Research on Medical Device Software Development and Design Based on CMMI Model

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Abstract: *In order to the problem of poor portability and confusion in management of medical device software, the Capability Maturity Model Integration (CMMI) is applied to optimize the design and development process of medical device software. IEC 62304 is used as a software development standard to improve the software process capability. Firstly, this paper makes a detailed comparison between medical device software and other application software. On this basis, the timing of CMMI implementation and the process of risk management improvement are studied and discussed. Then the interface framework of CMMI process area and IEC 62304 was obtained and the optimized flow of two domains in risk management was reasonably used in the evaluation process. The software portability based on CMMI has been significantly improved, and the management level is clear. The deviation rate of each stage is less than 10%. The simulation result shows that in the field of medical device software research and development, CMMI can be used and optimized, so as to improve software process capability.*

Keywords: *Medical device software, Capability maturity integration model, IEC 62304, Process area, Risk management.*

Introduction

With the improvement of people's living standards, medical devices are more widely used, and medical device software has become an important part of medical devices [6]. More and more medical devices need to rely on software to store, communicate and analyze information. For example, medical magnetic resonance imaging system, 24-hour full-information dynamic electroencephalogram (EEG) recording and analysis system and other software are indispensable important tools for medical diagnosis. With the development of information technology and modern medical means, software manufacturing has become a new development direction and inevitable trend of medical device industry. Quality management is the most important part of medical device supervision [8, 11]. It has a practical relationship with the safety of people's lives. Similarly, the quality management of medical device software should not be neglected. Due to the characteristics of software products and the immaturity of the software industry, recalls due to software problems are increasing [3].

Capability Maturity Model Integration (CMMI) is a methodology for process improvement, which combines best practices from various industries. CMMI believes that process improvement is a step-by-step process. Only by focusing on process improvement can we improve organizational maturity and product quality. According to SEI statistics, after introducing CMMI, the productivity of software enterprises increased by 35% on average, and the error rate decreased by 39% [1, 4, 10]. CMMI has been proved to be an effective way to improve the quality of software products and enhance the core competitiveness in many enterprises. CMMI includes three models: development model, procurement model and service model. CMMI-DEV (CMMI for Development), or CMMI development model, provides a comprehensive and integrated series of guidelines for development activities to meet the needs of customers and end users [7].

In order to the problem of poor portability and confusion in management of medical device software, in this paper, the CMMI is applied to optimize the design and development process of medical device software.

Materials and methods

The necessity of applying the capability maturity integration model

CMMI is upgraded from the traditional software maturity model. It provides a perfect architecture for the improvement and evaluation of integrated processes for system engineering and product development and maintenance. The CMMI is composed of best practices in the fields of software engineering, system engineering, integrated product development, and system procurement [9].

In CMMI, a process domain is a set of practices and goals that can achieve a set of goals by performing these practices. Therefore, it is very important to implement and satisfy a set of goals correctly in the process domain. In the 5 maturity level, there are 22 process domains, and each process domain must meet a certain extent [5]. There are similarities between medical device software and general computer software, but what is more noteworthy is its particularity. Because medical device software is closely related to human life safety, safety and risk issues become the focus. In view of the special requirements of medical device software, IEC and ISO jointly issued and published the IEC62304 “Medical device software – Software life cycle process”. This is the first special standard for medical device software, which is used for the development and maintenance of medical device software. The R & D organization of medical device software should be based on the IEC 62304 standard.

IEC 62304 defines the concept of medical device software as follows: as a medical device or an application software built into medical devices. Compared with other applications, the patient's life and health and medical device software have a direct and close connection, so the risk and security become the focus of the development and design of medical device software. Therefore, ISO and IEC have formulated and passed the Medical device software – Software life cycle process, IEC62304 standard, and has now become a common standard for developing and designing medical instrument software in China [2].

Problems existing in the software engineering process of the medical device industry

Medical software development organizations use IEC 62304 as a development basis to guarantee the quality of product output, but for organizations, development costs and development cycles are also essential. To achieve the success of the development project, the risk and software management level must take into account. The large risk of software development is due to the low ability of software process. The key problem is that the software development organization can manage its software process well, so that some good development methods and techniques can be expected. The purpose of CMMI is to help software enterprises to manage and improve the software engineering process, enhance the ability of development and improvement, so that high quality software can be developed on time and without excess budget. But CMMI is not aimed at the medical industry software, but a universal software engineering optimization model.

