NEW EDITION GUIDE TO THE QUALITY AND SAFETY OF TISSUES AND CELLS FOR HUMAN APPLICATION NOW AVAILABLE

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.

The European Directorate for the Quality of Medicines and HealthCare (EDQM, Council of Europe) has released a new edition of the Guide to the Quality and Safety of Tissues and Cells for Human Application (2nd Edition, 2015). 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. 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.

The 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. 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.

The EDQM also publishes a 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.

For more information on the new Edition and how to order, please visit the EDQM website.

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Note for the Editor: Further information is available on the internet site www.edqm.eu
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

The work of the Council of Europe in the area of organ, tissue and cell donation and transplantation started in 1987, contributing actively to the implementation of high standards for the protection of public health and for the promotion of human rights and dignity. The European Committee on Organ Transplantation (CD-P-TO) is the steering committee in charge of these activities at the EDQM. It actively promotes the non-commercialisation of organ, tissue and cell donation, the fight against organ trafficking, and the development of ethical, quality and safety standards in the field of organ, tissue and cell transplantation.
There are thirty-eight members of the European Pharmacopoeia Commission: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union. There are twenty-eight observers: Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, Georgia, Guinea, Israel, Kazakhstan, Republic of Korea, Madagascar, Malaysia, Republic of Moldova, Morocco, Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.