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Biotechnology — Biobanking — Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines

Biotechnologie — Biobanking — Exigences de processus et de qualité pour la génération, le maintien et la caractérisation des lignées cellulaires de mammifères

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of 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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Scientific research using cell lines has contributed greatly to the understanding of human health. Cell cultures are increasingly used to complement studies using animal models. Although cell lines are important research tools, potential problems have recently been identified.

Cell lines have unique characteristics and behaviour that can change as they continue to be passaged. The original phenotype (e.g. expression of specific biomarkers) can be lost or new characteristics or behaviour (e.g. development of tumorigenicity) may develop. It is important to minimize passaging to retain the original characteristics that were present when the cell line was first established.

Other problems such as contamination, either with microorganisms or another cell line, and misidentification can also arise. Cultures can become contaminated during cell line establishment or later when cultures are passaged. These problems are often not visible by eye and require specific testing to be detected.

In order to help address these issues, the research community has called for an international effort to create standards for biobanks. ISO 20387 was published to provide an overarching standard for biobanks. This document provides additional technical specifications for biobanks that handle mammalian cell lines. Such biobanks can demonstrate their competence in biobanking by complying with the specifications within this document, in addition to the requirements prescribed in ISO 20387.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

Biotechnology — Biobanking — Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines

1 Scope

This document specifies process and quality requirements for the biobanking of mammalian (including human) cell lines. It describes requirements for the fundamental procedures of the biobank handling cell lines, such as establishment, reception, identification, propagation, preservation, storage, quality control, and distribution of cell lines.

This document can be used by organizations performing biobanking activities with mammalian cell lines used for research and development, biobank users, organizations and schemes using peer-assessment and accreditation bodies.

This document does not apply to biological material intended for therapeutic use.

NOTE International, national or regional regulations or requirements can also apply to specific topics covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 20387:2018, *Biotechnology — Biobanking — General requirements for biobanking*

ISO 20391-1, *Biotechnology — Cell counting — Part 1: General guidance on cell counting methods*

ISO 20391-2, *Biotechnology — Cell counting — Part 2: Experimental design and statistical analysis to quantify counting method performance*

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:

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

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

3.1
cell culture
growth of cells dissociated from the parent tissue by spontaneous migration or mechanical or enzymatic dispersal for propagation and consecutive passages in vitro

Note 1 to entry: Additional information can be found in Reference [6].