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AMENDMENT 1

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

AMENDMENT 1

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

AMENDEMENT 1

PROOF/ÉPREUVE

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

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3.6

Replace the definition with the following text:

3.6

cryopreservation

process by which cells are maintained in an ultra-low temperature in an inactive state so they can be revived later

3.11

Delete the term "informed consent" and its definition.

3.12 to 3.17

Adjust the numbering according to the deletion of 3.11.

4.1

Add the following text as the last sentence of this subclause:

ISO 20387:2018, Clause 4, shall be followed.

4.2

Replace the entire subclause with the following text:

4.2 Legal and ethical requirements

ISO 20387:2018, 4.3 shall be followed.

The biobank shall consult a competent institutional/independent ethics review committee, which is responsible for the investigation and evaluation of any related ethical principles/requirements.

The biobank shall comply with ISO 20387:2018, 4.1.6 and 7.2.3.4. The biological material, which is the source of the cell line, shall be collected, transported and handled according to internationally accepted procedures.

The biobank shall be aware of and able to demonstrate compliance with relevant nationally, regionally and internationally approved ethics, laws and regulations relating to the biological material held in the biobank.

4.4.1

Replace the second paragraph after i) with the following text:

The biobank shall equip its facility with appropriate biosafety equipment based on the assessed biological safety level (documented risk analysis); see 4.3.2. ISO 20387:2018, 6.3.5, shall be followed.

4.6

Delete the whole subclause.

4.7

Renumber the subclause to 4.6.

Renumber 4.7.1 to 4.6.1; 4.7.2 to 4.6.2; 4.7.3 to 4.6.3; and 4.7.4 to 4.6.4.

5.3.2

Add h) as an additional point to the list with the following text:

h) passage number.

5.3.3, fifth paragraph

Replace the text with the following text:

When contamination is detected in a cell line (i.e. microbial contamination or contamination with another cell line), the biobank should check if other batches are also contaminated. The biobank may dispose of contaminated cell lines if at least one other batch is uncontaminated. If, however, there is no uncontaminated batch, the biobank can request another deposit from the provider or perform removal of contaminants (e.g. with antibiotics) and re-culture the cell line. The biobank shall record and track contamination events.

5.3.4, Table 1

Replace with the following:

Table 1 — Example of cell line storage condition

Purpose	Storage condition	Minimum cell number per vial	Minimum number of vials
Seed stock	Vapour-phase of liquid nitrogen (recommended) (≤ –130 °C)	1×10^6 cells/ml (each vial)	12
Distribution stock			20

