



**Rational** software

## **Requirements engineering for the medical device manufacturing industry.**

*Improving development processes using IBM Rational  
DOORS software*

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**Requirements engineering and its role in the medical device manufacturing industry**

Even the most renowned surgeon cannot perform a lifesaving operation without a skilled medical team to assist him or her. Collaboration and communication are vitally important to a successful operation and to patient safety. Nurses ensure that the surgeon has the correct instruments at hand, while the anesthesiologist monitors the patient's vital signs. And the entire team is ready to respond immediately to unexpected changes in the patient's condition. The operating room team must also keep lines of communication open with others located throughout the hospital—specialists, pathologists, lab professionals, blood bank personnel and others—who must coordinate services seamlessly in order to deliver accurate, safe care.

Likewise, successful development of high-tech medical devices depends greatly on the collaboration of the many individuals and teams involved in the engineering process. Requirements engineering is a critical process that helps companies manage complex requirements, improve team collaboration and ultimately produce high-quality products more cost-effectively.

This white paper explores requirements engineering and its important role in product development and engineering in the medical device manufacturing segment. It discusses the best practices and benefits of requirements engineering and how they can be achieved through solutions from IBM. The paper also details how requirements engineering can help manufacturers of embedded systems for the medical device industry overcome today's quality, cost, time-to-market and regulatory challenges. A case study illustrates how a leading medical device manufacturer has improved communication and collaboration through the requirements engineering process using IBM Rational® DOORS® requirements management software, resulting in increased productivity, time and cost savings; improved processes for regulatory compliance; and a higher-quality end product.

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Highlights

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***The medical device industry is facing unique marketplace changes that demand greater agility and a more strategic approach to mature and emerging marketplaces.***

**Meeting challenges in the medical device manufacturing industry**

Like other embedded systems developers, medical device manufacturers must manage complex systems, be first to market with new products, adopt globally distributed development and produce high-quality and reliable products. But the medical device industry is facing additional, unique marketplace changes that demand greater agility and a more strategic approach to mature and emerging marketplaces, both domestic and global. These changes center on increasingly strict regulatory standards for quality and patient safety mandated by national and regional agencies, which include the U.S. Food and Drug Administration (FDA), the U.K. Medicines and Healthcare products Regulatory Agency (MHRA), the European Union Medical Devices Directives, and the Pharmaceuticals and Medical Devices Agency (PDMA) in Japan.

Quality and safety standards in embedded software development — and the importance of developers getting it right the first time — are critical. As a result, medical device manufacturers are seeking systems development solutions to help meet the following specific challenges.

**Ensuring quality and safety**

High-quality design and performance to ensure patient safety are critical to the success of medical device systems. If a pacemaker fails, if a laser surgical tool misses its mark or if an automated external defibrillator malfunctions, lives can be lost or irreparably damaged.

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**Highlights**

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***High-quality design and performance to ensure patient safety are critical to the success of medical device systems, which can sometimes literally mean the difference between life and death.***

***Ensuring correctness and legibility of recorded manufacturing and control documentation is a key mandate of the globally recognized Good Manufacturing Practices.***

Medical device manufacturers are liable for quality and can lose money even before the product goes to market. If documentation for a device is not ready or is inadequate when the device is released, regulatory bodies can perform audits and charge heavy fines. In general, medical device companies often face higher-than-average legal exposure to patient lawsuits, patient infringement claims and product recalls.

Therefore, manufacturers must have reliable processes to validate and verify all the tools in the manufacturing process and the tools that manage that process. Also, they must have a robust requirements management system in place to accurately trace requirements and changes throughout the entire lifecycle. When lives are at stake and regulatory agencies threaten heavy fines, spreadsheets and documents for requirements and change management are not enough to ensure quality device builds.

