European Regulatory Compliance in the Manufacture of Human Cellular Therapeutic Products

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Introduction

The emergence of novel categories of regenerative cell-based therapeutic products and procedures for repairing damage to human tissues and organs has been hailed for the potential to revolutionize the future of medicine. These novel therapies include tissue engineering and somatic cell therapy products for use in a wide range of clinical applications such as skin grafts, replacement tissues (heart valves/cartilage/blood vessels), modulation of immune responses for the potential treatment of numerous disease conditions including diabetes, cardiovascular disease, osteoarthritis, irritable bowel disease, graft-versus-host disease, age-related macular degeneration, and certain types of cancer.

These new therapies involve the use and manipulation of autologous or allogenic human cells as the basis of the product used, and as such represent significant challenges to traditional regulatory pathways for conventional medicinal products. The European Union (EU) has responded in recent years through the implementation of a new regulatory framework ensuring high, consistent minimum standards of health protection within the EU, whilst promoting innovation in this newly emerging sector.

In particular, the Tissues and Cells Directive (2004/23/EC) sets high safety and quality standards for the procurement, testing, processing, storage and distribution of human tissues and cells. The Directive applies to tissues or cells, and manufactured medicinal products derived from human tissues and cells intended for human application, with a few notable exceptions. The directive, with complementary legislation, provides a regulatory framework within Europe to facilitate:

- system to guarantee anonymity and confidentiality, whilst allowing for traceability;
- communication system in the case of adverse events and an information exchange system;
- register for tissue and cell procurement, processing and distribution activities, and a list of accredited centres and authorized activities;
- appropriate system for selecting and evaluating donors to avoid transmissible diseases;
- high standards for the facilities, personnel and processes used in tissue procurement and banking, including an inspection system.

Discussion and Conclusions

The presented paper discusses certain specific requirements of the legislation in relation to donor selection and qualification, traceability, quality management and infrastructure.

References


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