INTERNATIONAL STANDARD

ISO 20391-1

First edition
2018-01

Biotechnology — Cell counting —

Part 1: General guidance on cell counting methods

Biotechnologie — Dénombrement des cellules —

Partie 1: Lignes directrices générales relatives aux méthodes de dénombrement des cellules

Reference number
ISO 20391-1:2018(E)

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

This document was prepared by ISO/TC 276, *Biotechnology*.

A list of all the parts of ISO 20391 can be found on the ISO website.

Introduction

Cell counting (or cell enumeration) is a fundamental measurement that broadly impacts many aspects of biotechnology, from biomanufacturing to advanced therapy. The cell count (or discrete number of cells) is often expressed as cell concentration (i.e. cell count per volume) when in suspension and area density of cells (i.e. cell count per unit area) when adhered to a surface. Cell count is critical in evaluating potency and efficacy for cell-based therapy. The cell concentration within a bioreactor can serve as a quality assurance metric in cell-based manufacturing processes. Many cell-based bioassays need to be normalized to the respective cell count to allow data inter-comparability. This document (which is Part 1 of a multi-part standard on cell counting) defines terms and provides general guidance for the cell counting measurement process, including method selection, sample preparation, measurement, qualification and validation, and data analysis and reporting.

Biotechnology — Cell counting —

Part 1:
General guidance on cell counting methods

1 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).

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
accuracy
closeness of agreement between a measured quantity value and a true quantity value of a measurand

Note 1 to entry: The concept of “measurement accuracy” is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.

Note 2 to entry: “Measurement accuracy” is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

[SOURCE: ISO/IEC Guide 99:2007, 2.13, modified]

3.2
agglomerate
<cells> two or more cells clustered weakly together and detected as a larger object

Note 1 to entry: Agglomerates of cells can be separated into nominally single cells without causing significant damage to the cell.