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## General requirements of tissue- engineered medical products



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## Foreword

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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](http://www.iso.org/directives)).

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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](http://www.iso.org/members.html).

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## 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 TEMP as well as cells, critical materials, processing steps and appropriate controls ensuring the safety of TEMP.