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Biotechnology — Ancillary materials present during the production of cellular therapeutic products and gene therapy products

Biotechnologie — Matériaux auxiliaires présents lors de la production de produits thérapeutiques cellulaires et de produits de thérapie génique

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Contents

Page

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 276, *Biotechnology*.

This first edition cancels and replaces ISO/TS 20399-1:2018, ISO/TS 20399-2:2018 and ISO/TS 20399-3:2018, which have been technically revised.

The main changes are as follows:

— merging of the three parts of the ISO 20399 series;

— change in definitions of key terms including “ancillary material” and “cellular therapeutic product”;

— addition of Clause 5 “Strategy”, including key concepts, animal-derived components, mutual responsibilities and qualification;

— revision and rearrangement of requirements and recommendations with emphasis on clarifying responsibility of involved parties and emphasis of a risk-based approach.

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

Ancillary materials (AMs) refer to materials that come into contact with the cellular therapeutic product during cell processing but are not intended to be part of the final product formulation. See Annex A for a list of AM examples.

AM can be a complex mixture of many components. AMs include, for example, salts, buffers, culture media, supplements such as growth factors, enzymes and antibodies for immuno-purification. Where a material is composed of multiple materials such as culture media, all components are AMs. Variation in their lot-to-lot composition can hamper the ability to produce consistent cell and gene therapy products with specified quality attributes.

As such, AMs can have implications with regard to the safety and effectiveness of cell and gene therapy products. Appropriate control of AMs is determined by a risk-based approach.

This document specifies definitions for AMs.

This document provides recommendations and requirements to the AM suppliers and the AM users to ensure consistent manufacture and performance of AMs. This document also describes the information that can be obtained and provided to the AM users to demonstrate lot-to-lot consistency of the AM with respect to identity, purity, storage and stability, traceability, biosafety, and performance. Furthermore, this document provides recommendations and requirements to ensure that the quality of AMs enables the production of safe and effective final products.

Presently, a number of standards and guidance documents define the proper processing of cell and gene therapy products to ensure safety and efficacy. However, these standards only indirectly relate to AMs. This document is separate from the standards governing cell processing requirements. This document addresses issues with AMs and makes the expectations of the AM suppliers and the AM users clear.