CBER Standards Recognition Program for Regenerative Medicine Therapies
Standards Recognition Summary (SRS)

Recognition Number: 049 **Date of Recognition:** 12/9/2025

SDO Name/Designation: ASTM F3659 **Year of Publication:** 2024

Title: Standard Guide for Bioinks Used in Bioprinting

Scope: 1.1 This guide is a resource for bioprinting tissue engineered medical products (TEMPs) with bioinks and biomaterial inks. There are existing standards that cover biomaterials and scaffolds in a more general fashion (Guide F2150, Guide F2027, ISO 10993 series).

This guide focuses specifically on extrusion bioprinting utilizing bioinks and biomaterial inks with inherent or inducible fluidic properties with or without encapsulated cells used to construct TEMPs. For the remainder of this guide, both bioinks and biomaterial inks will be collectively referred to as bioinks.

1.2 For the purposes of this guide, bioprinting is defined as the three-dimensional printing of materials (bioinks) to fabricate structured constructs for use in biological or medical applications.

1.3 TEMPs may be produced by many different bioprinting modalities, including but not limited to the following: electrospinning, electrospray, extrusion-based, droplet-based, inkjet-based, and laser-assisted bioprinting. Extrusion-based bioprinting is the primary focus of this document since it is currently the most well-understood modality used to construct TEMPs, but other bioprinting modalities are also addressed.

1.4 This guide will focus on bioinks, and biomaterials used as inks with inherent or inducible fluidic properties. These inks may or may not contain encapsulated cells. Chemical properties of the inks and other factors that affect printability are addressed.

1.5 Pre-printing and printing considerations are the focus of this guide, but considerations regarding post-printing product stabilization are also addressed.

1.6 This guide will address assessments regarding the sterility and cytocompatibility of bioinks, including chemical and physical benchtop tests, as well as measures of post-printing cell viability.

1.7 *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 determine the applicability of regulatory limitations prior to use.*

1.8 *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: Complete Recognition

Rational for Recognition: This standard is applicable to regenerative medicine therapy products, and is not in conflict with FDA regulations and policy.

Standards Development Organization 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 .