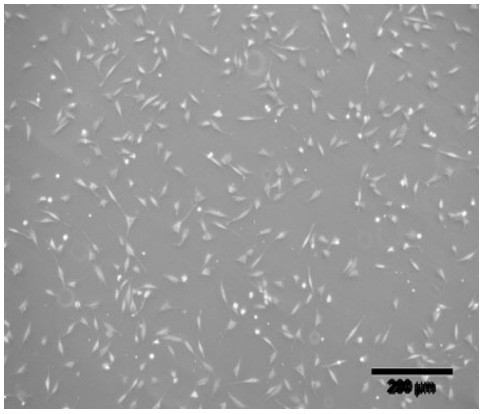
GMP and cell manufacturing

Written by Danielle Nicholson
Reviewed by Prof. Willem Fibbe, Leiden University Medical Center

Good manufacturing practice (GMP) is the production and testing practice that helps to ensure a quality product. Several countries have legislated that pharmaceutical and medical device companies must follow GMP procedures, and have created their own GMP guidelines that correspond with the legislation. GMP guidelines are designed to safeguard the health of the patient as well as producing high quality, consistent batches of medicine, medical devices or active pharmaceutical products. Complying with GMP is a mandatory aspect in pharmaceutical manufacturing.

GMP guidelines are not prescriptive instructions on how to manufacture products. Instead, they are a series of general principles that must be observed during manufacturing. When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements. It is the company's responsibility to determine the most effective and efficient quality process.



GMP guidelines and regulations are based on quality principles that pharmaceutical and healthcare manufacturers have been using for many years. Regenerative medicine raises new questions about the best ways to maintain quality. Emerging regenerative medicine therapies use techniques such as tissue engineering and involve new kinds of medical products, such as lab-grown or lab- modified cells. A therapy that uses living cells cannot be standardized in the same way as a conventional tablet. Therefore, cell therapies require different safety and quality standards. Under new EU legislation, cells that are expanded in culture are considered a new class of medicines termed *Advanced Therapy Medicinal Products* (ATMP). These ATMPs must be produced under GMP guidelines and treatment protocols require the approval of a National Ethical Committee.

SEVENTH FRAMEWORK PROGRAMME

REDDSTAR

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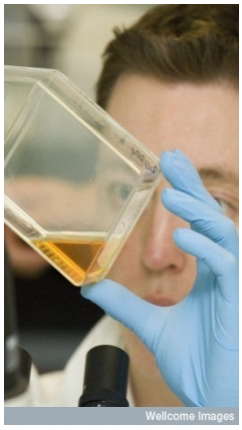
So, what then is GLP?

Good Laboratory Practice (GLP) is the set of principles that serve as a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are typically pre-clinical ones and are undertaken to generate data examining the risks and dangers to users, consumers and third parties and the environment. GLP studies are assessed in the development of pharmaceuticals, cosmetics, food and feed additives, biocides and detergents. GLP helps to assure regulatory authorities that the data submitted are a true reflection of results obtained during the study and can be relied upon when making risk and safety assessments.



Supporting, quality systems and documentation must be maintained by the manufacturer.

Mesenchymal stromal cells (MSCs) are isolated from the bone marrow of human donors. Once separated and purified from the mixture that makes up the bone marrow, the specified stromal cells are prepared for a medicinal product according to GMP legislation. GMP legislation defines the quality requirements that must be met for cells to be grown, handled and stored at each step of the process in advance of their use as a therapeutic agent to treat patients.

Each step of the cell therapy production process must be tracked starting with the bone marrow donor right through to the patient. This includes checking for infectious diseases and the ethical considerations regarding the recruitment of donors. Follow up occurs with both the bone marrow donor and the patient treated with the cells.

Funded by the European Commission's FP7, REDDSTAR is a three year, 10 partner project that will comprehensively examine if stromal stem cells derived from bone marrow can safely control blood glucose levels while also alleviate damage caused by six diabetic complications. **www.REDDSTAR.eu**

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