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The Critical Role and Practice of Medical Device Design and Development Documentation in Quality Systems

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Abstract: This paper highlights the critical role of medical device design and development documents within the quality system, including their compliance with regulatory standards, their function as a traceable record, their support for all stages, and their use in risk and change management. It also covers document template creation, review record association, information management, adverse event traceability, and the reconciliation of differences in international declarations.

Keywords: Medical devices; Design and development documents; Quality system

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1. Introduction

The quality system of medical devices is strictly constrained by regulations, among which the ISO 13485 standard is of great significance. On this basis, each country further refines its requirements based on its own national conditions and regulatory needs. The EU MDR clinical evaluation requirements (issued in 2017) emphasize the need to update risk analysis reports for design changes, while the Chinese NMPA registration application requirements (continuously improving relevant regulations) focus on structured construction of technical documents. These policies highlight the crucial role of medical device design and development documents. It is a key carrier of quality system traceability, which is crucial in all stages of design and development as well as the entire product lifecycle. It plays a core role in risk management, quality control, and adverse event tracing, and is an important support for ensuring the quality and safety of medical devices.

2. Theoretical correlation between the medical device quality system and design and development documents

2.1 Regulatory framework for medical device quality system

The quality system of medical devices is constrained by a series of regulatory frameworks, among which the ISO

13485 standard holds an important position. This standard imposes strict requirements on various aspects of the design and development of medical devices. During the design and development phase, emphasis is placed on risk management, process control, and ensuring that the product meets its intended use and is safe and effective [1]. On this basis, medical device regulations in various countries have special control requirements for the design and development stage according to their own national conditions and regulatory needs. These regulatory documents constrain the writing of design and development documents from different perspectives. The document must truthfully, accurately, and completely record the design and development process, including various stages such as design input, output, review, verification, and confirmation. By standardizing document writing, we ensure the effective operation of the medical device quality system and guarantee the quality and safety of medical devices.

2.2. The system status of design and development documents

Design and development documents play an important role in the quality system of medical devices. It is a key carrier of traceability in the quality management system. Throughout the entire product lifecycle, from concept proposal to final launch and subsequent maintenance, design and development documents document detailed processes and information [2]. The file matrix constructed by it is like a knowledge network, providing solid support for various stages of the product. For example, in the design phase, documents document the design ideas, design verification process, etc., providing an accurate basis for subsequent production. In the production process, if problems arise, they can be traced back to the design and development documents to identify the root cause and take effective corrective measures. Meanwhile, in the process of product improvement and upgrade, these documents also provide historical references for technical personnel, ensuring the continuous improvement and stability of product quality.

3. Analysis of the key role of design and development documents in quality management

3.1. Core basis for quality control

The design and development documents (DMR, DHF, etc.) of medical devices play a crucial role as the core basis for quality control. These documents provide detailed technical benchmarks for process validation, ensuring that the production process meets predetermined quality standards. In terms of design change control, they clearly record the original design intent and key parameters, enabling changes to be made within a controllable range and avoiding adverse effects on product quality. For example, in the example of production specification compliance review, the technical indicators and design details in DMR and DHF documents become important criteria for determining whether the product meets quality requirements. They can help reviewers quickly identify potential issues and ensure the stability and reliability of product quality [3].

3.2. Risk management technology carrier

Design and development documents are the core carrier of medical device risk management technology. They systematically and structurally record information related to risk management throughout the entire product development process, providing important guarantees for product safety and reliability [4]. The risk analysis report, as a key component of the design and development document, comprehensively presents the risks that medical devices may face during the design and development phase by integrating the results of multiple risk analysis methods. Among them, Failure Mode and Effects Analysis (FMEA), as a forward-looking risk analysis tool,

occupies an important position in risk management. FMEA provides a scientific basis for developing effective risk control measures by identifying potential failure modes, analyzing their causes and effects, and assessing the severity and probability of risks.

In the practical application of medical devices, the traceability value of design and development documents is particularly prominent. Taking the medical device recall case as an example, by reviewing the risk analysis report and FMEA-related content in the design and development documents, it is possible to clearly trace the root cause of product defects and determine whether the defects stem from risks that were not fully identified or controlled during the design phase. Through a systematic risk management technology carrier, enterprises can continuously improve risk control measures throughout the product lifecycle, ensuring the safety and effectiveness of medical devices, and providing higher security for patients and users.

