

First edition
2016-02-01

AMENDMENT 1
2022-06

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

AMENDMENT 1

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

AMENDEMENT 1

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 18362:2016/Amd 1:2022

<https://standards.iteh.ai/catalog/standards/sist/31ff27ba-260a-43ab-aa1d-0725eed25255/iso-18362-2016-amd-1-2022>



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

© ISO 2022

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 18362:2016/Amd 1:2022

<https://standards.iteh.ai/catalog/standards/sist/31ff27ba-260a-43ab-aa1d-0725eed25255/iso-18362-2016-amd-1-2022>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

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 198, *Sterilization of health care products*.

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.

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

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

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).

[ISO 18362:2016/Amd 1:2022](https://standards.iteh.ai/catalog/standards/sist/31ff27ba-260a-43ab-aa1d-0725eed25255/iso-18362-2016-amd-1-2022)

<https://standards.iteh.ai/catalog/standards/sist/31ff27ba-260a-43ab-aa1d-0725eed25255/iso-18362-2016-amd-1-2022>

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".

