TECHNICAL ISO/TS

First edition
2020-08

General requirements of tissue-engineered medical products

Reference number
ISO/TS 21560:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 7, *Tissue-engineered medical products*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Advances in the field of biological sciences have made possible the generation of a new type of medical product that when administered to the human body, may repair, replace, regenerate or enhance the function of impaired tissues or organs.

Extensive experience acquired through the administration of living human cells has yielded solid knowledge about the quality requirements and the risks associated with their use.

However, the development of tissue-engineered medical products (TEMPs) that are not simply obtained from a human donor or by separating living tissues, but rather are grown from various cell sources and are manipulated during manufacture to meet the medical needs of the patient, introduces new challenges with regard to quality requirements and risk management for the benefit of patients.

TEMPs utilizing human material are quite diverse but share a set of common quality requirements for their safe use. These kinds of products require special attention for contamination control, such as infectious agents transmitting disease (e.g. hepatitis, HIV, TSE) and harmful chemicals, unintended decomposition or degradation induced by inappropriate handling at any stage of the manufacturing process, tumorigenic potential, induction of an immunogenic reaction in the recipient, traceability of cells, critical materials, and the final product are key to product quality and its safe use.

This document has been developed with the objective of assisting interested parties, such as manufacturers and regulators, establish suitable quality parameters and specifications for the final TEMPs as well as cells, critical materials, processing steps and appropriate controls ensuring the safety of TEMPs.