IBM **Engineering**

Engineering Solutions for Medical Devices

Accelerate development of innovative products while meeting IEC 61508, IEC 62304, ISO 14971, ISO 13485 and 21 CFR 820.30 standards

IBM

Solution for Medical Devices

As the medical device industry becomes increasingly competitive, systems and software delivery are emerging as key value differentiators. Companies that can get high-quality products to market more quickly will gain a major advantage—but the rigorous standards mandated for medical devices and the inherent difficulties of system and software implementation make product development a complex challenge. Proving compliance with relevant industry standards and government regulations can be costly and time-consuming, but it is necessary to avoid legal and product quality issues, and the risk of heavy fines, delayed product launches and brand erosion.

Dependability is a very critical concern in medical device development as well. Safety, security and reliability are the main components of dependability. These three components can define risk and implementing an ISO 14971 compliant risk management approach to address safety, security and reliability concerns can help make products more dependable. Higher dependability results in fewer product recalls (FDA has issued 137 Class III products recalls only in 2017 and 2018), less rework and shorter certification processes.

In most medical device companies, development processes are still catching up with the needs of the business. If a company cannot integrate its development disciplines and its teams cannot collaborate, the time and cost required to develop and launch new products will increase, impacting sales and profitability.

An implementation of a scalable Quality Management System (QMS) is required nearly by all regulations. European Union Medical Device Regulations expects a risk-based approach and includes a post market surveillance plan as part of the safety profile. In addition to medical devices, now Software as a Medical Device (SaMD) is considered to be in the QMS context and many SaMD's are expected to be up classified. Compliance to ISO 13485 is considered to be a good implementation of QMS since it covers both lifecycle support processes like risk management, planning, outsourcing etc, and realization and use processes like design, develop, verification and validation etc. An implementation fully compliant with ISO 13485 would be able to answer many regulatory requirements on this subject.
Embedded processor technology can help to accelerate product development by adding functionality to a product more quickly than a purely mechanical approach. For this reason, it is becoming increasingly important to integrate embedded software development methods into the overall product engineering process.

Highlights

- Reduce product development costs and deliver high-quality medical devices to market faster
- Manage compliance with international standards such as IEC62304, IEC 61508, and 21 CFR 820.30
- Integrate systems and software engineering into the overall product development process
- Implement reliable systems with proper safety analysis and risk assessments compliant with ISO 14971
- Incorporate systematic quality management throughout the development lifecycle via implementing quality management systems compatible with ISO 13485
- Create intuitive system delivery workflows that provide instant access to all documentation and artifacts
- Design and develop devices using agile approach, scale agility to enterprise via SAFe®
- Automate reporting processes and generate FDA documentation instantly

