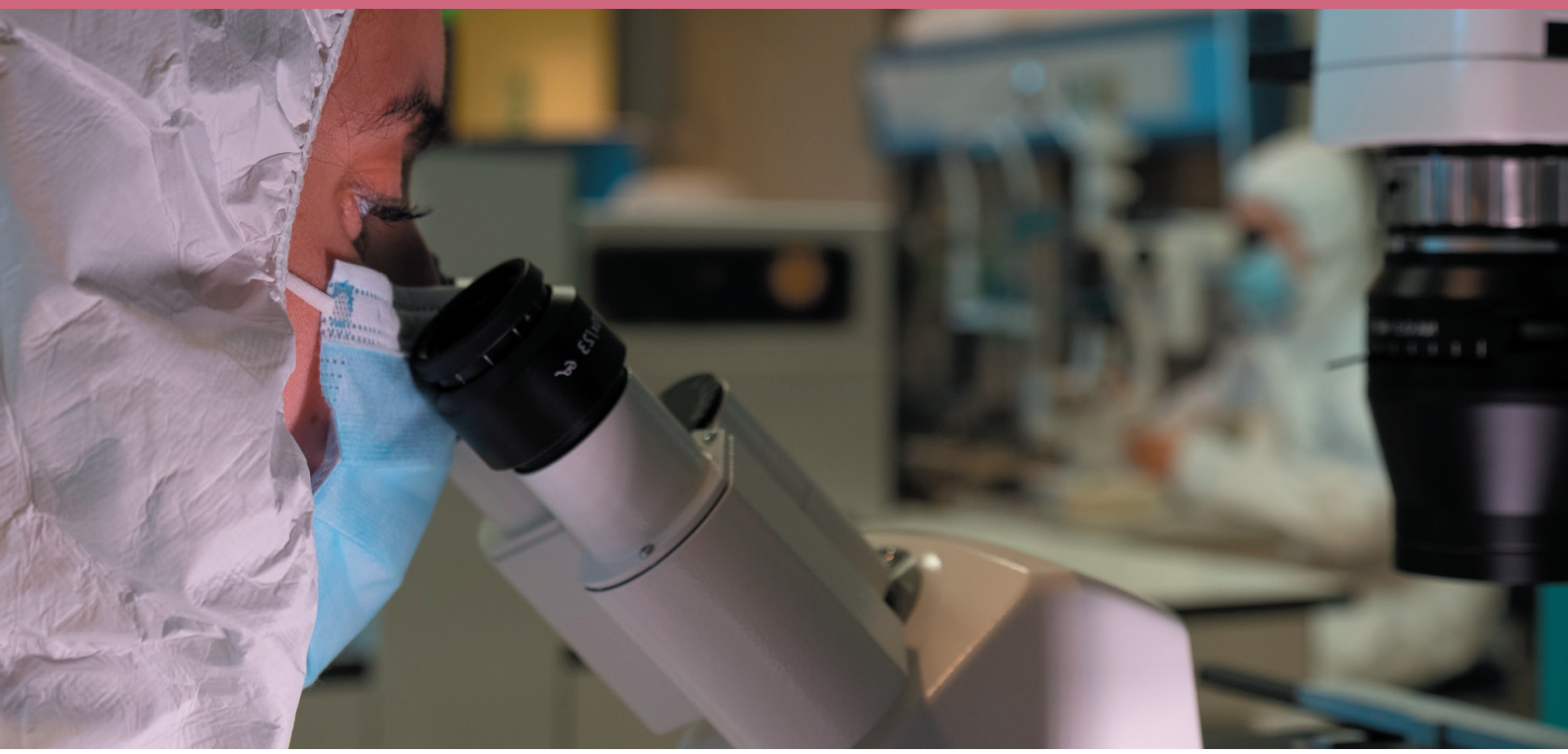
# Guide to the quality and safety of TISSUES AND CELLS for human application



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# GUIDE TO THE QUALITY AND SAFETY OF TISSUES AND CELLS FOR HUMAN APPLICATION

## PURPOSE AND BACKGROUND

The *Guide to the quality and safety of tissues and cells for human application* provides readers with a comprehensive 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.

This guide has been elaborated by a dedicated working group of internationally recognised experts, working under the aegis of the European Committee on Organ Transplantation (CD-P-TO), which is responsible for transplantation activities at the European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe). The CD-P-TO actively promotes the non-commercial donation of organs, tissues and cells, the fight against organ, tissue and cell trafficking, and the development of ethical, quality and safety standards in the field.

## WHO CAN BENEFIT

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.

## THE GUIDE IN BRIEF

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 human tissues and cells.

All material of human origin carries intrinsic risks of disease transmission that must be controlled by the application of scrupulous criteria for donor selection and testing, and comprehensive systems to assess quality. The guide therefore provides professionals with the guidance necessary to improve the rate of successful clinical applications of tissues and cells. The ethical principles and guidelines relevant in the context of tissue and cell donation and related human applications are also addressed.

In addition to experts from member states, 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) and the European Society for Blood and Marrow Transplantation (EBMT).

## NEW IN THE 5th EDITION

This new edition of the guide has been fully revised and updated with the most recent developments in the field of tissues and cells. It is divided into several sections.

- **Part A** (Chapters 1-18) 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 19-34) contains specific guidelines and requirements for the various tissue and cell types.
- **Part C** presents the Good Practice Guidelines (GPGs) for tissue establishments that follow EU legislation, with the objective of promoting and ensuring high levels of quality in this field. The GPGs constitute a complementary document for tissue establishments and inspectors or auditors, specifying the key factors in achieving comprehensive quality management in tissue establishments, as required by applicable EU legislation.
- **Part D** includes "Tissue and Cell Monographs" providing information on 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.
- In addition, the new online EDQM Microbiological Risk of Contamination Assessment tool (dubbed "**MiRCA**") is a major innovation designed to help users identify potential risks in novel, existing or modified aseptic processes; to alert users to the degree of risk of introducing microbiological contamination during the procurement or processing of tissues and cells; and to support decisions and changes to mitigate risks during aseptic processes. The tool is available at: https://soho-guides.edqm.eu/home/.

## HOW TO OBTAIN A COPY

The *Guide to the quality and safety of tissues and cells for human application* is available in English, in print and electronic form. The electronic version can be downloaded for free and the print version purchased from the EDQM Store. For more details, visit the EDQM website: https://go.edqm.eu/TCg or scan the QR code overleaf.

## ADDITIONAL GUIDANCE IN THE FIELD

*Guide to the quality and safety of organs for transplantation*: https://go.edqm.eu/OTg.

*Guide to the preparation, use and quality assurance of blood components*: https://go.edqm.eu/BTg.

*Newsletter Transplant*, published annually by the EDQM in conjunction with the Spanish Organización Nacional de Trasplantes, contains data on organ donation and transplantation throughout Europe and beyond: https://go.edqm.eu/NLTransplant.

For further information on additional guidance documents in the transplantation field for governments, professionals and the general public, please visit https://go.edqm.eu/TransplantReports.

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