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Biotechnology — General requirements for transportation of cells for therapeutic use

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National foreword

This British Standard is the UK implementation of ISO 21973:2020.

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

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

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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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*.

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

Cells for therapeutic use provide potential cures for the most challenging disease conditions. However, in contrast to the unprecedented clinical benefits, managing the production and logistics of cells for therapeutic use proves to be challenging. Not only the cost is exceedingly high to produce and transport these products, the concerns over product safety and efficacy due to potential manufacturing or transportation deficiencies have started mounting as more products are being developed and tested.

The cell therapy workflow begins with collection of cells (including tissues). With autologous cells for therapeutic use, cells are collected from patients in the clinical setting before shipping to manufacturing sites for processing and production. After manufacturing and testing for release, cells for therapeutic use are transported to clinical sites for administration into patients.

Issues related to cell transportation have been identified in the product workflow. Some of these issues include monitoring and controlling transportation conditions, managing traceability and maintaining chain of custody, and establishing clear expectations and communications between cell product manufacturer and transportation service provider. These issues all have significant impact on cells for therapeutic use quality that can ultimately affect product safety and effectiveness. Therefore, there is a need for standards to ensure cell transportation is appropriately and adequately planned, executed, traced and documented.

This document intends to provide general requirements and points to consider for transportation service providers, clients and senders to ensure cell quality, safety and efficacy during the transportation process.

Application of this document presupposes awareness of applicable legal requirements.

ISO 13022:2012, Annex G contains guidance for transport of human cells.

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Biotechnology — General requirements for transportation of cells for therapeutic use

1 Scope

This document specifies general requirements and reviews the points to consider for the transportation of cells for therapeutic use, including storage during transportation.

Transportation starts from the transfer of the packaged cells by the sender to the transportation service provider and ends when the package is delivered to the receiver at its destination.

This document does not apply to transportation of cells within one facility.

This document includes the development of a transportation plan including verification and validation, communication between the client and the transportation service provider, and associated documentation.

This document does not specify particular conditions for transportation such as specification for shipping container, ambient temperature control, etc.

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
cells for therapeutic use
product containing cells as the active substance

EXAMPLE Cell therapy medicinal product, tissue engineered product.

Note 1 to entry: For the purpose of this document, “cells” mean human cells and tissues of autologous as well as allogeneic.

Note 2 to entry: For the purpose of this document, this term includes cells collected as starting materials and cultured as intermediate materials.

Note 3 to entry: The expression “therapeutic use” includes clinical research, hospital exception and testing use.

3.2
chain of custody
responsibility for or control of materials as they move through each step of a process

Note 1 to entry: For the purpose of this document, “chain of custody” is the proven path starting from the transfer of the packaged cells from the *sender* (3.11) to the *transportation service provider* (3.13) and ends when the package is received at its destination.

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3.3
client
entity requesting cell transportation by contract with *transportation service provider* (3.13)

3.4
document
information and the medium on which it is contained

EXAMPLE Record, specification, procedure document, drawing, report, standard.

Note 1 to entry: The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or combination thereof.

Note 2 to entry: A set of documents, for example specifications and records, is frequently called "documentation".

Note 3 to entry: Some requirements (e.g. the requirement to be readable) relate to all types of documents. However there can be different requirements for specifications (e.g. the requirement to be revision controlled) and for records (e.g. the requirement to be retrievable).

[SOURCE: ISO 9000:2015, 3.8.5]

3.5
documented information
information required to be controlled and maintained by an organization and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

— the management system, including related processes;

— information created in order for the organization to operate (documentation);

— evidence of results achieved [*records* (3.8)].

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

[SOURCE: ISO 9000:2015, 3.8.6]

3.6
inspection
determination of conformity to specified requirements

[SOURCE: ISO 9000:2015, 3.11.7, modified — Notes to entry have been deleted.]

3.7
receiver
entity that gets *cells for therapeutic use* (3.1) from the *transportation service provider* (3.13)

3.8
record
document (3.4) stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalize *traceability* (3.12) and to provide evidence of *verification* (3.15), preventive action and corrective action.

Note 2 to entry: Generally records need not be under revision control.

[SOURCE: ISO 9000:2015, 3.8.10]

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