



Classification of biomaterials as medical devices or medicinal products

NMI Technology Transfer GmbH

NMI

Technologietransfer GmbH

BACKGROUND and BASICS

Biomaterials are often an essential part of tissue engineered products. This group of drugs belongs to the "advanced therapies" and needs a centralized market authorization by the end of 2012.

Any applicant must deliver a GMP compliant quality description of the biomaterial. The biomaterial must be characterized with chemical, biological, physical and biomechanical techniques.

If a new biomaterial does not meet the GMP-quality standards it will be rejected by the European authority.

CONCEPT and SOLUTION

This autumn, the renovated clause §13 of German drug law will allow the establishment of GMP compliant quality control laboratories to certify GMP compliance in some steps in a manufacturing process.

In order to provide this type of service, NMI-TT GmbH will establish a GMP quality control laboratory.

Benefit:

- NMI-TT can provide GMP compliant techniques to perform quality controls of biomaterials.
- With improved controls a manufacturer may transform a non-GMP into a GMP compliant product.
- The manufacturer QC system will not be expanded to the external laboratory.

Old law	New law
Biomaterial Manufacturer GMP-Compliant	Biomaterial Manufacturer GMP-Compliant QC-System of manufacturer
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External QC Lab NON-GMP compliant	External QC Lab GMP-compliant
QC-System of manufacturer	QC-System of lab

Fig. 2

STATUS and OUTLOOK

- NMI-Technology Transfer GmbH is preparing an application as GMP compliant quality control laboratory.
- NMI-TT has already performed a series of pilot experiments with partners to elaborate a suitable set of methods.
- NMI-TT is qualifying and validating techniques for GMP compliant biomaterial characterizations.
- NMI-TT seeks partners with a need of GMP compliant quality controls in the process of biomaterial production.


	AIM: GMP compliant production of a hydrogel
	NMI-TT Action
Gel-Components	Identification of GMP-Suppliers
Gel-Components	GMP-QC: IR, UV-VIS, GC-MS
Hydrogel	GMP-QC: Rheometry

Fig. 3

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