CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 011 **Date of Recognition:** 4/17/2023

SDO Name/Designation: ISO 23033 **Year of Publication:** 2021

Title: Analytical methods — General requirements and considerations for the testing and characterization of cellular therapeutic products

Scope:
This document provides general requirements for the testing of cellular therapeutic products intended for human use. This document also provides considerations for the characterization of cellular therapeutic products, including approaches to select and design analytical methods that are fit for purpose. Such considerations can be used to establish critical quality attributes for a cellular therapeutic product. This document is applicable to cellular starting materials (including those for tissue engineered products) and intermediates of cellular therapeutic products. This document is not applicable to tissues used in transplantation.

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. To note, users of this standard should reference regulatory requirements (e.g., 21 CFR 2171 Subpart C) in conjunction with this standard.

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.