CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 019 **Date of Recognition:** 03/06/2023

SDO Name/Designation: ISO 21973 **Year of Publication:** 2020

Title: General requirements for transportation of cells for therapeutic use

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.

Extent of Recognition: Complete Recognition

Rational for Recognition: This standard is relevant to regenerative medicine therapies and is recognized because it is scientifically and technically valid and does not conflict with existing regulations and policies.

Standard Development Organization: https://www.iso.org

Please note that this standard may also be recognized under the Center for Devices and Radiological Health's (CDRH) Recognized Consensus Standards Database for Medical Device, found here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.