SOFTACUS
Business and IT Solutions

ENGINEERING LIFECYCLE MANAGEMENT

FOR MEDICAL DEVICES

Develop medical devices with the high quality, and with high quality by leveraging reuse concepts, collaboration, traceability and full compliance to medical standards

DEVELOP DEVICES BY LEVERAGING THE BEST IN THE MARKET SOLUTION FROM IBM FOR:

- Requirements Management
- Risk Management, FMEAs, Mitigation
- Design - Model Based System and Software Engineering & Simulation
- Planing Execution and Software Development
- Verification, Validation and Test Automation
- Methods and Compliance to Medical Standards like Medical Device Directives (MDD) Medical Device Regulations (MDR), Vitro Diagnostic Device Regulations (IVDR)

Get compliant with easily with FDA, IEC 623014

Ensure core processes such as quality insurance, risk management, and post-market expectations have been updated in order to comply with the new requirements.

IBM Gold Business Partner

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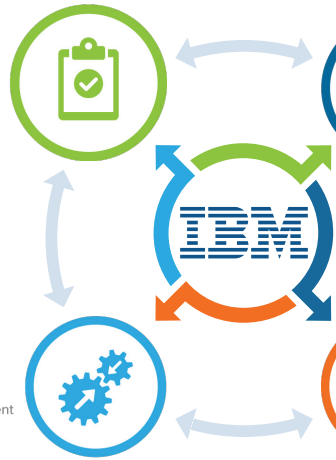
9 OF THE TOP **10** MEDICAL DEVICE MANUFACTURERS USE RATIONAL

IBM Engineering for Medical Devices include workflows deployable in Rational Team Concert and a DOORS project template for medical devices, which contains pre-defined DOORS modules that users can instantiate to deploy DOORS more quickly in projects required to comply with FDA QSR and IEC 62304.




REUSE OF REQUIREMENTS AND TESTS


DEVELOPMENT LIFECYCLE TRACEABILITY


MODELING AND SIMULATION


AUTOMATION OF COMPLIANCE AND DOCUMENTATION


TRADITIONAL & AGILE PRACTICES & METHODS

INDUSTRY LEADERS ARE AMONG OUR **3000+** CLIENTS FOR IBM **ENGINEERING LIFECYCLE MANAGEMENT SOLUTIONS**

IMPROVE YOUR MEDICAL DEVICES

- As devices become more complex and connected, IBM helps you to develop on time, to budget and safely every time
- As regulations increase complexity and add more risks on project timeline, IBM helps you to comply with regulations like IEC 62304, FDA Design Controls (21 CFR P. 820.30), FDA electronic records & signatures (21 CFR P. 11).
- As new business models emerge from acquisitions and merges, or from new technology trends like IoT, blockchain, 3D-Printing etc, IBM helps you implement innovative ideas, new functionalities integrally via managing changes and digital transformations into your products and services.
- As patient centricity drives customizations, and eventually evolves into variations and versions of products, IBM helps you effectively manage versions and variants in your projects. ... Just like we support many other companies from other complex industries

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DRASTICALLY REMOVE THE BURDEN OF COMPLIANCE

- 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

KEY STAGES IN SOFTWARE DEVELOPMENT PROCESS

Each of the following key process stages 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.

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.

IBM

ENGINEERING FOR MEDICAL DEVICES

Execute best practices and collaborate through an integrated product lifecycle solution