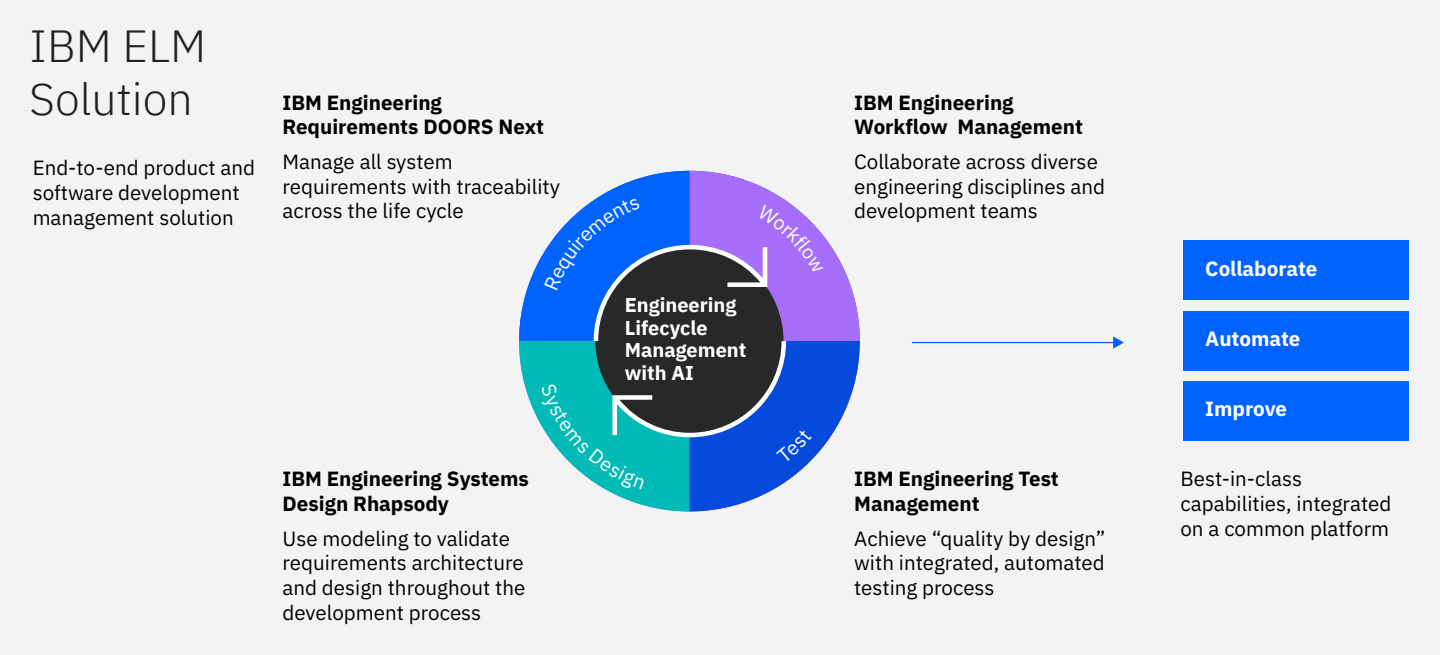

Figure 1. The typical process phases that both software and hardware teams use for analysis, design, implementation and testing

However, embedded technology adds an extra layer of complexity to the device development process, since the required hardware and software need to be developed in parallel. Flexible development methods are required, because requirements can no longer be frozen early in the development cycle. The problem is that these flexible methods are not always immediately compatible with international standards, such as the IEC 62304 medical device standard for software development, the IEC 61508 standard for functional safety of electronic devices, or the 21 CFR 820.30 standard on design controls in medical device development. Although mainstream agile methods such as Scrum can help teams move in the right direction, they need to be extensively modified to include requirement and configuration management changes.

When it comes to teams of teams (of teams), the Scaled Agile Framework (SAFe®) proves its efficacy because this methodology can scale up the agile approach to the enterprise level. So, an agile implementation doesn't have to be confined to the team level, it can be very effective at the enterprise level as well, carrying a strategic product and portfolio view all the way down to a team and function & feature level. As an example, this approach can provide complete traceability in hardware and software development to improve the speed and reliability of which updates are tested and released and are aligned with product and portfolio strategies.

The challenges of medical device development can no longer be solved by examining and tackling individual problems—instead, a solution is needed that addresses all the issues in a holistic way. The IBM® Engineering Lifecycle Management (ELM) solution is designed to help companies deal with increased product complexity, competitive challenges, and increasingly strict standards for quality and patient safety, while still improving time-to-market. This comprehensive solution makes it easier to manage regulatory mandates, while helping product development teams work more efficiently and effectively.

The IBM ELM solution offers integrated, end-to-end traceability and fault and failure analysis that can help improve processes, automate FDA document generation, manage regulatory standards such as IEC 62304, IEC 61508 and 21 CFR 820.30, and bring innovative, safe, high-quality products to market. Product development processes are supported by IBM Engineering tools to help medical device manufacturers develop reliable, compliant, high-quality systems and software. An open standards-based architecture also gives medical device manufacturers the option to supplement the IBM tools with those of other vendors.

