

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



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**EDQM**  
3rd Edition  
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## Why a European Guide?

Human tissues and cells are being used in an increasing variety of ways. They can save lives or restore essential functions, but their use 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. Therefore, 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's European Directorate for the Quality of Medicines and HealthCare (EDQM) approaches the donation and human application of tissues and cells 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 of the EDQM. 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 3rd 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, transplant co-ordinators managing the process of donation after death, bone marrow and cord blood collection centres, tissue establishments processing and storing tissues and cells, testing laboratories, fertility clinics, 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?

This Guide collates the most up-to-date information to provide transplant professionals with a comprehensive overview of the most recent advances in the field as well as technical guidance on ensuring the quality and safety of human tissues and cells applied to patients.

This Guide includes recommendations considered to be "minimum standards" that align with the principles set out in the various relevant European Union (EU) directives. Thus, the Guide provides technical support both to EU member states that have implemented the directives and to those non-EU states that are considering their adoption. These minimum standards state "what must be done"; however, this Guide goes further by providing additional technical advice based on good manufacturing practice (GMP) guidelines and on best practice consistent with current scientific knowledge, expert opinion and the results of many EU-funded projects. It describes background information that should be considered in forming policy decisions and educational initiatives by explaining the "why and how". It also refers to recent developments that may be reflected in future updates of EU legislation, where necessary and relevant, thereby providing advance information and recommendations regarding developments in the field.

This Guide has been divided into three 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. Part B contains specific guidelines and requirements for the different tissue and/or cell types. The new Part C introduces novel therapeutic approaches such as cell-based therapies, decellularisation techniques and the use of natural scaffolds for clinical application, or the human application of other human-derived substances such as breast milk, faecal microbiota, platelet-rich plasma or serum eye drops.

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 3rd Edition?

In this third edition, all 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.

### Evolutions:

- ▶ In Part A, principles to be respected in new and developing therapies with cells or tissues for human application are introduced in the introductory chapter.
- ▶ Chapter 2 on "Quality management, risk management and validation" has been expanded to provide more specific guidance on the validation and qualification of premises, materials and technical procedures and methods.
- ▶ General quality and safety aspects of processing and storage and quality aspects of premises now have separate dedicated chapters. In addition, the chapter on the principles of microbiological testing of tissue and cell preparations, introduced in the 2nd edition of the Guide, has been expanded.
- ▶ The chapter on "Distribution and import/export" of tissues and cells has been updated according to new EU Commission directives and requirements (as of April 2017) and a separate chapter on coding, labelling and packaging added. Due to its importance and requirement, traceability has its own dedicated chapter.
- ▶ In Part B, chapters on specific tissues and cells have all been revised, updated and extended with additional information provided by experts from scientific and professional organisations, including the American Association of Tissue Banks (AATB), the European Association of Tissue Banks (EATB), 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 & EBMT (JACIE). In particular, the chapter on haematopoietic progenitor cells has undergone a major review and revision, and the established use of pancreatic islets in the clinic justified a chapter of its own.
- ▶ The previous "place holder" on adipose tissue has been expanded into a full chapter providing complete guidance for its procurement, testing, storage and human application. Likewise, the chapter on fertility preservation is now a more complete chapter covering the state of the art on how and when fertility preservation may be useful.
- ▶ In Part C, "General considerations for cell-based therapies" 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. This chapter includes information about the regulatory framework governing the production and use of some of these therapies in the EU.
- ▶ "Decellularisation and preparation of natural scaffolds" provides technical guidance to any tissue establishment in decellularisation techniques and the preparation and potential use of scaffolds.
- ▶ "Developing applications for somatic cells" focuses on developing applications for several types of cell that are rapidly becoming important tools for the treatment of patients. Specific issues in donor selection, procurement and testing (including testing for quality/specificity if applicable) are covered.
- ▶ Finally, the last chapter updates information about 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.

## Where can I get the Guide?

The Guide is available in English. It can be downloaded in **electronic format free of charge**: [www.edqm.eu/freepub](http://www.edqm.eu/freepub)

Paper copies are available for purchase at the EDQM Store: [www.edqm.eu/store](http://www.edqm.eu/store).

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