Guide to the Quality and Safety of TISSUES AND CELLS for Human Application

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Guide to the Quality and Safety of Tissues and Cells for Human Application

Why a European Guide?

We are entering a new age of medical and biotechnological progress, where medical procedures that were unimaginable a generation ago have become reality today. Human tissues and cells are being used in an increasing variety of new ways and many of these developments, from advances in transplantation therapy to medically assisted reproduction (MAR), have unquestionable benefits. However, using human tissues and cells in different ways also raises questions of safety, quality and efficacy, and presents new ethical dilemmas.

The **4th Edition of the Guide to the quality and safety of tissues and cells for human application** provides healthcare professionals with **an extensive overview of the most recent advances** in the field, as well as **technical guidance to ensure the quality and safety** of human tissues and cells for human application. It is intended to support professionals on a **practical level and increase the rate of successful clinical applications**.

Elaborated by **internationally recognised experts**, this Guide constitutes a common European standard based on the **long-standing expertise and knowledge** of the European Directorate for the Quality of Medicines and HealthCare (EDQM, Council of Europe).

Who is the Guide designed for?

This Guide is intended for professionals involved in identifying potential donors; transplant co-ordinators managing the process of donation after death; bone marrow and cord blood collection centres; fertility clinics; tissue establishments processing and storing tissues and cells; testing laboratories; organisations responsible for human application; inspectors auditing the establishments; and Health Authorities responsible for tissues and cells for human application.

What information does the Guide contain?

The Guide provides sound information and guidance - aligned with **current scientific knowledge, expert opinion and the results of many international projects** - to optimise quality and minimise risks associated with the use of tissues and cells. All material of human origin carries intrinsic risks of disease transmission that must be controlled by application of scrupulous criteria for donor selection and testing, and comprehensive systems to assess quality. The Guide **aims to support professionals on a practical level by providing the type of guidance that will help improve the rate of successful clinical applications of tissues and cells**.

In addition, the Guide includes the **ethical principles and guidelines** that have to be taken into consideration in the context of tissue and cell donation and related human applications.

This guide was elaborated by a dedicated working group, composed of renowned international experts, who made a high-level contribution sharing their expertise, reviewing the literature in their respective specialist areas and extracting and distilling knowledge from numerous international guidelines, collaborative projects and diverse specialised publications and websites. A final draft of the Guide was submitted for public consultation, and the comments and recommendations received were carefully analysed by the Guide working group before the published version was finalised.

Several scientific and professional organisations were actively involved in the elaboration of this Guide, including the European Association of Tissue and Cell Banks (**EATCB**), the European Eye Bank Association (**EEBA**), the European Society for Human Reproduction and Embryology (**ESHRE**), the European Society for Blood and Marrow Transplantation (**EBMT**) and the Joint Accreditation Committee ISCT-Europe & EBMT (**JACIE**).

What has changed in this 4th Edition?

This 4th Edition has been fully revised and updated with the most recent developments in the field of tissues and cells.

The Guide is now divided into 5 sections:

Part A (Chapters 1-16) contains **general requirements** applicable to all tissue establishments and organisations involved in the donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells.

Part B (Chapters 17-28) contains **specific guidelines and requirements for the various tissue and cell types**.

Part C (Chapters 29-35) addresses **novel therapeutic approaches**. As the fields of donation and transplantation of tissues and cells evolve, new and more sophisticated technologies provide opportunities to make tissues and cells safer and their engraftment more effective. This section includes not only tissues and cells that are already in routine use in patients but also others that are in the research and development phase and are currently undergoing clinical trials.

Part D includes the new "**Tissue and Cell Monographs**" providing information on those tissue and cell preparations and clinical applications which are precisely defined and have been shown to be safe and effective when used in patients (consolidated processing for a consolidated use). Tissue and cell monographs are complementary to other sections of the Guide and can be useful tools for tissue establishments and Health Authorities, providing the minimum criteria and controls necessary for ensuring the quality of tissues and cells processed by tissue establishments.

Part E contains the newly developed **Good Practice Guidelines (GPGs) for tissue establishments** that follow EU Directives with the aim of promoting and ensuring high levels of quality in the field of human tissues and cells. These guidelines consolidate: the guidance already defined in the EU legislation; the recommendations from the main chapters of the Guide; the relevant elements derived from the detailed principles of GMP; the results of relevant EU-funded projects; and expert opinion consistent with current scientific knowledge. The GPGs, which should be seen as a complementary document for tissue establishments and inspectors/auditors, describe in detail, and from a practical point of view, the key elements to be defined and controlled for achieving comprehensive quality management in tissue establishments, as required by applicable EU legislation.

How can I obtain the Guide?

The Guide is available in English and can be downloaded in electronic format free of charge at www.edqm.eu/freepub

Paper copies are available for purchase at the EDQM Store: www.edqm.eu/store

The EDQM also publishes and regularly updates the **Guide to the quality and safety of organs for transplantation** and the **Guide to the preparation, use and quality assurance of blood components**. Additionally, the **Newsletter Transplant**, published yearly by the EDQM, contains figures on organ donation and transplantation throughout Europe and beyond.

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