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BSI Standards Publication

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

Part 2: Best practice guidance for ancillary material suppliers

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National foreword

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Part 2: Best practice guidance for ancillary material suppliers

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Partie 2: Lignes directrices de bonne pratique pour les fournisseurs de matériaux auxiliaires

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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*.

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.

Introduction

Ancillary materials (AM) 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, growth factors, and other biological and non-biological components. They can be a complex mixture of multiple components and variation in their lot-to-lot compositions can hamper the ability to produce a consistent product based on therapeutic cells with specified quality attributes.

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

This document provides guidelines to AM suppliers on best practice to ensure consistent manufacture of AM products. It also describes the information that should be obtained and provided to the AM user to demonstrate lot-to-lot consistency of the AM product with respect to AM characteristics and quality attributes, biosafety, and performance.

A number of standards and guidance documents define the proper processing of cell based therapeutic products to ensure safety and efficacy. However, these standards only indirectly relate to the suppliers of AM products. This document clarifies the expectations for AM suppliers which are distinct from the standards governing cell processing requirements.

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 materials (AM) products and documentation provided by the suppliers can help AM users.

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TECHNICAL SPECIFICATION **ISO/TS 20399-2:2018**

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

Part 2: Best practice guidance for ancillary material suppliers

1 Scope

This document provides guidance for ancillary material (AM) suppliers to maintain a high level of lot-to-lot consistency in the aspects of identity, purity, stability, biosafety, performance, as well as the accompanying documentation.

This document is applicable to cellular therapeutic products, including gene therapy products whereby cells form part of the final product. It does not apply to products without cells.

The AMs described in this document include those of biological origin [e.g. sera, media (including media additives), growth factors, and monoclonal antibodies] and chemical origin. This document does not address dimethyl sulfoxide (DMSO) for cryopreservation, beads, scaffolds, feeder cells, apparatus and instruments, or additives used post bioprocessing.

This document does not cover the selection, assessment or control of starting materials and excipients.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 20399-1, *Biotechnology — Ancillary materials present during the production of cellular therapeutic products — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TS 20399-1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Abbreviated terms

ADCF	animal-derived component free
AM	ancillary material
CoA	certificate of analysis