When an organization uses CMMI to improve the software process, it often involves a variety of software life-cycle models, so it is very important to clarify the roles and relationships of the two to improve the success of the activities. On the one hand, if software development activities are divided into engineering activities (requirement analysis, design, coding, testing) and not engineering activities, the software life-cycle model focuses on engineering activities, while CMMI focuses on the whole of software development activities, including not engineering activities, such as project management, configuration management, etc., to ensure development activities.

Process area

Process Area is a very important concept of CMMI. It refers to a set of related practices belonging to a certain field. CMMI provides 23 process areas which are shown in Table 1.

Table 1. The process areas of CMMI

Process area	**Class**	**Maturity level**
Product integration	Engineering class	3
Technical solutions		3
Confirm		3
Demand development		3
Verification		3
Organizational process definition	Process management class	3
Organizational process concern		3
Organization-level process performance		4
Organizational performance management		5
Organizational training		3
Risk management	Project management class	3
Supplier agreement management		3
Integrated project management		2
Quantitative project management		3
Project plan		4
Project supervision and control		2
Demand management		2
Measurement and analysis	Support class	2
Support class		2
Process and product quality assurance		2
Decision analysis and solution		3
Configuration management		2
Cause analysis and solution		5

Process areas can be understood as a set of process activities. 22 process areas have common objectives, and each process area has specific objectives. The aggregation of all objectives is the improvement of the process. In order to achieve these goals, we need some practice. General objectives correspond to general practices, and specific objectives correspond to specific practices. The aggregation of all practices is the method and approach to process improvement. In order to achieve these goals, some practice is needed. CMMI provides a comprehensive explanation of the target practice to ensure consistency and accuracy of the implement understanding. CMMI process improvement is to apply these 22 process areas to the actual organization, so that the process can be improved.

CMMI provides two models, continuous and phased. It can also be used as two implementation methods of CMMI. Continuity emphasizes the capability of a single process area, without the concept of maturity, and divides 22 process areas into four categories: process management, project management, engineering and support (as shown in Table 1). The improved organization can flexibly select the process domain classes that need to be improved. In this paper, a CMMI model suitable for medical device software will be established in a continuous way. Phased phases divide 22 process areas into five maturity levels which is shown in Fig. 1. The higher the grade, the more capable the organization is to produce high-quality products, while saving time and cost. The usual CMMI assessment is usually carried out in stages.

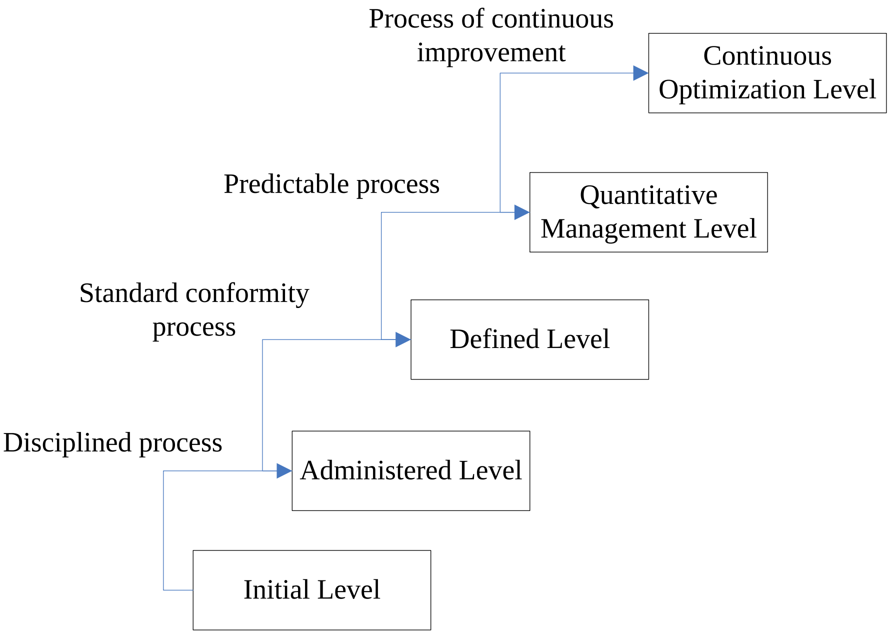
Process of continuous improvement
Continuous Optimization Level
Predictable process
Quantitative Management Level
Standard conformity process
Defined Level
Disciplined process
Administered Level
Initial Level

Fig. 1 The stage model

Problems existing in the software engineering process of the medical device industry

After describing the process and the process area of CMMI itself, it is considered that the waterfall model can clearly illustrate how to effectively map CMMI into IEC 62304. Software process activities in IEC 62304 are divided into two main processes and a support process, as shown in Fig. 2, expressed in a waterfall model, and dark shadows in the graph represent two main processes: R & D process and maintenance process; light color shadow represents support process: risk management, configuration management, problem solving.