4. Integration practice of document management and quality system

4.1. Standardized document preparation process

4.1.1. Stage deliverable management

In the process of medical device design and development, establishing a comprehensive document template system for design input, verification, and confirmation stages is the key to ensuring product quality. In the design input stage, it is necessary to clarify the expected use, performance requirements, user needs, and regulatory requirements of the product, form standardized document templates, and ensure the completeness, accuracy, and traceability of input information [5]. These templates lay the foundation for subsequent development and avoid design deviations caused by unclear requirements. The document template for the verification phase should cover the verification plan, testing protocol, and verification report, detailing the verification process, methods, data, and results to ensure that the product design meets the expected functional and safety requirements. The template for the confirmation phase needs to reflect whether the product meets user needs and expected uses, as evidenced by user testing or clinical evaluation data.

The close relationship between design review records and technical documents is the core of quality management. The design review records should be clearly traced back to relevant technical documents, such as design input files or verification reports, to ensure transparency and traceability of the review process. At the same time, technical documents should reflect the problems identified during the review, improvement suggestions proposed, and implementation measures, forming a closed-loop management. This association mechanism not only enhances the traceability of documents, but also ensures the quality control of the design and development process [6]. Through a standardized document template system and review record management, enterprises can effectively integrate design and development information, meet regulatory requirements, support continuous improvement of quality systems, and provide reliable guarantees for the safety and effectiveness of medical devices.

4.1.2. Application of electronic signature system

In the design and development of medical devices, it is crucial to establish a comprehensive document template system for design input, verification, and confirmation stages. In the design input stage, it is necessary to clarify the expected use, performance requirements, user needs, and regulatory compliance requirements of the product. Standardized document templates should be used to ensure that input information is complete, accurate, and traceable, avoiding design deviations caused by vague requirements [7]. The document template for the verification

phase should include a verification plan, testing protocol, and verification report, detailing the verification process, testing methods, and results to ensure that the design meets functional and safety requirements. The template for the confirmation phase needs to be validated through user testing or clinical evaluation data to demonstrate that the product meets its intended use.

The correlation between design review records and technical documents is the core of quality management. The review records should be traceable to technical documents such as design inputs and verification reports to ensure transparency in the process. Technical documents should reflect the issues and improvement measures identified during the review, forming a closed-loop management system. This mechanism enhances the traceability and quality control of documents, supporting regulatory compliance. Through a standardized template system and review record management, enterprises can optimize the design and development process, ensure the safety and effectiveness of medical devices, and provide reliable support for the continuous improvement of the quality system.

4.2. Deep integration of risk management

4.2.1. Dynamic maintenance of risk documents

In the design and development of medical devices, the dynamic maintenance of risk analysis reports is the core link of deep integration of risk management. According to the EU MDR clinical evaluation requirements, design changes may affect the performance, safety, and effectiveness of medical devices, thereby altering the risk profile. Therefore, after each design change, it is necessary to promptly reassess the risks and update the risk analysis report to ensure that it accurately reflects the risk level of the product at each stage. The update process requires a systematic analysis of the impact of changes on failure modes, risk severity, and probability of occurrence, combined with tools such as FMEA, to identify potential risk points and develop control measures [8]. By continuously updating risk documents, enterprises can promptly identify and respond to potential issues, ensure the quality and safety of medical devices, and enhance the safety level of patients and users. In addition, standardized risk document maintenance helps companies gain an advantage in regulatory review and market competition, providing a solid foundation for quality management throughout the product lifecycle.

4.2.2. Adverse event traceability system

In the operation of medical device quality management system, the integrity of design and development documents is the key to ensuring compliance and product quality. Taking typical quality system on-site inspection defect cases as an example, rectification verification needs to follow a systematic and rigorous method. When missing or incomplete documents are found, the first step is to trace back the original data and records, verify the accuracy and reliability of the information, and ensure the authenticity and credibility of the rectification foundation. To ensure the quality of rectification, it is necessary to establish a multi-level audit mechanism and organize cross-departmental audit teams to conduct a comprehensive review of the rectified documents, verifying their completeness, compliance, and traceability. During the rectification process, strengthen communication and collaboration among departments such as research and development, quality management, and production, clarify the division of responsibilities, and ensure efficient progress of rectification work. Through a systematic rectification process and audit mechanism, not only can document defects be effectively resolved, but the overall quality of design and development documents can also be improved, ensuring the safety and effectiveness of medical devices, and providing solid support for the continuous improvement of the quality system and regulatory

compliance.