Meeting global regulatory standards

Aging populations in the world's industrialized countries have fueled an exceptionally strong global demand for medical devices. This marketplace growth is tempered with customer demand for higher-quality, but less expensive, devices. While meeting these quality and cost challenges, medical device manufacturers must be vigilant in meeting the various regulatory standards for quality, safety and documentation from domestic and global agencies. Organizations worldwide recognize Good Manufacturing Practices (GMP) as the standard for controlling and managing the manufacturing and quality-control testing of medical devices, foods and pharmaceutical products. Ensuring correctness and legibility of recorded manufacturing and control documentation is a key mandate of GMP, embodied within country-specific regulations and enforced by local regulatory bodies.

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### Highlights

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***Medical device verification and validation are crucial to passing audits and avoiding costly recalls.***

Developing new products at a fast pace

In the medical device manufacturing industry, innovation drives success, and keeping a fast pace for new-product development is critical. Moreover, being first to market is a key strategic goal.

Yet gaining the FDA's and other regulatory bodies' approval is a lengthy process, and the process can drag on even longer if prerelease audits show that the manufacturer does not have proper documentation or if defects are found and the product must be recalled. So, once again, verification and validation are crucial to passing audits and avoiding costly recalls. Effective communication, accurate record keeping and requirements traceability are all critical to attaining a fast time to market.

Other pressing requirements and issues affecting the medical device manufacturing process include:

- ***Change control.*** *It's critical to keep track of the people who make changes, the date and time when they make changes, the reasons they make changes and the impact of their changes.*
- ***Traceability and risk analysis.*** *Multiple levels of traceability and risk analysis are required because the embedded systems in these products are so complex.*
- ***Qualification of requirements.*** *Manufacturers must determine which requirements are must-haves, want-to-haves, nice-to-haves, etc.*
- ***21 CFR Part 11 compliance.*** *To address compliance with this mandate, electronic signature and document management capabilities must be in place.*
- ***Audits.*** *Manufacturers must be prepared for audits conducted by the FDA and other global regulatory bodies.*

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Highlights

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***Requirements engineering – in terms of systems engineering – defines, manages and carefully tests requirements for a system.***

***Requirements management simplifies and enhances communication and collaboration between teams and stakeholders, resulting in better requirements management throughout the organization.***

### **Defining requirements engineering**

Requirements engineering—in terms of systems engineering—defines, manages and carefully tests requirements for a system. It does so in three stages: needs analysis, requirements analysis and requirements specifications.

Though this definition of requirements engineering is more than a decade old, a standard process has only recently evolved with the availability of integrated suites of automated lifecycle development tools featuring requirements management solutions. In basic terms, requirements engineering helps product development organizations understand—in two stages—what they intend to build. The first stage is up-front requirements definition. The second is requirements management, which provides clear visibility throughout the product lifecycle.

Requirements definition consists of four parts: discovery, analysis, specification and verification. Requirements management simplifies and enhances communication and collaboration between teams and stakeholders, resulting in better requirements management throughout the organization. This stage enables engineers to:

- *Evaluate the effect of proposed changes.*
- *Trace individual requirements to downstream work products.*
- *Track requirements status during development.*

As a result, organizations can monitor project status by knowing what percentage of the allocated requirements have been either:

- *Implemented and verified.*
- *Just implemented.*
- *Not yet fully implemented.*

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**Highlights**

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The requirements definition and requirements management stages make up a dynamic process that flows from ideas, requirements and feature definitions; to product and system specifications and models; to mechanical, electrical/ electronic and embedded software implementations; to testing and maintenance. All the while, requirements connect the global engineering teams — systems, software, electrical/electronic and mechanical — and keep them more keenly focused on common objectives. Furthermore, requirements provide a vital connection between the engineering teams and other peripheral stakeholders, including suppliers, customers and internal legal and quality assurance (QA) teams.

Using a requirements engineering framework and supporting tools for requirements management and traceability, engineers can thoughtfully tailor development practices to suit the project type, constraints and organizational culture.

