Construction Practice of Medical Device Product Life Cycle Management Platform

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Abstract: Medical device product life cycle management is one of the core contents of medical device quality management system construction, spanning the entire process of enterprise core business activities including market, research and development, procurement, production, and services. Building a comprehensive and efficient life cycle management system facilitates the implementation of quality management systems. Taking the example of the construction of a unified product life cycle management platform for medical device hardware and software that has been launched and operated, this article describes the general principles and practical experience of constructing a medical device life cycle management platform, including requirements collection, system design, product selection, customization development and confirmation, as well as platform trial, acceptance commissioning, and operation and maintenance management.

***Keywords*:** life cycle management, quality management, maturity

1. Overview of Medical Device Product Life Cycle Management Platform

Product life cycle management refers to the management of information and processes throughout the entire lifecycle of a product, from requirements, planning, design, production, sales, operation, use, maintenance, to recycling and disposal. It is not only a technology but also a concept for research and development, manufacturing, and even enterprise management. One of its important values is to promote communication, collaboration, and integration between development, production operations, and quality assurance (QA) departments. The life cycle management platform includes both hardware product data management (PDM), life cycle management (PLM), as well as software life cycle management (ALM), and can even extend to integrated development and operations (DevOps) [1-4].

1.1 Life Cycle Management Platform as One of the Three Pillars of Quality System Operation

The quality management system of medical devices covers all processes throughout the entire lifecycle of medical devices and is the foundation for ensuring the safety, effectiveness, and quality control of medical devices. Establishing a quality management system for medical devices is based on regulatory and relevant standard requirements [5-10]. The operation of the quality system for medical devices requires the joint action of people, processes, and platforms. As an important carrier for the operation of the quality management system, the life cycle management platform provides evidence for the realization and design development process of medical device products, even extending to the production process, establishing traceability chains, and providing the basic conditions for data centralization.

1.2 Trends in the Development of Life Cycle Management Platforms

The development trends of life cycle management platforms generally progress from being document-centric to item/part-centric, and towards model-based systems engineering, ultimately reaching data-driven product development. In the phase of data-driven product development, traditional collaborative PLM (Coordinated PLM) evolves into connected PLM [11]. From the perspective of platform products, future trends will support:

Various flexible development models: including traditional waterfall, agile, DevOps, hybrid models, etc.

Customizable solutions: more emphasis on providing customizable solutions to meet the specific needs of different industries and enterprises.

Efficient multi-level collaborative applications: further promoting the development of multi-level collaborative applications, from design to manufacturing, and then to supply chain management, achieving comprehensive and efficient collaboration.

Multi-cycle product data management: as the product life cycle continues to shorten, there is a need for better management of multi-cycle product data, not only managing current product data but also historical data and future planning.

1.3 Common Problems and Challenges in the Construction of Life Cycle Management Platforms for Medical Device Enterprises

(1) Lack of systematicness and completeness, using multiple small software to piece together, unable to cover the entire lifecycle process, fragmented, forming neither a systematic nor traceable chain;

(2) The coexistence of system and external operations leads to non-unique data sources;

(3) The platform system and the quality management system have two different faces. Due to the disconnect between the quality system and business departments such as R&D and production during the establishment of the quality system, procedures and processes are not implemented, while the construction process of the life cycle management platform simply follows the so-called classic models or templates from other industries;

(4) Lack of thorough understanding of the quality system by personnel, too doctrinaire or too rigid, lack of flexibility, platform processes are either too coarse or too fine, and fail to play the expected role;

(5) Operating independently of other systems and platforms of the company, either duplicating construction or deviating from the overall planning of company operations;

(6) Stuck in low-level stages such as document management, progress tracking, etc., with basic functions such as budget management, risk management, parts module library, engineering changes, global BOM management, etc., hardly utilized.

Currently, research on the life cycle management of medical devices mostly focuses on stages such as development phase division and responsibility allocation [1-4], with less emphasis on the construction and implementation of management platforms, and there has been no exploration of platform maturity. This article intends to focus on the construction and implementation of medical device life cycle management platforms, and evaluate maturity from the aspects of regulations, processes, and data.

2. General Process of Life Cycle Management Platform Construction

The establishment of a life cycle management platform can be considered as a process of new product development, managed using development processes. Based on the actual situation of the enterprise, it is generally divided into several main steps including project planning, requirement collection, platform construction, data migration, process customization, testing, and acceptance.

2.1 Project Planning

The construction project of a life cycle management platform usually originates from the construction of the quality system or enterprise informatization, initiated by the R&D department, production operation, and quality department, with the participation of the information department in implementation and subsequent operation. The project team should include personnel from these departments, and appropriate key users should be selected early to be responsible for proposing requirements, conducting testing, and training general users during the construction process. Resources-wise, considerations need to be given to hardware (such as servers) and software conditions (such as operating systems, databases, cloud platforms, virtual levels, bandwidth, etc.).

