

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



**EDQM**  
2nd Edition  
2015

## Why a European Guide?

Human tissues and cells are being used in an increasing variety of ways, and advances in transplantation therapy have unquestionable benefits. Human cells and tissues for human application can save lives or restore essential functions, but the use of human tissues and cells also raises questions of safety and quality. Only tissues and cells recovered, processed and stored following strict quality and safety standards are likely to function satisfactorily. Careful evaluation of donors is essential to minimise the risk of transmission of diseases. Furthermore, since human tissues and cells can currently only be derived from the body of a person, strong ethical principles need to be associated with their donation and use.

The Council of Europe, a leading standard-setting institution in this field, approaches tissue and cell transplantation in compliance with the principles of non-commercialisation and voluntary donation of materials of human origin. The European Committee on Organ Transplantation (CD-P-TO) is the Steering Committee in charge of transplantation activities for the European Directorate for the Quality of Medicines and HealthCare (EDQM, Council of Europe). As a result of the work of many leading European experts in the field, this Guide constitutes a common European standard, based on the long-standing expertise and knowledge of the EDQM.

## Who is the Guide designed for?

This 2nd Edition of the Guide to the quality and safety of tissues and cells for human application contains information and guidance for all professionals involved in identifying potential donors, managing the process of donation after death, bone marrow and cord blood collection, tissue and cell processing and storage (including assisted reproductive technology), and in the auditing of establishments and organisations responsible for human application of tissues and cells.

## What information does the Guide contain?

This Guide provides state-of-the-art information and guidance in order to optimise the quality and minimise the risks during donation, procurement, testing, processing, preservation, storage, distribution, transplantation and other clinical applications of human tissues and cells. All material of human origin carries risks of disease transmission that must be controlled by application of scrupulous criteria of donor selection (including testing) and comprehensive systems to assess quality. The idea behind this Guide is to help professionals on a practical level by providing generic guidance that will help improve the rate of successful clinical application of tissues and cells.

This Guide contains the instructions considered to be the 'minimum standards' that align with relevant European Union (EU) Directives in the field, and provides assistance for those states outside the EU that consider adopting the EU requirements in their legislation. These standards state 'what must be done'. Additionally, this Guide goes beyond these standards by providing additional technical advice, based heavily on Good Manufacturing Practice (GMP) Guidelines and on best practices consistent with current scientific knowledge and expert opinion. It describes background information that should be considered in forming policy decisions, as well as in educational initiatives. This additional information explains the 'why and how'. It also refers to developments that have yet to be incorporated in EU Directives, thereby providing advance information and recommendations regarding technical developments in the field.

This Guide has been divided into two parts. Part A contains general requirements applicable to all establishments involved in the donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells that are not manipulated extensively. Part B contains specific guidelines and requirements for the different tissue and/or cell types.

The EDQM also publishes and regularly updates the *Guide to the quality and safety of organs for transplantation*, which collates information

and guidance for professionals involved in donation and transplantation of organs, and the *Guide to the preparation, use and quality assurance of blood components*, which provides principles and standards designed to ensure the safety, efficacy and quality of blood components. Additionally, the EDQM annually publishes the *Newsletter Transplant*, which collates international figures on organ donation and transplantation throughout Europe and beyond.

## What has changed in this 2nd Edition?

In this second edition, all of the chapters have been revised thoroughly to update their contents with the most recent advances in the field. In addition, many new and important chapters have been added.

The former chapter on identification of potential donors, consent and evaluation has been divided into two new, more comprehensive chapters: one on 'Recruitment of potential donors' and another one on 'Donor evaluation'.

The chapter on 'Donor testing' now includes a detailed section that describes principles for validation of screening assays for infectious diseases used for testing blood from deceased donors, and considers differences in test results obtained by various types of testing laboratories (hospital-based versus reference laboratory).

The chapter on 'Processing and storage' has been updated to cover more detailed instructions on the requirements of processing facilities as well as monitoring of such facilities (viable and non-viable particles). The text has also been bolstered with more detailed information on the requirements of the cleaning of facilities, storage and exceptional release.

The chapters on 'Distribution and import/export' and on 'Traceability' now include the new EU requirements for the import and coding of tissues and cells.

The fields of assisted reproduction and fertility preservation are now addressed in detail in two dedicated chapters.

A very significant enhancement to the Guide has been the development of a new chapter dedicated to the principles of microbiological testing of tissue and cell preparations and their processing environments. This chapter recommends (among other features) the testing methods to be applied in the laboratory and outlines the principles that underpin validation of those methods.

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, or their engraftment more effective. Hence, new chapters have been introduced in the Guide to address the field of cell therapy in particular. One of these new chapters provides a didactic overview of the field by describing the different ways in which cells can be expanded, modified or combined with scaffolds to replace damaged or diseased tissues in the recipient. In a separate chapter, several types of cells (apart from haematopoietic stem cells) that are rapidly becoming important tools in the fight against disease are described.

A new chapter on adipose tissue has been added to provide general principles to be considered if banking adipose tissue, an activity that is showing promise for patients with scarring due to tumour removal or burns.

Finally, a new chapter introduces several other substances obtained from humans for autologous or allogeneic use: human breast milk, faecal microbiota, teeth/dental pulp, platelet-rich plasma, platelet-rich fibrin and serum eye drops. This chapter provides a generic quality and safety framework for healthcare professionals treating patients with these substances.

## Publication and purchase of the Guide

The Guide is available in book and online versions, in English. For more information, please visit the EDQM website: <https://go.edqm.eu/OTg> or scan the QR code.



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