

# Managing regulatory compliance in medical device development with IBM Engineering solutions



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# Executive summary

Today's healthcare, life sciences and medical device industries are faced with unpredictable market change, global competition, and constantly evolving regulatory mandates and guidelines. To remain viable and competitive, corporations must balance rapid innovation with compliance mandates that dictate safety and effectiveness. The necessity to innovate and evolve the business in order to leverage new technologies such as biologics, advanced drug treatments or software-enabled medical devices while maintaining compliance requires organizations to undergo significant business process and development life cycle transformations. Many in the industry have expressed concern that the processes dictated by the broad and evolving governmental regulations and guidelines (such as FDA, GMP, EU MDR, IVDR etc.) negatively impact time-to-market and increase development time.

The United States Food and Drug Administration (FDA) regulates over \$1 trillion in products including, but not limited to:

- Pharmaceuticals for human and animal use.
- Biological and related products including vaccines, and biological therapeutics.
- Medical devices.
- Radiation emitting devices.

The FDA monitors the production, import, transport, storage and sale of these products in the United States. Compliance with FDA regulations is a market requirement. Failure to comply can be very costly, not only due to expensive violations or recalls, but also due to criminal penalties and loss of market share for those who don't comply with regulations.

European regulations that became effective in May 2017 across the European Union countries increased regulation to include active implantable medical devices and in vitro diagnostic medical devices. The new EU Medical Device Regulations (MDR) and In Vitro Diagnostic Medical Device Regulations (IVDR) are changing the EU market since they affect not only new products but existing ones as well. The conformity assessment for CE marking has proven more time consuming given these new and stricter regulations, compounded by fewer notified bodies around supporting these new regulations. Solving the quality and speed dilemma unquestionably becomes a very critical factor.

Achieving development life cycle efficiencies and injecting more agile development practices while maintaining compliance to regulations such as those dictated by the FDA or any regulatory body is often reported as a foremost concern. It is our view that given high-quality development and design control processes and sufficient tools to support and automate these processes, time to market can actually be *decreased*, while resulting in higher quality, and higher reliability products and services. This document gives a brief overview of the current challenges that the healthcare industry faces and discusses how IBM® Engineering solutions can help address these challenges.

The IBM Engineering solutions for systems and software engineering can assist with reaching compliance goals through integration, collaboration, automation and reporting. The solutions support the



creation and management of life-cycle work products necessary to fulfill FDA and / or EU regulations and guidelines. The solutions provide a core set of best-in-class tools and processes for systems and software engineering teams, facilitating engineering collaboration with unprecedented high level of transparency of project progress, control of artifacts, traceability with audit trails, task management and change control.

Lastly, the IBM Engineering solutions address the FDA identified *lack of design controls as one of the major causes of device recalls* by:

- Maintaining design control specifications in a central, automated repository
- Providing design control specifications using customizable document templates
- Facilitating the design control process models, attributes and reports
- Maintaining up-to-date traceability matrices
- Facilitating change impact analysis and capturing design history
- Managing compliance

## Smarter healthcare

Today's healthcare field is quickly evolving and increasingly becoming more networked and interconnected. Whether you are developing a cutting-edge medical device, researching new drug therapies or providing healthcare services, the common thread is an increasing

reliance on interconnected information, networks, products, and complex systems.

To meet innovation goals and bring new products to market faster, companies must focus on optimizing the development processes supporting and automating these efforts. As today's healthcare providers, payers and consumers move towards electronic records management and smarter healthcare, this will mean that medical devices used to implement our care must not only communicate data to doctors, nurses and clinicians but may also transmit data for more accurate billing and more comprehensive patient data management. Medical devices are becoming more sophisticated and complex with the greater ability to give real-time statistics to clinicians in order to make better diagnosis and care decisions. Many devices today record and transmit patient and device data back to physicians and device manufacturers to aid in patient care, and to help influence development of new products and features in order to repurpose or modernize existing product lines. Devices are becoming more and more customized and offer variances that meet hospital, emergency response and field needs. Data is being continually analyzed to make diagnosis early and to predict outcomes.