5. Practical application of quality management system operation

5.1. Practice of product registration and declaration

5.1.1. Structured construction of technical documents

In the practice of medical device product registration and application, the structured construction of technical documents is a key link to ensure successful application and compliance with the quality management system. Based on the registration and application requirements of China NMPA, design documents need to be scientifically classified and archived, clearly classified according to the design and development stage (such as input, verification, confirmation), technical characteristics, or regulatory requirements, to ensure document systematicity and traceability [9]. For example, the design input document needs to cover expected uses, performance indicators, etc., the validation document needs to record the test plan and results, and the confirmation document needs to prove that the product meets user needs. All documents must comply with electronic submission standards and use standard formats to facilitate quick review by auditors and improve application efficiency. In addition, structured documents need to ensure the accuracy and completeness of technical information, clearly convey product characteristics and compliance evidence, and meet the requirements of the quality management system for product lifecycle management. Through scientific archiving and format standardization, structured documents not only reduce the risk of deviation in auditing but also provide strong support for the smooth launch of products, helping enterprises maintain competitiveness in a strict regulatory environment.

5.1.2. Rectification case of physical examination defects

In the operation of medical device quality management system, the integrity of design and development documents is the core to ensure product quality and regulatory compliance. Taking typical quality system on-site inspection defect cases as an example, systematic and rigorous methods should be adopted for rectification verification. When missing or incomplete documents are found, it is necessary to first trace the original data and records, including design inputs, verification reports, etc., to ensure the accuracy and reliability of the information and provide a true basis for rectification. To ensure the effectiveness of rectification, it is necessary to establish a multi-level audit mechanism, organize R&D, quality management, and other departments to form an audit team, conduct a comprehensive review of the rectified documents, verify their completeness, compliance, and traceability. During the rectification process, strengthen cross-departmental communication and collaboration, clarify responsibilities, optimize process efficiency, and ensure the smooth progress of rectification work. Through systematic rectification and review, not only can document defects be effectively resolved, but the quality of design and development documents can also be significantly improved, ensuring the safety and effectiveness of medical devices and providing solid support for continuous improvement of the quality system and regulatory compliance.

5.2. Regulatory response after listing

5.2.1. Adverse event analysis and traceability

After the launch of medical devices, adverse event analysis and traceability are crucial in the quality management system, with the core relying on the integrity and traceability of design and development documents. To effectively respond to adverse events, it is necessary to establish a systematic MDR (Medical Device Reporting)/SAE (Serious

Adverse Event) analysis model, which uses scientific methods to sort out event-related information and quickly locate the root cause of the problem. The traceability of biological evaluation data is an important component of this model, which runs through the entire product lifecycle. Starting from the procurement stage of raw materials, it is necessary to record their biological characteristics in detail, such as chemical composition, biocompatibility, etc. During the production process, it is necessary to track the impact of processing on biological performance, record process parameters and test data; In the finished product stage, a complete biological evaluation report must be kept, including toxicity, irritation, and other test results. These records form a continuous traceability chain, ensuring comprehensive and traceable information [10]. When adverse events occur, based on the design and development documents, companies can quickly trace back to the raw materials, production, or design stages, identify potential defects such as improper material selection or process deviations, and analyze their impact on product safety. By tracing the results, enterprises can develop targeted corrective and preventive measures, optimize product design or production processes, effectively reduce risks, and ensure patient safety.

5.2.2. Design change control practice

After the launch of medical devices, significant changes may pose challenges to document version control, involving adjustments to product design, raw materials, or production processes. To ensure compliance, it is necessary to strictly follow the requirements of the quality system and establish a standardized change management process. When changes occur, detailed records of the change content (such as design parameter adjustments, material replacement, or process optimization), reasons, time, and impact analysis should be kept, and DMR (equipment master file) and DHF (design history file) documents should be updated in a timely manner to ensure their traceability. These documents need to fully reflect the change process, maintain information integrity and accuracy, to comply with regulatory requirements such as China's NMPA or the EU's MDR. The re-registration application has strict requirements for document standardization, and any omissions or errors may result in application failure and affect product launch. Therefore, it is necessary to establish a multi-level document review mechanism, consisting of a review team composed of R&D, quality management, and other departments, to systematically review the changed documents, verify their compliance, consistency, and completeness, and ensure that they accurately reflect the current status of the product. Through standardized version control and review processes, enterprises can effectively manage change risks, reduce regulatory barriers caused by document issues, ensure that products continue to meet quality standards, smoothly complete re-registration applications, maintain market competitiveness, and provide reliable support for patient safety and product quality.

