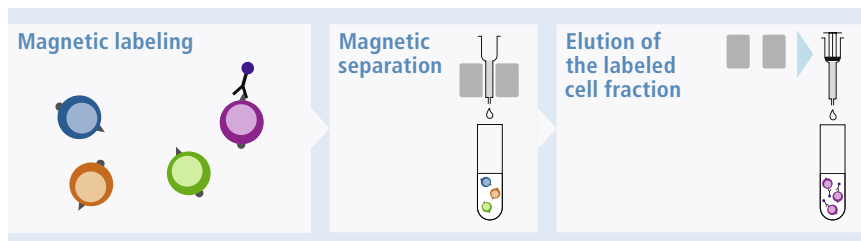


Cell Therapeutic Applications

Miltenyi Bioprocess, the contract manufacturing division of Miltenyi Biotec, provides in-depth knowledge and state-of-the-art facilities* for development and production of medical devices and reagents for the aseptic separation of specific human cells. This separation technology is based on monoclonal antibodies and alternative ligands, both directed to different cell surface markers or other specific targets, covalently immobilized to biodegradable super-paramagnetic beads or non-biodegradable beads. With the development, production, and registration of numerous CliniMACS® reagents, Miltenyi Bioprocess has established a generic reagent development and production process. This process will significantly reduce the "time-to-market" for your cell therapy application.



The following steps can be offered:

Cell separation reagents for clinical use

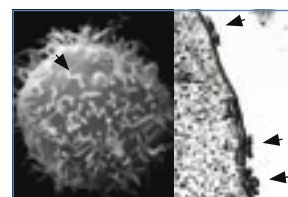
- reagents, definition, and design
- revalidation IPC and release QC
- protein-free master cell bank/working cell bank
- virus-validated production of purified mAB
- aseptic ligand conjugation to super-paramagnetic beads
- production of complete separation reagent (incl. consistency batches)
- stability program
- validation of the cell separation procedure
- preclinical testing according to ISO 10993
- risk analysis according EN14971:2000
- material safety data sheet
- registration
- preparation of the TÜV application file
- preparation of the device master file

Miltenyi Biotec has filed several US type II masterfiles for the protein-free and virus-validated mAB production process with the FDA and has received several CE marks for specific CliniMACS® reagent kits. The Miltenyi Biotec Microbeads used in this kind of applications are completely biodegradable and have shown no toxicological side effects in animals and humans.

*(ISO: 9001, 13485, as well authorized for GMP production of cell therapeutics and biopharmaceuticals)



CliniMACS® plus Instrument



Electron microscopy picture of dendritic cell and cell membrane with attached MicroBeads

CliniMACS® Reagents, Tubing Sets, Instruments and PBS/EDTA buffer are manufactured and controlled under an ISO 13485 and ISO 9001 certified quality system. In Europe, the CliniMACS system and reagents are available as CE marked medical devices. In the USA, CliniMACS® Reagents are available for use only under an approved Investigational New Drug (IND) application or Investigational Device Exemption (IDE). CliniMACS® MicroBeads are for research use only and not for use in humans.

CliniMACS is a registered trademark of Miltenyi Biotec GmbH.



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