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

Part 3: Best practice guidance for ancillary material users

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National foreword

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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).

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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*.

A list of all parts in the ISO/TS 20399 series can be found on the ISO website.

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.

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Introduction

Ancillary materials (AMs) are materials that come into contact with the cellular therapeutic product during the manufacturing process, but are not intended to be in the final product.

AMs include culture media and growth factors, among other biological and non-biological components. They can be a complex mixture of many components and variation in their lot-to-lot composition can hamper the ability to produce a consistent cellular therapeutic product with specified quality attributes.

As such, AMs can have implications with regard to the safety and effectiveness of a cellular therapeutic product. Appropriate control of ancillary material is determined by a risk-based approach.

This document specifies guidelines to AM users on best practice considerations for use of AMs, particularly those of biological origin, in the manufacture of cellular therapeutic product and contributes to their control by suppliers and users of such materials.

The ISO/TS 20399 series provides general requirements and guidance regarding ancillary materials to maintain a high level of lot-to-lot consistency, as well as the accompanying documentation, so that consistent ancillary material (AM) products and documentation provided by the AM suppliers can help AM users.

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TECHNICAL SPECIFICATION **ISO/TS 20399-3:2018**

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

Part 3: Best practice guidance for ancillary material users

1 Scope

This document provides guidance for ancillary material (AM) users. It is applicable to cellular therapeutic products, including those gene therapy products whereby cells form part of the final product. It does not apply to products without cells.

This document focuses primarily on ancillary materials (AMs) of biological (human and animal) origin and their potential impurities and contaminants.

NOTE 1 The decision chart in Figure 1 illustrates the rationale underlying the scope of this document.

However, diverse biological sources, including plants, insects and marine organisms, can also be used in the development of a cellular therapeutic product. Therefore the fundamental principles of risk management also apply for these sources of AMs.

This document does not cover the selection, assessment or control of starting materials and excipients. However, it is anticipated that these are still covered by general risk management procedures.

This document is applicable for users at all stages of clinical development and supply; however maximum benefits can be gained by the implementation of the recommendations in the early stages of development.

NOTE 2 International, regional or national regulations or requirements can also apply to specific topics covered in this document.

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