Healthcare reform will potentially impel tens of millions of citizens who do not currently have healthcare insurance into the healthcare network, driving demand for access to treatments such as drugs, biologics and increasing medical device usage. The push towards electronic medical records and mandates such as the Health Insurance Portability and

Accountability Act (HIPAA) and massive changes in electronic data interchange and International Classification of Diseases (ICD) codes will drive modernization of core healthcare applications and systems. The cost of reform and compliance will drive technology investments to modernize legacy systems and to develop new business models.

What is the common driver to delivering smarter healthcare such as sophisticated devices, drugs and biologics or modern health maintenance networks? Software. Software is increasingly becoming the key factor for injecting new features, functions, and providing protocols for networking and building system user interfaces. All these software-driven capabilities lead to what we call smarter healthcare—such as modern portal-based payer/provider/consumer networks, complex information data management systems, intelligent medical devices, and pioneering drug and biologics research and development. Software is the key to competitive advantage.

Today the healthcare industry is also investigating artificial intelligence (AI) - pharmaceutical companies aim to use this technology in drug discovery, medical device companies are exploring how to deliver better and faster diagnostics through AI machine learning to optimize treatment.

All innovations have a validity, provided they comply with regulations and adhere to safety, security and reliability standards. In 2017 and 2018 a total of 137 device recalls were issued by FDA for Class III devices alone.

In the next few sections we will look at some of the regulatory and compliance demands on the healthcare industry and look at the corresponding challenges created by compliance driven development within the medical device, healthcare payers, healthcare service providers and life sciences industries and explore how IBM Engineering solutions help address these challenges.

## Medical device and life sciences industry challenges

Medical device manufacturers must manage complex system requirements and provide quality development processes to manage portfolios of products. Medical device developers must base product strategies on real data, classify risks and ensure proper mitigation of hazards while controlling software and systems development life cycles to ensure quality through rigorous testing. Ongoing studies of effective product development point to significant failure rates—failure to deliver on time with the right features and functionality. Success depends on the ability to deliver faster, increase productivity and ensure high quality while reducing costs in the development cycle. All of these challenges are compounded by the need to ensure adherence to regulations and mandates.

Listed below are just a few of the challenges medical device developers face along with some of the key factors that they must control to remain competitive and successful:

- **Corporate strategy and planning:** Percentage of sales due to new products or new systems released, return on market investment, strategic planning operating budget per revenue, return on total assets. The introduction of new EU MDR, IVDR in May, 2017.
- **Product/Platform strategy:** Number of products per platform, amount of software per platform, cost for each new product or system, cost of modernization. With the new EU MDR, a product and platform strategy is required. This may cause some product portfolios to divest since cost of compliance will increase dramatically.
- **Functional innovation:** Improving time to market, increasing market share, achieving price premiums and return on investment for development.
- **Prototype development and testing:** Time from development to maturity, new product or system success rate, cost per engineering change, time and cost for conceptual mockups.
- **Risk and hazard mitigation:** Meet mandates for classification and management of risks and hazards (Failure Modes and Effects Analysis [FMEA], Fault Tree Analysis [FTA]).
- **Legal and regulatory compliance:** FDA, number of notices of violations from regulatory agencies, dollar value of potential legal liabilities, patents, corrective and preventive actions (CAPA)

Life sciences companies face the need for increased operational efficiency and cost containment as payers worldwide actively push-back on new and existing health care pricing. New innovations are always necessary to retain market share: discovery research is an important area with considerably growing risk, compliance and change control requirements. There is a need for a reliable infrastructure for reducing the possibility and impact of clinical data security and compliance vulnerabilities. Increasingly, scientists who are testing new discoveries are using outdated and inefficient tools and techniques at the same time that research and development has become more expensive. The result is a slow and costly process. Drug manufacturers must support collaborative environments, automate the change control process and more effectively capture and communicate data to encourage quicker development.

Listed below are just a few of the challenges life sciences companies face along with some of the key factors that they must control to remain competitive and successful:

- **Product portfolio management:** Make the right R&D investments, return on investment, strategic product planning, percentage of sales due to new products, impact of generics and competition on product lines.
- **Security:** Ensure security of data and reliable management of the infrastructure; reduce the possibility and impact of security vulnerabilities.



