IBM Rational systems and software solutions for the medical device industry

Improve processes, manage IEC 61508 and IEC 62304 standards, develop quality products

Highlights

- Manage compliance with government regulations such as IEC62304 and IEC 61508 in the medical device industry
- Automate FDA document generation
- Lower product development costs and expedite time-to-market for cutting edge solutions
- Integrate software development into the overall product engineering process
- Build in system quality from the start of the development life cycle
- Link the various artifacts developed over the course of the product life cycle into cohesive system delivery workflows
- Use IBM Rational tools to help develop reliable and quality software

In an increasingly competitive medical device industry, software is emerging as the key value differentiator. However, the rigorous standards mandated for medical device software and the inherent difficulties of system and software implementation have introduced complexities into the management of product development. Although it is difficult and time consuming to prove compliance with various government regulations, not doing so will result in legal and product quality issues with the possibility of heavy fines, delayed product launches and brand erosion. Current product development processes are neither suited for addressing the compliance requirements nor for managing the development of the increasing amount of software embedded in these devices. The current economic climate demands a reduction in product development costs and an expedited time-to-market for cutting edge solutions. If a company cannot integrate its disciplines and its teams cannot collaborate, the time to launch innovative and new products increases, which can hurt sales and profitability.

Innovative embedded software has the ability to bridge this challenge of rapid product development because it can be used to add functionality quicker to a product. Therefore, software development methods need to be closely integrated into the overall product engineering process. The inherent complexities of product delivery today necessitate flexible development methods because requirements can no longer be frozen early in the development cycle. Yet these processes are not always

compatible with regulatory standards such as the new IEC 62304 medical device standard for software development. Although they can help teams move in the right direction, mainstream agile methods such as Scrum or XP need to be extensively modified to include requirement and configuration management changes.

The challenges of medical device manufacturing can no longer be solved by examining and tackling individual problems. As they face increased product complexity, time to market, competitive challenges, and increasingly strict regulatory standards for quality and patient safety, the IBM® Rational® solution for the medical devices industry can help. This comprehensive solution makes it easier to manage regulatory mandates, while helping improve the efficiency and effectiveness of product development teams.

The Rational solution for the medical devices industry offers integrated, end-to-end traceability that can help improve processes, automate FDA document generation, manage regulatory standards such as IEC 62304 and bring innovative, safe, high-quality products to market. Product development processes are supported by IBM Rational tools that can help medical device manufacturers develop reliable and quality software and manage regulatory norms. With an open standard architecture, the medical device manufacturer has the option to supplement these tools in the IBM solution with other tools.

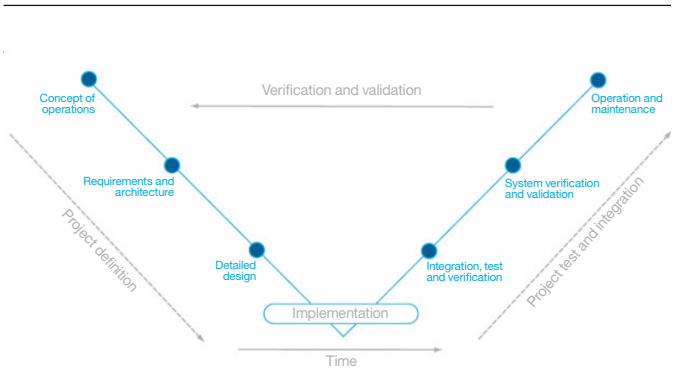

Figure 1: The typical process stages that both software and hardware teams use for analysis, design, implementation and testing

Key stages in software development process

Each of the following key process stages (Figure 1) in the software development process requires careful analysis to determine whether the development process is compatible with various regulatory mandates:

- **Requirements analysis.** It is possible to develop higher-level system requirements and the derived lower-level requirements iteratively using an agile process, but the IEC 62304 standard, for example, mandates that requirements be documented. Requirements must also link to other phases of the process, including software architecture, test cases and so forth.
- **Architectural design.** This process stage turns the requirements into a coherent architecture so developers can understand how each requirement will be met and ensure there are no overlaps or gaps in the requirements. Graphics are often used and should map to the actual code; this mapping serves as the traceability from requirements to code.

