CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 027 **Date of Recognition:** 9/11/2024

SDO Name/Designation: ISO 20391-2 **Year of Publication:** 2018

Title: Biotechnology - Cell counting - Part 2: Experimental design and statistical analysis to quantify counting method performance

Scope: This document defines terms related to cell counting for biotechnology. It describes counting of cells in suspension (generally cell concentration) and cells adhered to a substrate (generally area density of cells). It provides key considerations for general counting methods (including total and differential counting, and direct and indirect counting) as well as for method selection, measurement process, and data analysis and reporting. This document is applicable to the counting of all cell types – mammalian and non-mammalian (e.g. bacteria, yeast) cells. This document is not intended for counting of cells while in a tissue section or a biomaterial matrix. Several sector/application-specific international and national standards for cell counting currently exist. When applicable, the user can consult existing standards when operating within their scope (specific measurement techniques and/or applications).

Extent of Recognition: Complete recognition

Rational for Recognition: The standard is relevant to cell therapy, gene therapy and tissue engineered products.

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