Through the application of the software life cycle model, the unstructured software design and R & D activities can be processed and structured. After that, there will be more and more problems such as risk management, project management and so on. This is the advantage of CMMI, which pays more attention to the overall situation of software development activities, effectively improves and manages software processes, and ensures the efficiency and smooth development of software.

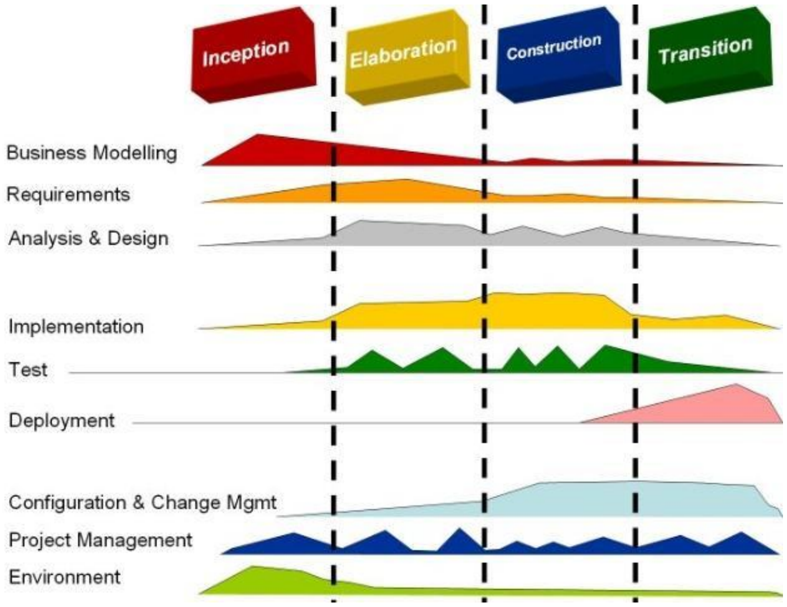

Fig. 2 Software process activities in IEC 62304 for E-medicine system

Results and discussion

In order to establish a more suitable model for organizational quality improvement of most medical device software, this paper chooses small and medium-sized medical device companies as the research object. H Medical Technology Co., Ltd. is mainly engaged in R & D, production and sales of high-end medical imaging and other advanced diagnostic and therapeutic equipment with core intellectual property rights. The software department is responsible for the development of medical device software. At present, there are 13 people in the software department.

Process area reducing

Combined with CMMI, there are several aspects that need to be improved in medical device software enterprises at present.

(1) Selecting strong matrices. Strong matrix is a form of project management organization. Compared with weak matrix, the role of project manager is more obvious. Strong matrix is suitable for small-scale organizations, weakening the concept of departments. Everyone is working for the project and obeying the requirements of project management. This can reduce the cost of inter-departmental communication and make the work more efficient. Whether hardware or software belongs to a general project, hardware and software can become sub-projects of the general project separately. Project managers have more authority than functional managers.

(2) Establishment of project management system. Because the medical device software project is often a sub-project of the medical device project, which has a strong dependence on the hardware sub-project. Therefore, it is necessary to integrate project management and standardize the management of all sub-projects in the project management model to ensure the consistency and accuracy of project processes and products. From project planning to project supervision and control, project execution can be guaranteed. Strengthen demand management, reduce the arbitrariness of demand change, and improve product quality. Strengthen risk management to mitigate the impact of project emergencies on the project.

(3) Standardize the software development life cycle. From the point of view of software engineering, standardize the process of medical device software project. Referring to

IEC62304:2006, the life cycle of medical device software project is standardized as requirement development, system design and development, testing and product integration. Incorporate the evaluation into the field of engineering activities to ensure that the project products can be verified and validated.

(4) Attach importance to the role of supporting management. In the process of medical device software project, we need to focus on improving the quality assurance process. Because the consequences of medical device software defects may be fatal, reliability and stability should be better than advanced, and the amount of work spent in quality assurance is worth the money. Configuration management is also needed to manage the product well to prevent the adverse effects of version errors or conflicts. The measurement and analysis process helps to accumulate project experience and improve the project spirally. To sum up, CMMI quality assurance model is more suitable for small and medium-sized medical device software organizations. It is divided into three sub-models: project management model, engineering model and support management model. In order to build a more suitable CMMI quality assurance model for small and medium-sized medical device software enterprises, nine of the 22 CMMI process areas need to be tailored which are shown in Table 2.

