CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 004 **Date of Recognition:** 06/14/2023

SDO Name/Designation: ASTM F2739 **Year of Publication:** 2019

Title: Standard Guide for Quantifying Cell Viability and Related Attributes within Biomaterial Scaffolds

Scope:

1.1 This guide is a resource of cell viability test methods that can be used to assess the number and distribution of viable and non-viable cells within porous and non-porous, hard or soft biomaterial scaffolds, such as those used in tissue-engineered medical products (TEMPs).

1.2 In addition to providing a compendium of available techniques, this guide describes materials-specific interactions with the cell assays that can interfere with accurate cell viability analysis and includes guidance on how to avoid or account for, or both, scaffold material/cell viability assay interactions.

1.3 These methods can be used for 3-D scaffolds containing cells that have been cultured in vitro or for scaffold/cell constructs that are retrieved after implantation in living organisms.

1.4 This guide does not propose acceptance criteria based on the application of cell viability test methods.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 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, health, and environmental practices and deter-mine the applicability of regulatory limitations prior to use.

1.7 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Extent of Recognition: Partial Recognition.

Section not recognized: 5.8.

Rational for Recognition: This standard references ASTM F748, which conflicts with ISO 10993-1, for which FDA has published a guidance. Until ASTM 748 and ISO 10993 are reviewed by this program, the standard should be recognized except for the reference to ASTM F748.

Standard 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.