CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 036 **Date of Recognition:** 04/29/2024

SDO Name/Designation: ISO 23511 **Year of Publication:** 2023

Title: Biotechnology — General requirements and considerations for cell line authentication

Scope:
This document defines terms related to cell line authentication in the field of biotechnology. It describes the general principles, detection strategies and analytical methods for cell line authentication. It specifies requirements and key considerations for method selection, quality control parameters, data analysis and reporting. This document is applicable to routine inspection of cell lines in culture and in storage in the fields of basic research, translational studies and product manufacturing. It is also applicable to cell line origin validation in academic and industrial laboratories, cell banks and manufacturing sites. It is primarily applicable to mammalian cells, including human cells. This document does not apply to non-animal cells (e.g. microbial contamination, plant cells), nor to cells in complex matrices (e.g. tissues, organs, organoids, plants)

Extent of Recognition: Complete recognition

Rationale for Recognition: This standard is relevant to regenerative medicine products and does not conflict with FDA regulations or policy.

Standard Development Organization: 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