

ISO 21709:2020 (E)

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

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Requirements
4.1	General
4.2	Legal and ethical requirements
4.3	Facilities
4.3.1	General
4.3.2	Cell culture facility
4.4	Equipment
4.4.1	General
4.4.2	Equipment inspection
4.5	Reagents
4.6	Informed consent
4.6.1	General
4.6.2	Procedure of obtaining informed consent
4.6.3	Special circumstances for informed consent
4.6.3.1	General
4.6.3.2	Donor/patient needing legally designated or nominated representatives
4.6.3.3	Human donor/patient unable to read or write
4.6.4	Information provided to the donor/patient or the donor's/patient's legally designated or nominated representative
4.6.5	Informed consent signature
4.7	Personnel
4.7.1	General
4.7.2	Personnel competence
4.7.3	Personnel training
4.7.4	Biorisk and biosafety of personnel
5	Process requirements
5.1	Establishment of cell lines within the biobank
5.1.1	General
5.1.2	Isolation and purification of primary cells
5.1.3	Primary cultures
5.1.3.1	Culturing
5.1.3.2	Characterization
5.1.4	Cell lines
5.1.4.1	Establishment of cell lines
5.1.4.2	Authentication and characterization
5.2	Reception of established cell lines
5.2.1	General
5.2.2	Review of the deposit request
5.2.3	Decision on the deposit request
5.2.4	Transfer of material and associated data
5.2.5	Characterization and authentication of the cell line
5.2.6	Assignment of accession number

- 5.3 Cell line management
 - 5.3.1 Planning for cell banking
 - 5.3.2 Accession
 - 5.3.3 Propagation of cell lines
 - 5.3.4 Preservation and storage
 - 5.3.5 Inventory management
 - 5.3.6 Disposal management
- 5.4 Distribution
 - 5.4.1 General
 - 5.4.2 Acceptance of order request
 - 5.4.3 Distribution review
 - 5.4.4 Transport
 - 5.4.4.1 General
 - 5.4.4.2 Preparation for shipment
 - 5.4.4.3 Packaging
 - 5.4.4.4 Shipment
- 5.5 Quality control, validation and verification
 - 5.5.1 Quality control
 - 5.5.2 Validation and verification

6 Performance evaluation and improvement

Annex A (informative) Recommended units for biobanking of cell lines

- A.1 Deposit unit for reception of cell lines
- A.2 Distribution unit of cell lines

Page count: 20