Table 2. The CMMI process areas need to be tailored

Process area	**Class**	**Reasons for reducing**
Organizational process definition	Process management class	Relevant process areas at the organizational level are not suitable for small and medium-sized enterprises and should be carried out in the early stage of process improvement.
Organizational process concern	Process management class	Relevant process areas at the organizational level are not suitable for small and medium-sized enterprises and should be carried out in the early stage of process improvement.
Organization-level process performance	Process management class	High maturity level, suitable for large-scale enterprises
Organizational performance management	Process management class	High maturity level, suitable for large-scale enterprises
Organizational training	Process management class	Relevant process areas at the organizational level are not suitable for small and medium-sized enterprises and should be carried out in the early stage of process improvement.
Supplier agreement management	Project management class	The purchasing tasks of domestic companies are generally undertaken by the purchasing department, not by the project.
Quantitative project management	Project management class	High maturity level, suitable for large-scale enterprises
Cause analysis and solution	Support class	High maturity level, suitable for large-scale enterprises
Decision analysis and solution	Support class	High maturity level, suitable for large-scale enterprises

Implementation of the system

The process of system design and development is divided into two parts: system design and system implementation. The flow chart is shown in Fig. 3.

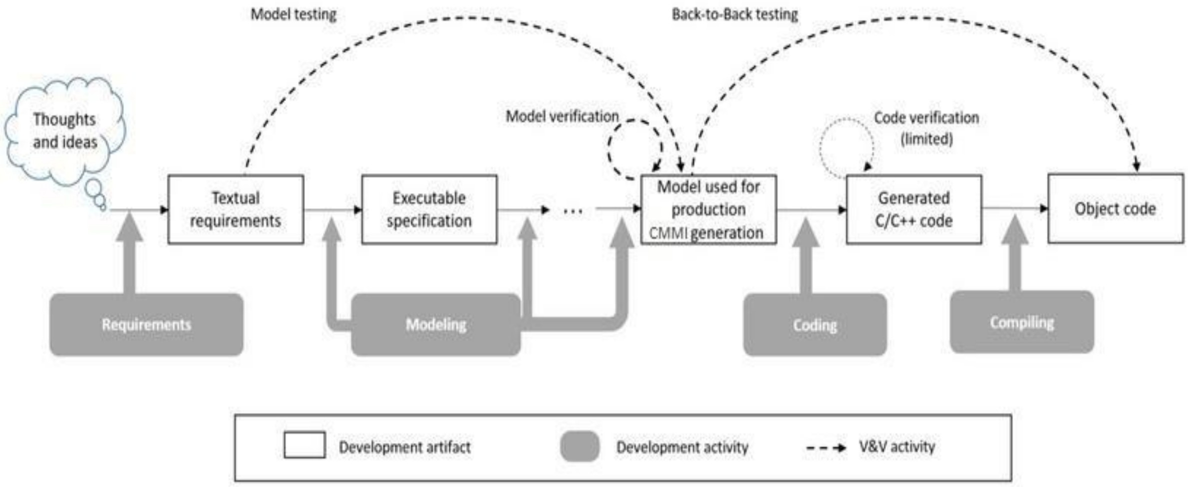

Fig. 3 The flow chart based on CMMI architecture

Test cases are divided into functional test cases and non-functional test cases (non-functional test cases include performance test cases, stress test cases, graphical interface test cases, database test cases, etc.). When the project enters the design stage, the test manager organizes the decomposition of test cases according to the requirements. The test cases need to include the following elements: test case name, test purpose, designer, review information, test description, test steps, expected results, actual results, corresponding software requirements (or test requirements). The duration comparison is shown in Fig. 4.