- **Testing.** Unit level testing verifies each individual component while integration testing ensures that different components actually work together and do not cause unanticipated actions. System testing treats the whole system like a black box and validates the high level requirements. Each testing discipline is critical for meeting the requirements of standards like IEC 62304.
- **Reports.** Although not a phase by itself, reports are part of various points in the life cycle and need to be sent out to the regulatory agencies at the end of product development. These reports, along with the complete traceability report that links the entire process cycle are essential, for quality and to fulfill compliance mandates.

These key process phases need to be carefully examined to find the extent that current processes deviate from expected standards. For example, IEC 62304 requires complete traceability and hence there is a need for a requirements management method that maintains a link to the specific code that addresses each requirement, not simply a line number or some other reference. Additionally, there is also a need to know how closely the actual code maps to the requirements. Tools with the ability to link the architecture and generate context-specific references help address this problem. There are a variety of tools and practices that can accomplish this. When system quality is not built in from the start of development, the rollout of the medical device might be delayed and there is a possibility of design errors and cost overruns. Additionally, adhering to a new, improved process based on the principles of agile development with the added rigor of modeling, architecture and sophisticated requirements management is necessary to meet a standard such as IEC 62304. Finally, automated reporting makes it far easier for the sales teams or those in charge of handoffs in the supply chain to demonstrate regulatory compliance.

Addressing these challenges with IBM Rational solutions

The IBM Rational solution for systems and software engineering offers a comprehensive life-cycle management platform that supports collaborative development of complex systems, including their embedded software. It helps link the various artifacts developed over the course of the product life cycle into cohesive system delivery workflows and provides task management capabilities for effectively running the system delivery project. The solution helps development teams focus on the systems engineering of medical devices and their embedded software with support for safety, reliability, security analysis, mapping to CMMI maturity levels and medical standards, including IEC 61508 and IEC 62304. This full development life-cycle solution supports electronic signatures that are compliant with FDA CFR21 Part 11 for signing requirements baselines and change approvals. It can also automatically generate FDA submission documentation.

