First edition
2020-06

Biotechnology — General requirements for transportation of cells for therapeutic use

Reference number
ISO 21973:2020(E)

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Published in Switzerland

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Foreword

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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.

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.