

Translated English of Chinese Standard: YY/T0287-2017

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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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**YY/T 0287-2017 / ISO 13485:2016**

Replacing YY/T 0287-2003

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**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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## Table of Contents

Foreword.....	6
Introduction.....	7
1 Scope.....	11
2 Normative References.....	12
3 Terms and Definitions.....	12
4 Quality Management System.....	18
4.1 General requirements.....	18
4.2 Documentation requirements.....	19
4.2.1 General.....	19
4.2.2 Quality manual.....	20
4.2.3 Medical device file.....	20
4.2.4 Control of documents.....	20
4.2.5 Control of records.....	21
5 Management Responsibility.....	22
5.1 Management commitment.....	22
5.2 Customer focus.....	22
5.3 Quality policy.....	22
5.4 Planning.....	22
5.4.1 Quality objectives.....	22
5.4.2 Quality management system planning.....	23
5.5 Responsibility, authority and communication.....	23
5.5.1 Responsibility and authority.....	23
5.5.2 Management representative.....	23
5.5.3 Internal communication.....	23
5.6 Management review.....	24
5.6.1 General.....	24
5.6.2 Review input.....	24

---

5.6.3	Review output.....	24
6	Resource Management.....	25
6.1	Provision of resources.....	25
6.2	Human resources.....	25
6.3	Infrastructure.....	26
6.4	Work environment and contamination control.....	26
6.4.1	Work environment.....	26
6.4.2	Contamination control.....	26
7	Product Realization.....	27
7.1	Planning of product realization.....	27
7.2	Customer-related processes.....	27
7.2.1	Determination of requirements related to product.....	27
7.2.2	Review of requirements related to product.....	28
7.2.3	Communication.....	28
7.3	Design and development.....	29
7.3.1	General.....	29
7.3.2	Design and development planning.....	29
7.3.3	Design and development inputs.....	29
7.3.4	Design and development outputs.....	30
7.3.5	Design and development review.....	30
7.3.6	Design and development verification.....	31
7.3.7	Design and development validation.....	31
7.3.8	Design and development transfer.....	31
7.3.9	Control of design and development changes.....	32
7.3.10	Design and development files.....	32
7.4	Purchasing.....	32
7.4.1	Purchasing process.....	32
7.4.2	Purchasing information.....	33
7.4.3	Verification of purchased product.....	34

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7.5	Production and service provision .....	34
7.5.1	Control of production and service provision.....	34
7.5.2	Cleanliness of product.....	34
7.5.3	Installation activities.....	35
7.5.4	Servicing activities .....	35
7.5.5	Particular requirements for sterile medical devices .....	36
7.5.6	Validation of processes for production and service provision .....	36
7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems .....	36
7.5.8	Identification .....	37
7.5.9	Traceability .....	37
7.5.10	Customer property.....	38
7.5.11	Preservation of product.....	38
7.6	Control of monitoring and measuring equipment .....	38
8	Measurement, Analysis and Improvement .....	39
8.1	General .....	39
8.2	Monitoring and measurement .....	40
8.2.1	Feedback.....	40
8.2.2	Complaint handling.....	40
8.2.3	Reporting to regulatory authorities.....	41
8.2.4	Internal audit.....	41
8.2.5	Monitoring and measurement of processes.....	41
8.2.6	Monitoring and measurement of product.....	42
8.3	Control of nonconforming product.....	42
8.3.1	General.....	42
8.3.2	Actions in response to nonconforming product detected before delivery	42
8.3.3	Actions in response to nonconforming product detected after delivery ..	43
8.3.4	Rework .....	43
8.4	Analysis of data.....	43

8.5 Improvement .....	44
8.5.1 General .....	44
8.5.2 Corrective action .....	44
8.5.3 Preventive action .....	44
Appendix A (Informative) Comparison of Content between YY/T 0287-2017 and YY/T 0287-2003 .....	46
Appendix B (Informative) Correspondence between YY/T 0287-2017 and GB/T 19001-2016 .....	51
Bibliography .....	58

# 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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<sup>2)</sup> Available from website: <http://www.imdrf.org/documents/doc-ghtf-sg1.asp>

<sup>3)</sup> Available from website: <http://www.imdrf.org/documents/doc-ghtf-sg5.asp>

<sup>4)</sup> Available from website: <http://www.imdrf.org/documents/doc-ghtf-sg1.asp>

<sup>5)</sup> Available from website: <http://www.imdrf.org/documents/doc-ghtf-sg1.asp>