**Requirements engineering for the medical device manufacturing industry**

The sophisticated embedded systems and components in a medical device have many interlinked, interdependent parts. Developers must understand how all of the different parts work together. To do so, they must be able to understand and visualize all of the connections — even those that are invisible. Otherwise, the end result will be a marketplace failure: a product unexpected by the customer — or worse — a device that does not meet regulatory or patient safety requirements. Manufacturers risk incurring stiff fines, while medical professionals using poorly performing devices risk the lives of their patients. So it's critical that engineering teams work as a cohesive unit to capture customer and regulatory requirements and to manage changes with strict accuracy and traceability. Rational DOORS software can help address these and other challenges common to the medical device manufacturing industry.

***Rational DOORS software can help engineering teams work as a cohesive unit to capture customer and regulatory requirements and to manage changes with strict accuracy and traceability.***

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Highlights

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***Rational DOORS gives engineering teams greater control over the management and analysis of the many critically interdependent requirements for medical devices***

***Using Rational DOORS as the foundation of their requirements engineering approach, companies can test each requirement to validate the performance of their medical devices.***

Manage the complexity of developing highly regulated devices  
Requirements engineering for developing embedded systems using Rational DOORS can help manage complexity by helping teams:

- *Deconstruct initial user requirements to detailed requirements.*
- *Link requirements and design to check whether requirements are satisfied by the design.*
- *Trace dependencies between requirements and changes.*
- *Analyze the impact of requirements changes.*

As a result, with Rational DOORS, engineering teams can have greater control over the management and analysis of the many critically interdependent requirements for medical devices, including embedded systems as well as software and nonsoftware components. By using this automated requirements management tool as the cornerstone of the requirements engineering environment, engineers can reduce development time and increase productivity through standardized processes. And using the traceability functionality of Rational DOORS, they can trace a large volume of features back to the requirements to help ensure the quality and safety of the device and to prepare themselves with accurate documentation for regulatory audits and reviews.

Build higher-quality devices

Quality is critical to the performance and safety of medical devices. Using Rational DOORS as the foundation of their requirements engineering approach, companies can test each requirement to validate its performance. Teams can also integrate requirements and validate them against developed models, enabling systems engineers to provide high-quality, high-performance, innovative products that truly meet the customer's needs and that address strict government regulations and safety standards.



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## Highlights

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***By managing requirements in Rational DOORS, medical device manufacturers can create accurate and comprehensive documentation to demonstrate a clear audit trail.***

***A requirements management tool such as Rational DOORS can help teams align design and product development with rapidly changing customer requirements.***

In addition, Rational DOORS—when integrated with model-driven development and test management and execution tools—can support the highly important validation process for quality assurance. This includes testing to validate requirements, regression testing for completeness on major functionality changes and testing to ensure that regulatory standards have been met.

Improve speed to market

Good manufacturing practices coupled with efficient, automated lifecycle-development technologies can help manufacturers overcome competitive hurdles to achieve faster time to market. An important first step is to better prepare for product and documentation audits with accurate, easily accessible requirements and change data.

By managing requirements in Rational DOORS, medical device manufacturers can create accurate and comprehensive documentation to demonstrate a clear audit trail. For example, Rational DOORS has an electronic signature capability built in—specifically for industries like medical device manufacturing that must comply with federal and industry regulations.

Moreover, the traceability in Rational DOORS helps teams isolate potential production issues to the batch or serial level—versus a much wider product or regional level. If audits reveal any discrepancies, or if a device is recalled, teams can resolve the problem with greater speed and accuracy.

Improve collaboration with teams and partners

On the manufacturing side, using a requirements management tool such as Rational DOORS can help teams align design and product development with rapidly changing customer requirements. It can also help increase product quality and reduce time to market and cost. Rational DOORS helps teams capture the requirements of customers and technology partners quickly, reliably and in a collaborative environment.