Key phases in systems and software development process

Each of the following key phases (Figure 1) in the systems and software development process requires careful analysis to determine whether the development process is compatible with various international standards and regulatory mandates. Note that these phases can, and usually will, overlap.

– Requirements analysis. Higher-level system requirements and the lower-level requirements derived from them can be developed using an agile process—yet standards such as IEC 62304 mandate that all requirements be properly documented. Reconciling the desire for agility and the need for documentation is often seen as a challenge but approaches such as the one defined in the Association for the Advancement of Medical Instrumentation's Technical Implementation Report TIR-45 show how it can be achieved. Requirements must be linked to other activities in the process, including software architecture, test cases and so forth.

– Architectural design. This phase creates a coherent architecture to deliver the requirements. From this architecture, developers can understand how each requirement will be met and ensure that there are no gaps or unnecessary overlaps. The architecture is defined using models (usually graphical) that map to the actual implementation, whether hardware or code. This mapping provides the traceability from requirements to implementation.

– Testing. Traditionally, testing was generally treated as a separate activity that was only triggered at certain points in a development process. A more modern approach to systems and software development involves continuous validation throughout the development lifecycle. This is ideal for meeting standards such as IEC 62304, because it helps to verify that requirements are being met at every phase in the process.

– Reports. Reporting is needed at various points in the lifecycle. For example, reports usually need to be sent to regulatory agencies at the end of product development. These reports, including the complete traceability record that links the entire process, are essential to fulfill compliance mandates and to ensure quality.

Development processes need to be carefully examined to ensure that they do not deviate from expected standards. For example, IEC 62304 requires complete traceability, which means there is a need for a requirements management method that maintains links between each requirement and the design elements that meet it. Additionally, there is a need to know how closely the actual design maps to the requirements. Tools with the ability to link the requirements to the architecture and generate con-text-specific references can help address this problem.

In summary, building system quality into medical device development from the start of the process can help to avoid delays in rollout and the risk of design errors and cost overruns. 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 a huge advantage in meeting standards such as IEC 62304. Finally, automated reporting makes it far easier for product sales teams or those in charge of handoffs in the supply chain to demonstrate compliance with regulations and international standards.

