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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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

生物技术 生物过程 用于治疗用细胞制造设备系统的通用要求和考虑

(English Translation)

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Foreword

This document is a standard or guiding technical document.

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents". Drafting.

This document is equivalent to ISO /T S23565.2021 "Biotechnology, Bioprocesses - Equipment and Systems for Therapeutic Cell Manufacturing".

The document type, "Requirements and Considerations," has been changed from an ISO technical specification to a national standardization guidance technical document in my country.

1 Scope

This document specifies the basic requirements and general considerations for therapeutic cell manufacturing equipment (including hardware, software, and consumables). This includes equipment used for... Equipment for therapeutic cells, from cell isolation/sorting, expansion, washing and volume reduction, to final cell processing and application in therapeutic applications. Cryopreservation of cells.

This document addresses the needs of suppliers and users from the perspectives of the target party (i.e., supplier or user) and the relevant task phases (i.e., design, use, or maintenance).

It provides guidance on the design, use, and maintenance of equipment and equipment systems.

This document applies to any unit operating system used for the manufacture of therapeutic cells that meets user requirements, whether used alone or in combination.

This document is applicable to equipment used for monitoring device status.

This document does not apply to.

---Cell processing equipment for bedside therapy;

--- Equipment used for analytical purposes;

---Biosafety cabinets, standard cell culture equipment (such as CO₂ incubators), and control systems for multiple devices or multiple unit operations. The software.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

The URLs for the terminology databases maintained by ISO and IEC for standardization are as follows.

3.1 Batch

The quantity of material is considered as a single unit and has a unique reference identifier.

Note: Batch is primarily a processing term.

[Source: ISO 15270:2008, 3.3]

3.2 Products that use cells as active substances

Examples. Cell therapy pharmaceutical products (allogeneic, autologous, somatic cell, genetically modified), tissue engineering products.

Note: In this document, "cell" refers to human cells and autologous and allogeneic tissues.

[Source: ISO 21973:2020, 3.1, with modifications]