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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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Replacing YY/T 0287-2003

Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

(ISO 13485:2016, IDT)

医疗器械 质量管理体系 用于法规的要求

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Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

1 Scope

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 and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of this Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by this Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to this Standard reflect any exclusion of design and development controls.

If any requirement in Clauses 6, 7 or 8 of this Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.2.

Bibliography

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[2] ISO 10012 Measurement Management Systems - Requirements for Measurement Processes and Measuring Equipment

[3] GB/T 19633.1-2015 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems (GB/T 19633.1-2015, ISO 11607-1:2006, IDT)

[4] ISO 11607-2 Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes

[5] ISO 14644 (all parts) Cleanrooms and Associated Controlled Environments

[6] ISO 14689 (all parts) Cleanrooms and Associated Controlled Environments - Biocontamination Control

[7] YY/T 0316-2016 Medical Devices - Application of Risk Management to Medical Devices (YY/T 0316-2016, ISO 14917:2007, modified edition, IDT)

[8] ISO 19011 Guidelines for Auditing Management Systems

[9] IEC 62366-1 Medical Devices - Part 1: Application of Usability Engineering to Medical Devices

[10] GHTF/SG1/N055.2009[2)] Definition of the Terms “Manufacturer”, “Authorized Representative”, “Distributor” and “Importer”

[11] GHTF/SG5/N4.2010[3)] Post-Market Clinical Follow-Up Studies

[12] GHTF/SG1/N70.2011[4)] Label and Instructions for Use for Medical Devices

[13] GHTF/SG1/N071.2012[5)] Definition of Terms “Medical Device” and “In Vitro Diagnostic (IVD) Medical Device”

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[3)] Available from website: http://www.imdrf.org/documents/doc-ghtf-sg5.asp
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