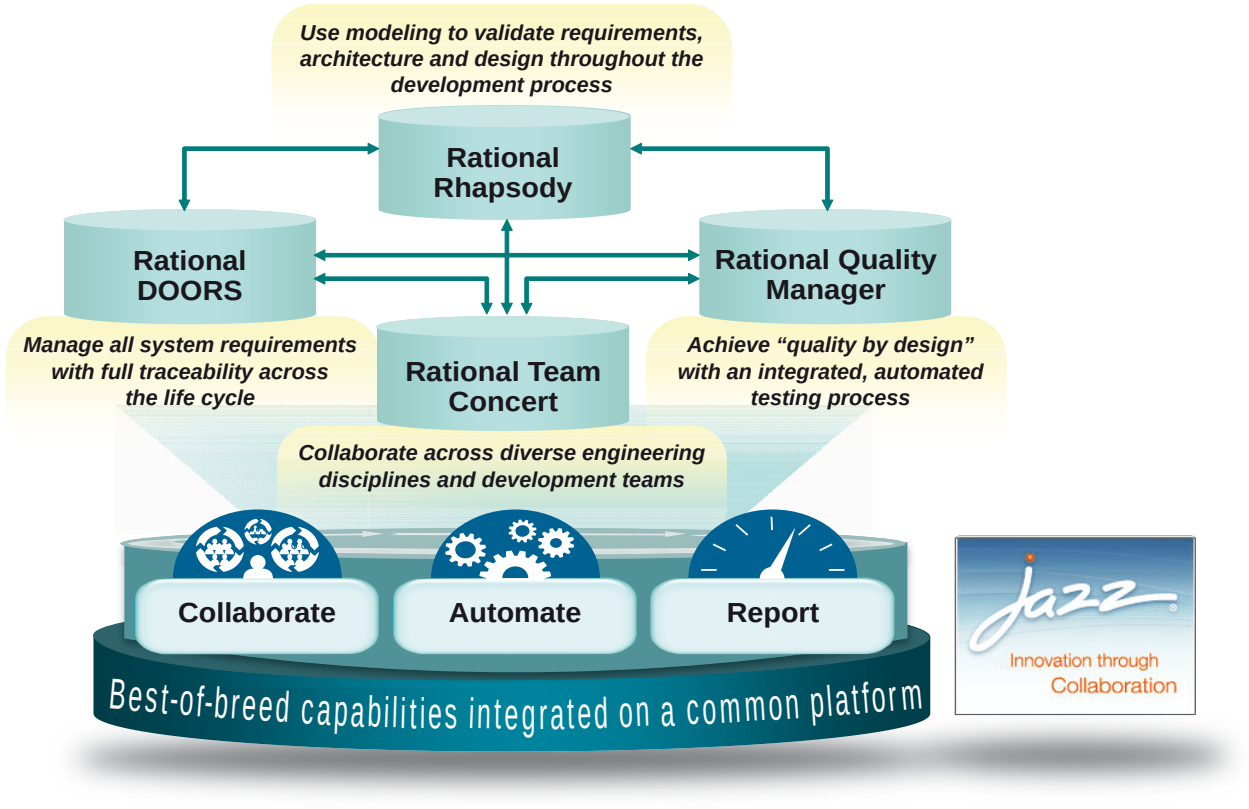

Figure 2: IBM Rational solution for systems and software engineering

The IBM Rational solution for systems and software engineering (Figure 2) provides this integrated solution.

The Rational products in Figure 2 are based on the IBM Jazz™ open and extensible software platform. Each phase uses an IBM Rational tool that has been specifically designed for it and all these tools are tightly integrated. Therefore, the solution bridges the individual phases of development to provide an integrated system life-cycle solution. Further, it helps systems and software engineering teams perform efficiently and collaborate to manage all the life-cycle work products. This in turn helps medical device manufacturers make products that meet changing medical needs and standards. The solution maps the various team roles with products that satisfy the needs of each role as shown in the following table.

Role	Needs	IBM Rational Tools
System engineers	A collaborative environment for requirements analysis, architecture management and change management	IBM Rational DOORS® and IBM Rational Rhapsody® software for system engineering tasks; IBM Rational Team Concert™ software for life cycle management of the change artifacts; IBM Rational Quality Manager software for collaboration with system validation teams from the start of the project
Safety engineers	Focus on the safety requirements and assurance	Rational DOORS and Rational Rhapsody software with the Safety Analysis Profile for identifying and classifying hazards, faults and safety measures
Reliability engineers	System reliability as measured by metrics such as mean time between failures and availability.	Rational DOORS and Rational Rhapsody software
Project, development and test team leads	Work and plan management for system delivery teams for the entire project life cycle	Rational Team Concert software and Rational Quality Manager software to help with live transparency through collaboration, automation and reporting to the system delivery work products
Software engineers	Complete software development solution for model-driven development, team collaboration, configuration management, work items, change sets and continuous software build support, traceability to upstream system engineering work products and downstream traceability to system integration and validation	Rational Rhapsody integrated with Rational Team Concert software in the Eclipse IDE to integrate model-driven development using UML with the Rational Team Concert software capabilities for team collaboration
Software and system testers	Collaborative environment for test planning, construction and execution, management of system validation and acceptance testing and improvement in efficiency of the testing and resource allocation	Rational Quality Manager software for the collaborative environment and test management of system validation and acceptance testing; IBM Rational Test Lab Manager software to help improve the efficiency of system test labs and manage how resources are requested and provided

Summary

Engineering medical devices is not an easy job. These devices include an increasing amount of software that integrates with hardware and electronics. To produce medical devices that meet changing healthcare needs and standards, the team that engineers the medical device systems and software must be efficient and collaborate to manage all the life-cycle work products. IBM Rational software provides an integrated life-cycle solution for these engineering teams so they can address the challenges of developing medical device software. The IBM Rational solution for systems and software engineering in the medical device industry provides tools for collaboration, automation and reporting to help these teams meet the demands today's complex medical device systems.

The IBM Rational solution for systems and software engineering offers integrated and collaborative capabilities for developing software for medical devices with particular focus on managing compliance with the IEC 62304 standard. It offers a process based on the principles of agile development and adds modeling, architecture, sophisticated requirements management and automated reporting capabilities to help medical devices not only meet the IEC 62304 standard, but also demonstrate compliance. This full development life-cycle solution also supports FDA CFR21 Part 11 compliant electronic signatures and automated generation of FDA submission documentation.

For more information

To learn more about IBM Rational solution for system and software engineering for the medical device industry, please contact your IBM marketing representative or IBM Business Partner, or visit the following website: **ibm.com**/software/rational/solutions/electronics/devices

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IBM Corporation
Software Group
Route 100
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