Regenerative medicine and regulation: what’s GMP got to do with it?

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GMP stands for Good Manufacturing Practice. GMP guidelines aim to maintain quality and safety standards across a range of industries, including medical and food manufacturing. But what has that got to do with regenerative medicine? Well, quite a lot if you want to bring a promising new therapy from the laboratory to patients.

What is GMP and why do we need it?

Good Manufacturing Practice guidelines set out quality standards for manufacturing medicinal products. They aim to make sure products such as drugs or vaccines have consistent strength, purity and quality. In fact, GMP guidelines cover quality and safety standards in all aspects of the manufacturing process - from buildings, equipment and staff training, to raw materials, operational processes and quality control systems. For example, specific GMP guidance defines the quality requirements for all the raw materials used to make a particular drug. In some cases, it also specifies how far a manufacturer must be able to trace back the source of each ingredient in the final product.

GMP guidelines are exactly that: they are *guidelines* not laws. Many countries have passed laws making it compulsory for pharmaceutical and medical device companies to follow the local GMP guidelines. This kind of regulation is important to protect our health, but new scientific developments can raise fresh challenges for regulators.

GMP and regenerative medicine

Current GMP guidelines and regulations are based on quality principles that pharmaceutical and healthcare manufacturers have been using for over 50 years. But the emergence of regenerative medicine raises new questions about the best ways to maintain quality. Regenerative medicine therapies use techniques like tissue engineering and involve new kinds of medical products, such as lab-grown or genetically modified cells. A therapy that uses living cells cannot be standardized in the same way as a conventional pill, so some different safety and quality standards are needed.

For example, researchers are investigating the possibility of using mesenchymal stem cells (MSCs) to treat certain diseases. MSCs can be obtained from the bone marrow of human donors. Specific GMP legislation defines the quality requirements that must be met before such cells can be used to treat patients. This legislation covers areas including:

* **The donor and the donated bone marrow**. For example, checks for infectious diseases and ethical considerations about recruitment of donors.
* **Traceability of the cells used in the treatment.** Everything must be tracked from the donor right through to the patient.
* **Follow-up** of both donor and patient over time.
* **Supporting quality systems and documentation** that must be maintained by the manufacturer.

And that’s just for one of the many materials that will be needed for a cell therapy using mesenchymal stem cells. Similar quality standards apply to all the raw materials, equipment and processes involved, right down to the smallest piece of laboratory equipment. Achieving, controlling and monitoring these important standards is a complex and expensive process. Dedicated GMP-approved facilities have to be set up to handle production of new cell-based therapies.

Who makes the rules?

Different regulatory bodies around the world provide GMP guidance. For example, the European Medicines Agency (EMA) provides guidance in Europe, whilst the Food and Drug Administration (FDA) covers the USA. Many other countries use GMP guidelines provided by the World Health Organization. These agencies aim to make sure only safe products are released to market. They need to balance any potential risks against the likely benefits of a particular therapy. This requires sound scientific evidence about the safety and effectiveness of therapeutic techniques. It often involves considering the particular needs of patients who have serious, currently incurable diseases. GMP checks and controls also increase the cost of new therapies significantly. Weighing up all these issues carefully will be a key part of making affordable and safe therapies available to patients in the future.

Keeping regulations up to date

Guidelines and regulations need to be updated regularly to keep in step with scientific developments and changing attitudes in society. Updating or making new regulations often involves gathering the opinions of many different stakeholders, from manufacturers to clinicians, researchers or patient groups.  Since 2005, the European Commission has been working on updating the part of its GMP guidelines that covers biological medicinal products. The planned changes attempt to take new therapies using biological material (such as cells) into account more effectively. Two public consultations have been held in 2008 and 2010 to help with this process.