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Biotechnology — General requirements for transportation of cells for therapeutic use



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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General concepts	4
5 Cell transportation specification	5
5.1 General.....	5
5.2 Items specified in the cell transportation specification.....	5
5.2.1 General.....	5
5.2.2 Information reflected in the cell transportation specification.....	5
5.2.3 Capability of the cell transportation service provider and its external service provider(s).....	6
5.3 Risk management, verification and validation.....	9
5.3.1 Risk management.....	9
5.3.2 Verification and validation.....	10
6 Best practices for shipping container and labelling	10
6.1 General.....	10
6.2 Shipping container.....	11
6.2.1 Shipping container systems.....	11
6.2.2 Shipping container requirements.....	11
6.3 Labelling of the shipping container.....	12
6.3.1 Information to be labelled.....	12
6.3.2 Physical requirements for the label.....	13
6.3.3 Handling of labels.....	13
7 Operation	13
7.1 General operation.....	13
7.1.1 General.....	13
7.1.2 Preparation of shipment.....	13
7.1.3 Transportation.....	13
7.1.4 Inspection at the time of delivery.....	14
7.2 Traceability.....	14
7.3 System to handle exceptional operations.....	15
7.3.1 Emergency handling.....	15
7.3.2 Management in case of an incident.....	15
8 Organization	16
8.1 General.....	16
8.2 Personnel training.....	16
8.2.1 General.....	16
8.2.2 Training plans.....	16
8.2.3 Training records.....	17
8.3 Quality management system (QMS) considerations.....	17
9 Storage facility	18
9.1 General.....	18
9.2 Storage facility considerations.....	18
10 Documented information	18
Bibliography	19

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).

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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*.

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.