

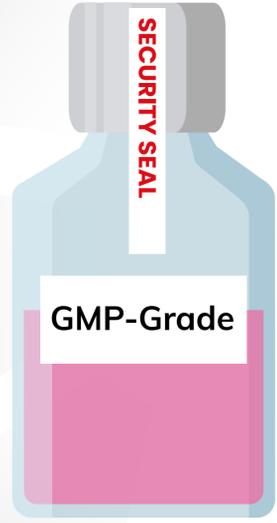
# Utilizing GMP-grade products for cell therapy manufacturing:

## What are GMP-grade products?

GMP encompasses a set of guidelines and standards implemented in pharmaceutical industries to ensure that the manufactured products meet high quality and safety standards.

GMP certificates guarantee materials have been produced according to strict guidelines, in facilities compliant with the high standards required.

By employing GMP-grade products throughout the cell and gene therapy production pipeline, the risk associated with the process can be minimized.



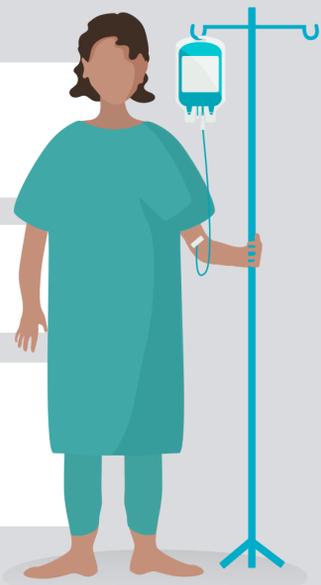
## What are the benefits of GMP-grade products?

### Patient safety

Cell therapy products involve the use of living cells that are introduced into the patient's body.

Microbial or viral contaminants in these products could jeopardize patient safety.

GMP-grade products ensure that the respective quality controls and standards are adhered to, ensuring the safety of the cells being used.



### Product consistency and efficacy

GMP-grade products guarantee lot-to-lot consistency for cell culture media, reagents and other materials used.

This ensures the reproducibility of biomanufacturing processes and that produced cell therapy products have the desired quality and efficacy.

### Traceability and documentation

GMP requirements call for documentation and tracing of the manufacturing process, from cell acquisition to final product administration.

This provides information about the manufacturing site, quality management system, the facility itself, the process, materials and more.

All to ensure quality, safety, and reproducibility.



### Regulatory requirements

The manufacturing of cell therapy products is subject to strict regulatory guidelines.

The use of GMP-grade products should ensure these requirements are met.

This is crucial for obtaining the necessary regulatory approvals for the clinical application of cell therapies.



“GMP grade” is a branding term used by PromoCell to denote reagents that are manufactured at the PromoCell manufacturing facility in Heidelberg, Germany, under strictly controlled processes to meet stringent product specifications and customer requirements. Reagents manufactured at PromoCell are produced according to EXCiPACT™ GMP standards, a quality management system that builds on our ISO 9001:2015 certification and the ANSI certification. Risk assessment procedures are carried out at the customer site.

Examples of GMP-grade products include PromoCell's new PromoExQ MSC Growth Medium XF, manufactured to the EXCiPACT™ GMP certification standard.