



## Adsorbers / affinity chromatography / magnetic beads

Miltenyi Bioprocess provides in-depth knowledge and state-of-the-art facilities for GMP manufacturing of custom-made adsorber or chromatography matrices which includes the covalent binding of either your proprietary material, or custom-made GMP-grade antibody and peptides for affinity resins. It is possible to start GMP production of small-scale batches in a class A isolator, installed in a class D environment, and to upscale the process to 50-liter working volume reactor technologies. Depending on the actual process and matrix, we are able to produce more than 1000 kg of resin per year.

Additionally, we provide extensive experience regarding the covalent coupling of monoclonal antibodies or recombinant proteins to magnetic beads under GMP conditions for human cell therapeutic use or drug immobilization development projects.

- Different procedures for covalent coupling of proteins and peptides under GMP conditions are already established. Our chemical reactors are adaptable to alternative technologies.

Our systems are validated, the personnel is well trained, and the thoroughly documented systematic process assures a sterile and save finished product.

The large-scale production of the adsorber-chromatography matrices and modified magnetic beads at Miltenyi Bioprocess is a straightforward one-to-one scale-up of the validated small-scale process which smoothly follows through the manufacturing steps, that are controlled by our two independent departments for quality assurance and quality control. Because conventionally accepted sterilizing methods like saturation with ethylene oxide, glutaraldehyde, gamma irradiation and steam cannot be used with matrices carrying biologically active proteins we have established our production processes under completely aseptic conditions.

All work at Miltenyi Bioprocess is performed according to international guide-lines for Good Development Practices (GDP) and Good Manufacturing Practices (GMP).



**Miltenyi Bioprocess**

*a division of Miltenyi Biotec*

For additional information please contact:

Miltenyi Biotec GmbH  
Friedrich-Ebert-Straße 68  
51429 Bergisch Gladbach  
Germany  
Phone +49 2204 8306-0  
Fax +49 2204 85197  
[bioprocess@miltenyibiotec.de](mailto:bioprocess@miltenyibiotec.de)

For US and Canadian customers:

Miltenyi Biotec Inc.  
12740 Earhart Ave  
Auburn, CA 95602  
USA  
Phone 800 367 6227 / 530 888 8871  
Fax 530 745 2806  
[bioprocess@miltenyibiotec.com](mailto:bioprocess@miltenyibiotec.com)

[www.miltenyibiotec.com](http://www.miltenyibiotec.com)