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Technical specifications of cleanroom design for cell culture

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Foreword

This document was issued on 17 March 2023 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 1 October 2023.

It is a GB/T standard: recommended rather than compulsory, but it is the text a Chinese reviewer applies when assessing a submission.

1 Scope

GB/T 42398-2023 covers the design of a cleanroom in which cells taken from an organism are grown, expanded and kept with their biological properties intact. Almost the whole document sits in a single requirements clause, and it works outward from the ground: site selection, then ventilation and purification, the envelope structure, electrical and information technology services, water supply and drainage, gas pipelines, and the safety requirements that apply to the finished suite. Terms are defined narrowly, cell culture among them, because the room is specified around the process rather than around a particle count alone. The services are treated as one design instead of as separate trades because a cell culture room fails differently from an ordinary cleanroom: the contamination that ruins the work is alive, an organism carried in on air, on a surface or back through a drain multiplies in exactly the warm, humid conditions the culture needs, and what is lost is not a rejected batch but a cell line and the months of work behind it. Pressure regime, air change, sealed penetrations, drainage routes and the gas lines feeding the incubators therefore stand or fall together. For laboratory and facility designers, HVAC contractors, cell therapy and biopharmaceutical manufacturers, and the people who qualify such rooms before use.

This document specifies the general requirements for cleanroom design for cell culture, ventilation and purification, enclosure structure, electrical and information technology,

water supply and drainage, gas pipelines, and safety requirements.

This document applies to cleanroom design for cell culture for human use. Other cell culture cleanrooms refer to this document.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB 5749, Sanitary standard for drinking water

GB 17945, Fire Emergency Luminaries

GB/T 29469, Cleanrooms and associated controlled environments - Evaluation of performance and rationality

GB/T 36372, Cleanrooms and associated controlled environments - General technical requirements of combined envelope structure

GB 50016, Code of Design on Building Fire Protection and Prevention

GB 50457, Code for design of pharmaceutical industry cleanroom

GB 50472, Code for design of electronic industry cleanroom

GB 50591, Code for Construction and Acceptance of Cleanroom

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 cell culture

A process of growing, expanding, and maintaining the biological properties of extracted cells.

4 Requirements

4.1 General requirements

4.1.1 The design of site selection, ventilation and purification, envelope structure, electrical and information technology, water supply and drainage, gas pipelines, safety and other aspects shall be carried out in combination with the cell culture process and

environmental requirements.

4.1.2 An area with less vibration, electromagnetic radiation, and noise shall be selected. When the area of a new cleanroom is greater than or equal to 3000 m2, while meeting the above requirements, the building where it is located shall be selected in an area with good natural environment and low gas pollution.

4.1.3 When the area of a newly built, renovated or expanded cleanroom is greater than or equal to 3000 m2, the design of the cleanroom shall be closely connected with the overall design of the building where it is located. After negotiating with the user to determine the process requirements and cleanroom location, the design will be prioritized based on consultation with the overall design. Propose requirements for building structure, power, HVAC, water supply and drainage, electrical and other aspects to the overall design.

4.1.4 Full consideration shall be given to preparation process flow, equipment configuration, safety and reliability of equipment and facilities, various interfaces, flow of people, logistics, storage of items (necessary) in-situ inactivation and disinfection of hazardous waste products, construction and installation, equipment installation, inspection and maintenance and other related requirements.

4.1.5 The cleanliness and other relevant requirements of each area shall comply with 4.2.

4.1.6 The purpose shall be to protect personal safety. Consider a plan to evacuate cleanroom staff as soon as possible in an emergency and minimize damage to the cleanroom and support areas.

4.1.7 On the basis of meeting the process requirements and operating cycle, it shall focus on saving energy, protecting the environment, and being economically reasonable.

4.1.8 When the cleanroom area is greater than or equal to 2000 m2, the design evaluation shall be carried out in accordance with the requirements of GB/T 29469. If the area is less than 2000 m2, it can choose whether to conduct design evaluation.

4.1.9 For cleanrooms containing cell cultures carrying infectious agents, a biosafety

plan shall be developed based on risk assessment. Ensure that its production and operation process does not cause pollution or harm to personnel and the environment. Avoid cross contamination.

humidity loads of various equipment within the system need to be considered at the same time).

NOTE: Pay attention to extreme climates, especially the demand for cold and heat sources with

sustained extreme temperatures and humidity.

4.3.1.3 The division of purification air-conditioning systems shall be determined after technical and economic comparison based on process requirements, floor plan, biological safety, etc. Take effective measures to avoid contamination and cross-contamination. Meet the following requirements:

a) The air conditioning system shall be set up separately from areas without cleanliness requirements.

b) Production units with different process requirements shall be equipped with separate purification and air-conditioning systems.

c) Functional areas with different operating shifts or usage times shall be equipped with separate purification and air-conditioning systems.

d) In areas with large differences in indoor heat and moisture load characteristics, separate purification air conditioning systems shall be installed.

4.3.1.4 When there are ventilation equipment such as biological safety cabinets and local exhaust devices in the cleanroom, measures shall be taken to maintain indoor pressure stability during the opening, closing and operation of the equipment.

4.3.1.5 It must be conducive to cleanroom disinfection, sterilization, automatic control and energy-saving operation. Comply with the following regulations:

a) Positive pressure cleanrooms shall use circulating air conditioning systems.

b) When toxic, harmful, or combustible gases are involved (excluding cell culture areas carrying infectious agents), a partial or overall full exhaust system shall be adopted based on risk assessment.