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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.01
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YY/T 0287-2003 / ISO 13485:2003

Replacing YY/T 0287-1996

Medical devices - Quality management systems - Requirements for regulatory purposes

医疗器械 质量管理体系 用于法规的要求

(ISO 13485:2003, IDT)

Issued on: September 17, 2003 **Implemented on: April 1, 2004**

Issued by: China Food and Drug Administration

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Foreword

This standard is identical to ISO 13485:2003 “Medical devices - Quality management systems - Requirements for regulatory purposes” (English version).

This Standard is a stand-alone standard basing on GB/T 19001-2000, and follows the structure of GB/T 19001-2000.

For the convenience of users in the medical device community, in the text of this Standard, the contents differ from those in GB/T 19001-2000 are in black block letters [Translator note: in italics in this Standard].

The “Notes” in this Standard are additional information provided to users of the English-version International Standard, in order to be identical to the International Standard, these contents are retained in this Standard.

Annexes A and B of this Standard are informative.

This Standard is proposed by Medical Devices Division of China Food and Drug Administration.

This Standard is under the jurisdiction of SAC/TC 221 National Technical Committee on Medical Device Quality Management and General Requirements of Standardization Administration of China.

Drafting organization of this Standard: National Technical Committee on Medical Device Quality Management and General Requirements of Standardization Administration of China, Beijing Hua Guang Certification of Medical Devices Co., Ltd. (formerly China Medical Device Quality Certification Center).

Main drafters of this Standard: Zhang Mingzhu, Chen Zhigang, Wu Junhua, Li Huimin, Qin Shuhua, Zheng Yihan, Meng Qingzeng, Li Zhaohui, Zhou Yajun, Liu Baoxia, Wang Huifang, Liu Jingzhuan.

0.3 *Relationship with other standards*

0.3.1 *Relationship with GB/T 19001*

While this is a stand-alone standard, it is based on GB/T 19001.

Those clauses or subclauses that are quoted directly and unchanged from GB/T 19001 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex B.

Where the text of this Standard is not identical to the text of GB/T 19001, the sentence or indent containing that text as a whole is shown in block letters [Translator note: in italics in this Standard]. The nature and reasons for the text changes are noted in Annex B.

0.3.2 *Relationship with ISO/TR 14969*

ISO/TR 14969 is a Technical Report intended to provide guidance for the application of ISO 13485/YY/T 0287.

0.4 Compatibility with other management systems

This Standard follows the format of GB/T 19001 for the convenience of users in the medical device community.

This Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management.

However, this Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this Standard.

Medical devices - Quality management systems - Requirements for regulatory purposes

1 Scope

1.1 General

This Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of this Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of GB/T 19001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this Standard cannot claim conformity to GB/T 19001 unless their quality management systems conform to all the requirements of GB/T 19001 (see Annex B).

1.2 Application

All requirements of this Standard are specific to organizations providing medical devices, regardless of the type or size of the organization.

If regulatory requirements permit exclusions of design and development controls (see 7.3), this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this Standard reflect exclusion of design and development controls [see 4.2.2 a] and 7.3].

If any requirement(s) in Clause 7 of this Standard is(are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system [see 4.2.2 a)].

The processes required by this Standard, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system [see 4.1 a)].

Bibliography

[1] GB/T 19001-2000 Quality management systems - Requirements

[2] GB/T 19022 Measurement management systems - Requirements for measurement processes and measuring equipment (ISO 10012:2003, IDT)

[3] GB 18278-2000 Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization (idt ISO 11134:1994)

[4] GB 18279-2000 Medical devices - Validation and routine control of ethylene oxide sterilization (idt ISO 11135:1994 and Corrigendum 1 published 1994)

[5] GB 18280-2000 Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization (ISO 11137:1995 and Corrigendum 1 published 1995)

[6] ISO 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic medical devices

[7] ISO 13683:1997 Sterilization of health care products - Requirement for validation and routine control of moist heat sterilization in health care facilities

[8] ISO 14155-1[1)] Clinical investigation of medical devices for human subjects - Part 1: General requirements

[9] ISO 14155-2[1)] Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans

[10] ISO 14160:1998 Sterilization of medical devices - Validation and routine control of sterilization of single-use medical devices incorporating materials of animal origin by liquid chemical sterilants

[11] ISO 14937:2000, Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilizing agent

[12] ISO/TR 14969[1)] Medical devices - Quality management systems - Guidance on the application of ISO 13485:2003

[13] YY/T 0316-2003 Medical devices - Application of risk management to medical devices (ISO 14971:2000, IDT)

[14] GB/T 19011-2003 Guidelines for quality and/or environmental management

[1)] To be published.

systems auditing (ISO 19011:2002, IDT)

[15] Global Harmonization Task Force (GHTF) - Study Group 1 (SG1), Document No. N029R11, dated 2 Feb., 2002

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