2.2 Requirement Collection

Requirement collection can be based on brainstorming by the project planning group, supplemented by basic functional specifications provided by potential suppliers, or based on prototype testing systems provided by suppliers. Since most participants in platform construction are expected users of the platform, who are only familiar with their own work scope responsibilities, it may not be comprehensive to start from scratch to propose requirements. Therefore, it is more reasonable to conduct requirement collection based on a template or testing system provided by a supplier.

The basic functionalities required for building a medical device software life cycle management platform include:

a) Project management: Typically, the life cycle of medical devices is completed in several different stages of projects, requiring the formulation, execution, and monitoring of project plans. For software medical devices, support for agile development should also be considered.

b) Document management: Classifying, archiving, accessing, and version controlling various documents in the product development and manufacturing process.

c) Resource management: Unified management of resources required in the development process of medical devices, including hardware resources, software resources, human resources, etc.

d) Product data management: Management of information such as product design, materials, performance, production processes, as well as uploading and downloading related documents. For products with multiple categories and reusability, such as robots, brackets, etc., data reuse needs to be considered.

e) Data analysis and reporting: Statistical analysis of collected data to provide decision support to management.

f) Supply chain management: Management of procurement, inventory, logistics, as well as selection and evaluation of suppliers.

g) Quality management: Comprehensive management of product quality including formulation of quality standards, development and implementation of quality plans, quality inspection, and monitoring, covering planning, organization, coordination, and control of the entire lifecycle from product development to sales.

h) Confidentiality requirements: Research and development and manufacturing data are important assets of a company, so data confidentiality requirements need to be considered during construction.

i) Records management: Research and development and product manufacturing data are important parts of company records. Typically, considerations need to be made on how to conveniently compile, backup, export, etc.

j) Informatization construction and information security: Integration of cloud platforms, other informatization management such as OA, instant messaging, as well as data capacity, expansion, upgrade, disaster recovery, etc.

k) Usability: Including the use of signatures, watermarks, image libraries, corporate identity, etc.

l) User access management: Including user role definition, permission assignment, and control functions to ensure system security.

2.3 Platform Selection

Common platform products include ZenTao, Pincode, Doors, Polarion, 3DE, Teamcenter, Jira, etc., to name a few. The selection of platform products needs to consider the maturity of the product itself, industry applications, the openness of interfaces, and the flexibility of secondary development. Also, attention should be paid to: (1) meeting the requirements of medical device quality system management; (2) conforming to the law of product life cycle management; (3) adapting to the established QMS management system; (4) ensuring compatibility with historical data file formats; (5) considering data exchange with production and delivery links; (6) balancing current and future company and product platform expansions.

2.4 Platform Design and Construction

After clarifying the requirements of the medical device life cycle management platform and selecting the product and supplier, construction and implementation of the platform can commence. Usually, the implementation plan is determined jointly with the implementation consultant of the supplier. First, tasks and deadlines for each stage need to be clearly assigned, such as the preparatory stage, system deployment stage, system debugging stage, etc. Then, specific implementation steps need to be formulated, such as requirement investigation, system design, programming implementation, testing acceptance, etc. Finally, quality control of the entire implementation process needs to be conducted to ensure that each stage of work meets expectations.

2.5 Testing and Acceptance

To ensure the stability and reliability of the medical device life cycle management platform, after deployment, a complete evaluation of regulatory compliance is required to ensure that the quality system and other relevant regulatory requirements considered at the beginning of the project platform construction are reflected in the platform and operate correctly. Rigorous testing and verification confirmation are also necessary. Below are some key steps:

1) Unit testing: Suppliers conduct unit testing for each functional module to ensure the normal function of each module.

2) Integration testing: Key users conduct integration testing for all functional modules to ensure coordination and stability between modules.

3) Performance testing: The project team conducts performance testing on the platform to ensure its stability and reliability under high loads.

3. Practice and Experience in Building a Unified Development Platform for Medical Devices

Our company began its medical device business in 2021. Since 2022, we have planned to establish a unified development platform for products, including PLM, ALM, and system integration. Considering compatibility with historical data and coverage of the entire process, we chose Dassault's 3DEXPERIENCE (3DE) and Siemens' Polarion (Fusion X) as the base platforms, customized and developed by system integrators. The platform was put into production operation in mid-2023. The life cycle management platform is led by Polarion (Fusion X) for product system and software lifecycle management, and 3DE for hardware lifecycle and release, with data interfaces enabling interoperability at the task level between the two. Additionally, external platform systems and interfaces such as SVN, GIT, EA, SAP, etc., were integrated, forming a unified

development platform for the entire life cycle.

4. Conclusion

The high-quality development of medical device enterprises relies on continuous improvement in technological innovation and research and development capabilities. From the perspectives of management and informatization complexity in business operations such as marketing, research and development, procurement, manufacturing, sales, and services, product development management and informatization work are the most difficult and key aspects of enterprise operation and management. Establishing a comprehensive and mature life cycle management platform is an important link in the construction of the medical device quality management system and a crucial tool for protecting organizational process assets. Forming a systematic and traceable organization, achieving completeness and uniformity in data, and achieving closed-loop management of overall and local processes are several basic characteristics of the maturity of the life cycle management platform.

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