CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 010 **Date of Recognition:** 04/12/2023

SDO Name/Designation: ISO 21560 **Year of Publication:** 2020

Title: General requirements for tissue engineered medical products

Scope:
This document specifies general requirements for tissue-engineered medical products (TEMPs), which are used in regenerative medicine. With regard to safety, this document outlines requirements for materials, manufacture, quality control, and unintentional biological effects elicited by TEMPs. This document does not address requirements for clinical trials and efficacy. This document is not applicable to tissue-engineered products used for diagnosis, ex-vivo testing or extracorporeal treatments of patients (e.g. dialysis with TEMP components). TEMPs containing viable xenogenic cells, genetically modified cells, or cells derived from abnormal cells or tissues (e.g. cancerous tissues) are also excluded from the scope. The combination of TEMPs with medical devices, with the exception of scaffolds comprised of synthetic and/or naturally derived (e.g. animal sourced) materials, is also excluded from the scope.

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.

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.