PD ISO/TS 20399-1:2018

BSI Standards Publication

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

Part 1: General requirements

bsi.

National foreword

This Published Document is the UK implementation of ISO/TS 20399-1:2018.

The UK participation in its preparation was entrusted to Technical Committee BTI/1, Biotechnologies.

Attention is drawn to the fact that during the development of ISO/TS 20399-1:2018, the UK committee voted against its approval.

The UK committee recognizes the advances made through the development of the ISO/TS 20399 series. However, in the opinion of the UK committee, there remain concerns relating to potential misunderstanding and limitations caused by the introduction and use of certain terminology in this document regarding the risk assessment of ancillary materials.

The UK committee advises users to be aware that, while it believes the meanings to be effectively the same, the term 'raw material' (RM) – rather than the term in this document, 'ancillary material' (AM) – is more consistent with terminology used by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The UK committee notes that raw materials are an integral part of any manufacturing control strategy and that to what degree raw material quality needs to be controlled, and how critical any one raw material is, can differ considerably from product to product. The UK committee also notes that the principle of selecting appropriate-quality raw materials does not differ between cell-based products and other medicines; it is the risk assessment that is distinct.

Furthermore, the UK committee notes that this document makes no reference to specific qualities or features of raw materials, the understanding of which would be necessary – in the UK committee's opinion – in order for users to undertake a risk assessment. It is also the UK committee's opinion that the document does not contain any specific recommendations for addressing risks arising from adventitious agents from standard raw material treatments that can impact the raw material's quality.

The UK committee believes that the introduction of the term 'animal-derived component free' (ADCF), and the use of multiple levels of ADCF (see Subclause 5.2.2), poses the potential risk that a user may not ask appropriate questions about the source of a raw material in cases where a supplier claims that the raw material is compatible with, for example, ADCF level 1. The UK committee believes that this document has potential limitations through suppliers not using terminology consistently and thereby introducing an unacceptable level of risk to both manufacturers' investment and patient safety.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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TECHNICAL SPECIFICATION

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

Part 1: General requirements

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

Partie 1: Exigences générales

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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 (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 a variation in their lot-to-lot composition can hamper the ability to produce consistent cellular therapeutic products 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 materials is determined by a risk-based approach.

This document specifies definitions and general requirements for AMs 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 materials products and documentation provided by the suppliers can help AM users.

It is intended to ensure the quality and consistency of AMs used in the manufacturing of cellular therapeutic products. Good manufacturing practice (GMP) is taken into account, when necessary.

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TECHNICAL SPECIFICATION **ISO/TS 20399-1:2018**

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

Part 1: General requirements

1 Scope

This document specifies definitions and general requirements for ancillary materials (AMs) used in cell processing of cellular therapeutic products.

This document 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 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

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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/

3.1
ancillary material
AM
material that comes into contact with the cell or tissue product during cell-processing, but is not intended to be part of the final product formulation

Note 1 to entry: AMs exclude non-biological consumables (e.g. tissue culture flasks, bags, tubing, pipettes, needles) and other plastic ware that comes into contact with the cell or tissue, but include consumables which can have a biological component (e.g. coated dishes or beads).

Note 2 to entry: AMs exclude cells (e.g. feeder cells).

Note 3 to entry: In some cases AM is described as raw material.

3.2
AM user
entity who makes use of *AM* (3.1) and conducts cell-processing for cellular therapeutic product

3.3
AM supplier
entity who manufactures and/or supplies the *AM* (3.1) for *AM user* (3.2)