INTERNATIONAL STANDARD

ISO 18362

First edition
2016-02-01

AMENDMENT 1
2022-06

Manufacture of cell-based health care products — Control of microbial risks during processing

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Manufacture de produits de soins de santé fondés sur les cellules — Contrôle des risques microbiaux durant le processus

AMENDEMENT 1

Reference number
ISO 18362:2016/Amd.1:2022(E)

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Published in Switzerland

Foreword

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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Manufacture of cell-based health care products — Control of microbial risks during processing

AMENDMENT 1

Page 1, Scope

Delete the last sentence, which explains that the standard does not replace national or regional regulations, which is redundant.

Page 5

Replace Clause 4 with the following new Clause 4:

4 General

4.1 The development, validation and routine control of a sterilization process is a critical element in product realization of health care product. To ensure the consistent implementation of the requirements specified in this document, the necessary processes need to be established, implemented and maintained. Processes of particular importance in relation to the development, validation and routine control of a sterilization process include but are not limited to:

— control of documentation, including records;

— assignment of management responsibility;

— provision of adequate resources, including competent human resources and infrastructure;

— control of product provided by external parties;

— identification and traceability of product throughout the process; and

— control of non-conforming product.

NOTE ISO 13485 covers all stages of the lifecycle of medical devices in the context of quality management systems for regulatory purposes. National and/or regional regulatory requirements for the provision of health care products can require the implementation of a full quality management system and the assessment of that system by a recognized conformity assessment body.

4.2 A process shall be specified for the calibration of all equipment, including instrumentation for test purposes, used in meeting the requirements of this document.

Page 8, 5.2.4

Delete the subclause.

Page 9, 6.3.2 b) NOTE

Change

NOTE Attention is drawn to national and/or regional regulations for the design of containment facilities.

to

NOTE National and/or regional regulations can apply for the design of containment facilities.

Page 9, 6.4 c)

Delete "and/or regional GMP regulations" at the end of the sentence to read:

Where negative air pressure areas or biological safety cabinets are used for CBHP processing, they shall be surrounded by cleanrooms as specified in ISO 14644-4.

Page 9, 6.4 d)

Delete the first sentence so that it reads:

The heating, ventilation, and air conditioning system (HVAC system) shall not interfere with the air flow of the biological safety cabinet.

Page 10, 6.5.3 c)

Delete c) and replace with the following NOTE:

NOTE National or regional regulations can apply to disposal of contaminated waste material (e.g. solid or liquid waste cell material, non-cell based materials, contaminated condensate of sterilizers, fermenter).

Page 11, 8.4, last sentence

Delete the last sentence on regional or national guidelines or regulations.

Page 12, 9.2.1 a)

Delete "and applicable national or regional regulatory requirements" at the end of the sentence and change "comply" to "conform" to read:

A documented procedure shall be established and implemented for procurement and storage of cell-based starting material. The procedure shall conform with applicable clauses of GMP Part II and/or ICH Q7 (for active pharmaceutical ingredients), ISO 13022, and ISO 22442 (all parts).

Page 31, Bibliographic reference [5]

Change dated reference “ISO 13485:2003”

to

undated reference “ISO 13485”.