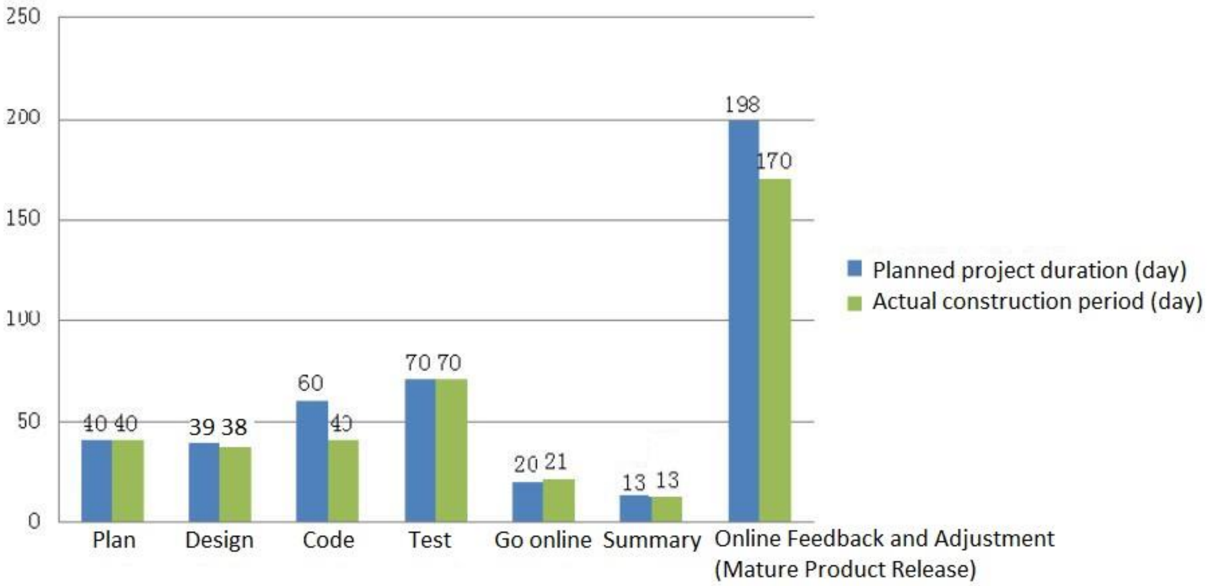

Fig. 4 The duration comparison

As shown compared with the projected construction period, only in the on-line stage, the projected construction period is more than one day, while in the other stages, the projected construction period is not exceeded. The total construction period is 45 days shorter than expected. The deviation rate of workload and management indicators is shown in Fig. 5.

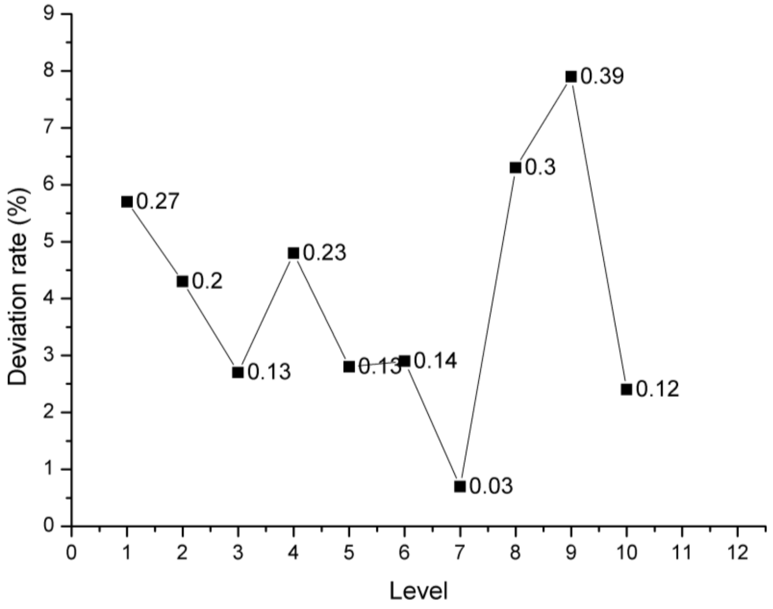

Fig. 5 The deviation rate of workload and management indicators

According to the figure, it shows that the deviation rate is less than 10%, which meets the technical target of the project.

Conclusion

Through the construction of the software project management platform based on CMMI, the management of the planning, monitoring and quality assurance of the organization's assets and software projects can effectively improve the quality and efficiency of the software. It also plays a great role in the accumulation of technology assets and the reuse of technology. The development and design of medical device software has special characteristics in the whole software development industry due to the particularity of medical industry. First, the development of medical device software has a lot in common with the development of general software. Secondly, the purpose of medical device software is service and health care. Therefore, the effectiveness and security have become the focus of attention. In the process of developing and designing medical device software, we should not only base the international standards, but also fully combine the current situation of the enterprise, optimize and improve the research and development process by absorbing the advanced international experience. On the basis of ensuring the medical instrument software, the efficiency of software development and the cost of software development are reduced.

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