5.3. International certification collaborative management

5.3.1. Conversion of declaration documents from multiple countries

In the field of medical devices, there are differences in technical documents between the United States, Europe, and China. To achieve the conversion of multi-country declaration documents under international certification collaborative management, it is necessary to reconcile these differences. Firstly, conduct in-depth research on the requirements of all parties and clarify the differences. On this basis, a modular document architecture design methodology is proposed. This methodology divides documents into functional, procedural, and other modules, with each module corresponding to the core requirements of different regions. In this way, while meeting basic functional and quality requirements, module content can be flexibly adjusted to adapt to certification standards in different countries. This not only improves the efficiency of document writing and reduces repetitive work, but

also ensures the compliance of documents when applying in different regions, providing strong support for the international market expansion of medical device enterprises.

5.3.2. Dual compliance of quality system

Building a design document management system that meets both ISO 13485 and FDA QSR is an important task for medical device companies. In the operation of the quality management system, it is necessary to clarify the commonalities and differences between the two standards. For design documents, it is important to ensure their completeness, accuracy, and traceability. From the formation of the product concept to final launch, documentation at each stage should adhere to double standards. In terms of file control procedures, optimization points include strict document approval processes to ensure that only authorized personnel can modify and publish documents. At the same time, establish an effective document version control mechanism to trace changes in different versions at any time. Through these practical applications, enterprises can better cope with the challenges of international certification collaborative management, ensure product quality meets the dual requirements of the quality system, and enhance their competitiveness in the international market.

6. Conclusion

Medical device design and development documentation plays a critical role in the quality system, serving as a vital link that integrates various aspects of the system. On one hand, through systematic organization, it establishes its pivotal role in ensuring standardized and normalized processes within the quality system. On the other hand, the adoption of digital twin technology for intelligent document management opens new opportunities for enhancing efficiency. Empirical studies demonstrate significant benefits: standardized document management reduces product registration cycles by 30% and improves quality incident traceability efficiency by 45%. These outcomes highlight the practical value of design and development documentation in quality management and provide a replicable, effective solution for the full lifecycle quality management of medical devices, contributing to the high-quality development of the medical device industry.

Disclosure statement

The author declares no conflict of interest.

References

[1] Li X, 2022, Design and Implementation of Traceability Coding System for Unique Device Identification of Medical Devices, thesis, Capital University of Economics and Business.

[2] Zhou Y, 2022, Research on Process Improvement and Quality System Enhancement for the NK Tablet Upgrade Project, thesis, University of Chinese Academy of Sciences.

[3] Chen P, 2022, Research on Medical Device Design Based on Cognitive Reliability: A Case Study of Nucleic Acid Extractor Design, thesis, Guangzhou University.

[4] Liu R, 2022, Design and Preparation of Polymer Films for Medical Device Packaging, thesis, Dalian University of Technology.

[5] Chu Z, 2022, Research on Supplier Selection in Medical Device Procurement at F Hospital, thesis, Ningbo University.

[6] Cheng J, Li G, Chen H, et al., 2022, Discussion on Problems and Countermeasures in the Operation of Quality Systems in Automotive Development Laboratories. Auto Time, 2022(22): 13–15.

[7] Qin Z, Lu Z, 2024, Brief Discussion on Key Points of Packaging Mold Design in the Design and Development Process of Medical Devices. China Packaging, 44(5): 33–37.

[8] Zhang Y, 2021, Application of Bionic Design Principles in Medical Device Development. Medical Equipment, 34(21): 187–189.

[9] Wang M, 2023, Analysis of Quality Control in Medical Device Design and Development (Part I). China Plant Engineering, 2023(11): 259–261.

[10] Wang M, Zhang W, Wang D, et al., 2023, Analysis of Quality Control in Medical Device Design and Development (Part II). China Plant Engineering, 2023(14): 222–224.