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Development of scaffolds for regenerative medicine

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Statement of the Problem: Regenerative medicine refers to methods to regenerate or replace human cells, tissues or organs in order to restore or establish normal function. The clinical use of stem cells, genes and tissues constitutes a new range of advanced therapy medicinal products (ATMPs) such as gene therapy medicinal products, somatic cell therapy medicinal products, tissue engineered products and combined advanced therapies' products. Each of them can be formulated with different types of biomaterials to provide greater cell viability, such as release systems, scaffolds, etc. The purpose of this study is to describe the different products with stem cells and scaffolds that should be considered ATMPs for clinical application, to classify the different types of medicinal products and meet the legal requirements for their marketing authorisation.

Methodology & Theoretical Orientation: The aim of this study was to define the main biomaterials used in ATMPs and medical devices, and the regulatory aspects for their clinical application. Thus, we searched the main available databases up to September 2016.

Findings: Major advances in advanced therapies focus on the development of matrices made of natural or synthetic origin biomaterials such as collagen, alginate, hyaluronic acid, polyethylene glycol, etc. All of them should be considered medical devices by themselves, but if each scaffold is combined with stem cells, tissues or genes, they will be considered medicinal products.

Conclusion & Significance: The ability to combine cells, tissues and genes with biomaterial manufactured structures to develop medicinal products, opens up new prospects in the administration of these ATMPs in the area of regenerative medicine.

Biography

Patricia Galvez-Martin, completed her PhD in 2014, MSc in Drug Development (2008) and MSc in Clinical Trials (2012). She has participated in several clinical trials, with great experience in the pharmaceutical industry, as Qualified Person and Quality Control Manager. She is expert in the design and development of new medicines with cells, genes and tissues to treat different pathologies. She is currently working in the biotech company Bioibérica as the Director of the Advanced Therapies Unit.

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