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### Highlights

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***Using Rational DOORS, distributed teams can work together to address compliance with regulations, helping the organization avoid steep fines and costly product recalls.***

***To replace a paper-intensive manual process, a healthcare leader implemented Rational DOORS for its robust requirements traceability capabilities and its ability to perform detailed risk analysis.***

In addition, because requirements are contained in the Rational DOORS central repository, geographically dispersed teams can share information, collaborate, and track changes more easily and efficiently. As a result, teams can better ensure that specifications are accurate at the beginning of the project because they are gathering information and working from the same—and the correct—documents.

Perhaps most important, using Rational DOORS helps ensure that distributed teams are working together to address compliance with regulations, thus helping the organization avoid steep fines and costly product recalls. By documenting requirements activity in Rational DOORS and using its electronic signature feature, manufacturers can more confidently address global regulatory requirements for legible and comprehensive documentation.

#### **Rational DOORS: a success story in the medical device manufacturing industry**

Many medical device manufacturers and their business partners have adopted requirements engineering—supported by IBM solutions—to successfully and cost-effectively increase team productivity and generate quality. Using Rational DOORS, manufacturers can manage and analyze large volumes of requirements in complex projects and satisfy changing customer demands and strict government regulations. Rational DOORS helps organizations improve requirements visibility throughout the engineering lifecycle, and the software's traceability capabilities help teams ensure that critical features are not missed.

A worldwide leader in the healthcare industry needed to develop and validate computer systems with exact requirements. These systems had to conform to a rigorous manufacturing process and comply with strict regulatory standards. To replace a paper-intensive manual process, the company implemented Rational DOORS, relying on its robust requirements traceability capabilities and its ability to perform detailed risk analysis.

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## Highlights

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***A requirements engineering approach can help product development organizations work in harmony as they communicate and collaborate through standardized processes for requirements management.***

***Requirements engineering can help medical device manufacturers ensure patient safety and avoid costly fines, recalls and rework.***

With Rational DOORS, the company's system quality department can more accurately generate design specifications and testing documentation to bridge the gap between user requirements and user testing. Iterative development checks show what has been done before and by whom. The team can also use Rational DOORS to perform critical risk analysis more efficiently and effectively. For example, DOORS can be used to build a risk assessment module as part of an existing project or system to be validated, helping the team to predict the impact that further development will have before committing time, effort and resources.

### **Conclusion**

Efficient and cost-effective product development is the key to success in today's global development environment. A requirements engineering approach can help product development organizations work in harmony as they communicate and collaborate through standardized processes for requirements management.

When manufacturing medical devices, requirements engineering is not optional. Linking requirements in an automated requirements management tool throughout the development lifecycle of medical devices is critical to product quality, reliability and safety. Traceability of requirements, plus automated validation and verification processes, also helps medical device manufacturers avoid the risk of product recalls and costly fines.

Better management of requirements complexity is the foundation of requirements engineering. Driving cost savings and on-schedule product development, requirements traceability can help a company keep track of stakeholder requirements as they evolve over the development lifecycle. Engineering teams can discover discrepancies and missed requirements far earlier in the development lifecycle, thus reducing rework costs and decreasing the risk of losing profits on products that don't meet customer needs.



Moreover, requirements engineering helps organizations achieve enhanced collaboration among globally distributed teams and suppliers. As a result, virtually all stakeholders can be involved in the requirements management process and be confident that everything they do is aimed at fulfilling customer requirements.

By embracing the requirements engineering best practices of managing complexity, requirements traceability and enhanced collaboration, medical device manufacturers can achieve time and cost savings, build higher-quality products, improve customer satisfaction, ease regulatory compliance processes and ultimately gain a greater competitive advantage.

#### **For more information**

To learn more about IBM Rational DOORS software, contact your IBM representative or IBM Business Partner, or visit:

[ibm.com/software/rational](http://ibm.com/software/rational)

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