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Standard Terminology Relating to Microphysiological Systems[1]

This standard is issued under the fixed designation F3570; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This terminology defines basic terms and presents the relationships of the scientific fields related to microphysiological systems (MPS). Committee F04 has defined these terms for the specific purpose of unifying the language used in standards for MPS.

1.2 The terms and nomenclature presented in this standard are for the specific purpose of unifying the language used in MPS standards and are not intended for labeling of regulated medical products.

1.3 *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.*

1.4 *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.*

2. Referenced Documents

2.1 *ISO Standards:*[2]

ISO 22442-1:2020 Medical Devices Utilizing Animal Tissues and Their Derivatives

ISO/TS 21560:2020 General Requirements of Tissue-Engineered Medical Products

3. Terminology

biomarker, *n*—a characteristic that is evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention. It is a portmanteau of "biological marker" and is sometimes referred to as a signature molecule.

biosensor, *n*—devices that use specific biochemical reactions and/or molecular recognition to detect the presence and/or the concentration of an analyte. Biosensors consist of three parts: a component that recognizes the analyte and produces a signal, a signal transducer, and a detector/reader device.

body-on-a-chip, *n*—interconnected organ mimics with continuous or recirculating flow, with organ sizes and flow determined by a physiologically based pharmacokinetic (PBPK) model. It can consist of human and/or animal cells and contains all organs with some listed explicitly and others grouped as "other tissues" integrated within a non-biological platform.

disease-on-a-chip, *n*—an *in vitro* model system with the desired genetic background disease, environmental factors, inducible symptoms, and/or interaction between disease-relevant cell types under physiological conditions. These systems incorporate or mimic a specific disease stage in organ(s) or tissues integrated within a non-biological platform.

disorganized 2D system, *n*—a cellular monolayer over a surface which lacks the anatomy of *in vivo* tissues and need not possess the physiological functions of in vivo tissues.

disorganized 3D system, *n*—a multilayered cellular system that substantially lacks the ordered histoarchitecture of the *in vivo* organ or tissue and need not possess the physiological function of *in vivo* tissue.

functional microphysiological system, *n*—a microphysiological system that reproduces electrical, mechanical, and/or barrier function without necessarily reproducing the anatomy. Can be 2D, 3D, or hybrid 3D model systems with functional characteristics of living.

human-on-a-chip, *n*—a subset of body-on-a-chip which consists of various human organ mimics using continuous or recirculating flow. Human-on-a-chip can include patient derived, stem cell derived, or primary cells/tissues integrated within a non-biological platform.

hybrid 3D systems, *n*—where a monolayered cellular system is integrated with a MEMs device or devices to provide a multilayered construct that enables the establishment of mechanical, electrical, and/or barrier functions that give at least one output similar to that of an *in vivo* output.

[1] This terminology is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.43 on Cells and Tissue Engineered Constructs for TEMPs.

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[2] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.