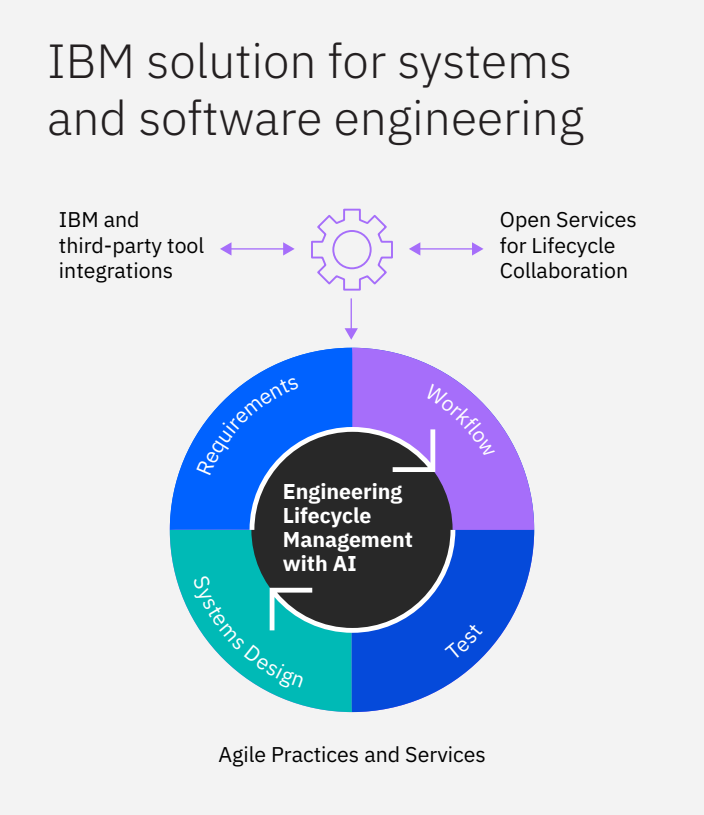

Figure 2. IBM Engineering solution for systems and software engineering

Addressing these challenges with IBM Engineering solutions

The IBM ELM solution offers a comprehensive lifecycle management platform that supports collaborative development of complex systems. It helps link the various artifacts developed over the course of the product lifecycle into cohesive system delivery workflows and provides task management capabilities that help move the system delivery project forward.

The solution helps development teams focus on the systems engineering of medical devices and embedded software with support for safety, reliability and security analysis, mapping to CMMI maturity levels and medical standards including IEC 61508, IEC 62304 and 21 CFR 820.30. This full development lifecycle solution supports electronic signatures that are compliant with 21 CFR Part 11 for signing requirements baselines and change approvals. It can also automatically generate FDA sub-mission documentation. The IBM ELM solution for systems and software engineering provides an integrated solution that is based on the open and extensible IBM Jazz™ software platform, as shown in Figure 2.

Each phase of the development process is supported by an IBM Engineering tool that has been specifically designed for it, and the tools are tightly integrated. Therefore, the solution bridges the individual phases of development to provide an integrated system lifecycle solution.

The solution also helps systems and software engineering teams perform efficiently and collaborate to manage all of the lifecycle work products. This in turn helps 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 Engineering Tools
Systems engineers	Collaborative environment for requirements analysis, architecture management and change management	IBM Engineering Requirements Management DOORS® Next and IBM Engineering Systems Design Rhapsody® software for system engineering tasks; IBM Engineering Workflow Management software for lifecycle management of the change artifacts; IBM Engineering Test Management software for collaboration with system validation teams from the start of the project
Safety engineers	Focus on safety requirements and assurance	DOORS Next and Rhapsody software with the Safety Analysis Profile for identifying and classifying hazards, faults and safety measures
Reliability engineers	Focus on system reliability, as measured by metrics such as mean time between failures and availability	DOORS Next and Rhapsody software
Project, development and test team leads	Work and plan management for system delivery teams across the entire project lifecycle	Engineering Workflow Management software and Engineering Test Management 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 both upstream system engineering work products and downstream system integration and validation	Rhapsody integrated with Engineering Workflow Management software in the Eclipse IDE to integrate model-driven development using UML with the Engineering Workflow Management software capabilities for team collaboration
Software and system testers	Collaborative environment for test planning, construction and execution; management of system validation and acceptance testing; improvement in efficiency of testing processes and resource allocation	Engineering Test Management software for the collaborative environment and management of system validation and acceptance testing

Summary

Engineering medical devices is not an easy job. These devices include an increasing amount of embedded software that integrates with hardware and electronics. To produce medical devices that meet ever-changing healthcare needs and standards, systems and software engineering teams must work and collaborate efficiently to manage all of the lifecycle work products.

IBM Engineering software provides an integrated lifecycle solution for these engineering teams, enabling them to address the challenges of developing medical device systems and software. The IBM Engineering Lifecycle Management provides tools for collaboration, automation and reporting, which help these teams meet the demands of today's complex medical device systems.

The IBM Engineering Lifecycle Management solution offers integrated and collaborative capabilities, with a particular focus on managing compliance with the IEC 62304, IEC 61508 and 21 CFR 820.30 standards. 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 these standards, but also demonstrate compliance. This full development lifecycle solution also supports FDA 21 CFR Part 11 compliant electronic signatures and automated generation of FDA submission documentation.

For more information

To learn more about the IBM Engineering Lifecycle Management solution, please contact your IBM marketing representative or IBM Business Partner, or visit the following website: https://www.ibm.com/internet-of-things/solutions/systems-engineering?lnk=hpmpr_iot&lnk2=learn

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