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Technical specification for cell culture operations in cleanroom and relevant controlled environment

洁净室及受控环境中细胞培养操作技术规范

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Foreword

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:

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This document is proposed and coordinated by the National Standardization Technical Committee for Clean Rooms and Controlled Environments (SAC/TC319):

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Cell culture operations in clean rooms and controlled environments specifications

1 Scope

This document specifies the requirements for mammalian cell culture operations in clean rooms and controlled environments and describes the corresponding verification methods:

This document is applicable to mammalian cell culture in clean rooms and controlled environments:

2 Normative reference documents

GB/T 25915

3 Terms and definitions

The following terms and definitions apply to this document: 3:1 cell culturecelculture The process of allowing cells to survive, grow, proliferate and maintain their biological properties and functions: 3:2 expansionexpansion The process of increasing the number of cells in cell culture: 3:3 Passage The process of re-culturing to provide larger growth space for cell growth:

4 Requirements

4:1 Environmental protection 4:1:1 An operation system should be established in accordance with the requirements of GB/T 25915:5, including risk control, personnel training, clean clothing, personnel behavior, indoor objects Clean room operation specifications in terms of flow, daily cleaning, etc:

4:1:2 An automatic detection system for controlled environments such as cleanliness, temperature and humidity, and pressure difference should be established: 4:2 Preparation 4:2:1 Controlled environments such as ultra-clean workbenches/biological safety cabinets/isolators should be disinfected with ultraviolet light or hydrogen peroxide before performing culture operations:

4:2:2 Reagents and consumables required for cell culture should be prepared, including but not limited to culture medium, physiological buffer solution (PBS), culture containers, etc:

4:2:3 The outer packaging of experimental supplies and reagent consumables should be

wiped with a suitable disinfectant (such as 75% ethanol):