CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 002 **Date of Recognition:** 06/14/2023

SDO Name/Designation: ANSI/PDA 02 **Year of Publication:** 2021

Title: Cryopreservation of Cells for Use in Cell Therapies, Gene Therapies, and Regenerative Medicine Manufacturing: An Introduction and Best Practices Approach on How to Prepare, Cryopreserve, and Recover Cells, Cell Lines, and Cell-Based Tissue Products

Scope:
The purpose of this document is to provide guidance on how to establish suitable procedures for the cryopreservation and recovery of biological cells for use in cell and gene therapy products and regenerative medicine manufacturing either as an intermediate step or when cryopreservation is the final step. This document presents cryopreservation as a modular process and describes key details that should be considered when developing a cryopreservation and recovery process for a specific-use case. The guide emphasizes the effect cryopreservation and recovery may have on cell viability and cell function. Although best practices for users in cell-based product manufacturing are discussed, specific procedures will likely depend on the nature of the biological cells being cryopreserved.

This document is not intended to provide information on the terms and procedures directly associated with regulatory requirements governing cell-based products. The best practices and guidance details outlined in the document provide general procedural support for cryopreservation of cell-based products during both the early and late phases of product development. References to scientific literature and other relevant documents are provided throughout this text for individuals interested in additional information.
This document is a current best practice standard and guide on how to establish suitable conditions for the cryopreservation and recovery of cells, cell lines, and cell-based products for use in cell and gene therapies and regenerative medicine manufacturing. This standard is intended to:

- Discuss considerations for cryopreservation;
- Address the challenges associated with maintaining the viable recovery and functionality of cell and gene therapy products; and
- Outline cryopreservation best practices for the manufacture of cell-based products.

Extent of Recognition: Complete Recognition

Rational for Recognition: The standard is scientifically sound and does not conflict with regulations or FDA guidance.

Standards Development Organization: https://www.pda.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