CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 005 **Date of Recognition:** 03/17/2023

SDO Name/Designation: ASTM F3206 **Year of Publication:** 2017

Title: Standard Guide for Assessing Medical Device Cytocompatibility with Delivered Cellular Therapies

Scope:
1.1 This guide outlines the parameters to consider when designing in vitro tests to assess the potential impact of a delivery device on a cellular product being dispensed. This guide does not provide specific protocols, but rather suggests what should be considered the minimum characterization necessary to assess device cytocompatibility. Topics discussed include selecting an appropriate cell line(s), cell physiology parameters to measure, and relevant test procedure variables. Only cells suspended in liquid and infused through a device are considered. Cell therapies paired with scaffolds, suspended in hydrogels, or administered via other methods (e.g., tissue grafting) are not included in the scope of this document. This document does not address physical characterization of delivery devices, such as mechanics, composition, or degradation.
1.2 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

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. Section 5: Cell Selection suggests selecting a cell line that represents the intended use of the delivery device. FDA expects that the test article is the cell therapy product.

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