



BSI Standards Publication

**Biotechnology — Bioprocessing —
General requirements and considerations
for equipment systems used in the
manufacturing of cells for therapeutic use**

National foreword

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Biotechnology — Bioprocessing — General requirements and considerations for equipment systems used in the manufacturing of cells for therapeutic use

*Biotechnologie — Bioprocédés — Exigences et considérations
générales pour les systèmes d'équipement utilisés dans la fabrication
de cellules à usage thérapeutique*



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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).

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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.

Biotechnology — Bioprocessing — General requirements and considerations for equipment systems used in the manufacturing of cells for therapeutic use

1 Scope

This document specifies minimum requirements and general considerations for equipment, consisting of hardware, software and consumables, used in the manufacturing of cells for therapeutic use. This includes equipment for processing cells for therapeutic use starting from cell isolation/selection, expansion, washing and volume reduction, from cell finish through to cryopreservation for the storage of cells for therapeutic use.

This document gives guidance on the design, use and maintenance of equipment and equipment systems to both suppliers and users from aspects including the target parties, i.e. supplier or user, and phase of involved task, i.e. design, use or maintenance.

This document is applicable to any unit operation system that is used, alone or in combination, for the manufacturing of cells for therapeutic use, meeting user requirements. It is applicable to devices used for the purpose of monitoring equipment status.

It does not apply to:

- processing equipment for cells for therapeutic use used at the point of care;
- devices used for analytical purposes;
- biosafety cabinets, general cell culture equipment (such as CO₂ incubators, etc.), and software to control multiple equipment systems or multiple unit operations.

2 Normative references

There are no normative references in this document.

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

batch

quantity of material regarded as a single unit, and having a unique reference

Note 1 to entry: Batch is primarily a processing term.

[SOURCE: ISO 15270:2008, 3.3]

3.2 cells for therapeutic use

product containing cells as the active substance

EXAMPLE A cell therapy medicinal product (allogenic, autologous, somatic, genetically modified), tissue engineered product.

Note 1 to entry: For the purpose of this document, “cells” mean human cells and tissues of autologous as well as allogeneic.

[SOURCE: ISO 21973:2020, 3.1, modified — The example has been replaced. Notes 2 and 3 to entry have been deleted.]

3.3 consumable

tubing, filter, culture vessel, bag or bottle used to transfer, culture or act as a container for the biologics or another consumable used in the production of *cells for therapeutic use* ([3.2](#))

3.4 corrective action

action to eliminate the cause of a nonconformity and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas *preventive action* ([3.15](#)) is taken to prevent occurrence.

[SOURCE: ISO 9000:2015, 3.12.2, modified — Note 3 to entry has been deleted.]

3.5 critical quality attribute CQA

physical, chemical, biological or microbiological property or characteristic that is within an appropriate limit, range or distribution to ensure the desired quality and consistency of a cellular therapeutic product

Note 1 to entry: CQA is generally related to the clinical efficacy and safety of the product.

3.6 equipment

device or machine that performs a specific field operation

[SOURCE: ISO 11783-1:2017, 3.20, modified — Note 1 to entry has been deleted.]

3.7 equipment system

set of *equipment* ([3.6](#)) that act together in a common purpose of producing *cells for therapeutic use* ([3.2](#))

3.8 impurity

constituent of the product not intended to be part of the final formulation

3.9 installation qualification IQ

process of establishing by objective evidence that all key aspects of the process *equipment* ([3.6](#)) and ancillary system installation comply with the approved equipment specification

[SOURCE: ISO 11139:2018, 3.220.2, modified — “approved equipment specification” has replaced “approved specification”.]