- **New scientific initiatives:** Targeted treatments and tailored medicine challenge traditional push-oriented development model.
- **Operational excellence:** Maintain requirements for manufacturing execution process, meet product, regulatory and productivity requirements.
- **Legal and regulatory compliance:** CGMP, GAMP (Current Good Automated Manufacturing Practice).
- **Verification and validation (V&V):** Validate tools and processes used in development and manufacturing of products, verify processes.
- **Change control:** Manage change, impact analysis of change during development or manufacturing processes.
- **Cost pressures:** Control costs of infrastructure for commercial and clinical development.

## Regulations impacting the medical device industry

The medical device industry is faced with ever increasing regulation and oversight of the design control process due to increased focus on device recalls and unintended consequences of improper use. In the FDA's own words, "Since 1984, FDA has identified lack of design controls as one of the major causes of device recalls. The intrinsic quality of devices, including their safety and effectiveness is established during the design phase"

In response to device safety concerns the FDA created the Quality Systems Regulations (QSR CFR 21 part 820) to ensure that products meet requirements and specifications and that current good manufacturing practices are followed in the development of devices.

Some of the key parts of the QSR that are of concern to device development organizations are:

- Strict design control measures.
- Use of tools to improve the development process.
- Separate definition and traceability of user requirements to design input.
- Separation of validation (user and patient needs are met) from verification procedures and record keeping (specified requirements are met).
- Software validation requirements that apply to software used as components in medical devices, to software that is itself a medical device, and to software used in production of the device or in implementation of the device manufacturer's quality system.

Most regulations and standards provide a framework but leaves it up to device developers to implement quality development procedures. It is the responsibility of manufacturers to establish requirements for each type or family of devices that will result in products that are safe and effective, and to establish methods and procedures to design, produce, and distribute devices that meet the quality system requirements. Lack of design controls is one of the major reasons for device recalls and

violation notices resulting from audits. Adherence to a development process that defines requirements, identifies risk, manages change and facilitates and supports simulation and test well before implementation lowers development risk and costs and reduces time to market. Product expenditure skyrockets when deficiencies are discovered late in the development life cycle. Following a design control process that is repeatable, scalable, and automated can provide better project visibility and predictability, lowering overall costs, reducing product development time, and helps to navigate regulatory acceptance into the market.

Moreover, the new EU MDR requires an enterprise-wide approach with a multi-disciplinary and cross-functional governance program.

The new EU MDR affects certain key areas in the product development and manufacturing. For instance, the manufacturers are required to monitor the safety profile of the product, not only involving safety, security and reliability assessment in product development, but also through implementation of a post-market surveillance plan. The controls around transparency and traceability within the whole supply chain will be strengthened. Establishing, implementing, documenting and maintaining a Quality Management System (QMS) is another mandate to device manufacturers. It is not yet a requirement but a recommendation to follow ISO 13485 as an internationally harmonized standard for designing a QMS for medical device development. The regulation (MDR, IVDR), when compared with the older version (MDD, IVDD), requires increased controls over supplier and outsourcing activities and a risk-based approach to QMS activities as well as implementation of risk management process throughout the product lifecycle. In addition to having a post-market surveillance plan to monitor the safety profile, strengthened supply chain controls, and QMS overhaul, medical device manufacturers are also required to understand the new clinical evaluation process and clinical evidence requirements. The new EU MDR and IVDR will have an impact on the development process of new products due to these new clinical requirements. Moreover, current products on the market will also be affected. Because the certification process of the current products will not be exempt by the new clinical evidence requirements.

All these facts aside, developers often view compliance to the design control standards from FDA, QMS activities, documentation needs, risk mitigation plans, etc. as overhead, interfering with their design work. The regulatory and quality populace is ultimately responsible for design control compliance, but they depend on hardware, software and mechanical designers and developers to do the actual work. Developers often respond to the regulatory professionals with “What do you want, a product or documentation?” However, medical device manufacturers require confirmation that user needs are met by design inputs and that the design elements that are essential to the proper functioning of the device are identified, recorded, and tracked, in order to survive inspections and bring safe products to market. Companies must also establish reasonable design control processes and ensure that risk analysis is performed, changes to requirements and development artifacts are controlled and design history files are maintained. Management and proper tracing of requirements from the original design and development phase through the verification and

validation phase along with an accompanying risk management plan is crucial to remaining viable in the medical device market.

A significant change that has been introduced by the new EU MDR is the clinical evaluation as an application of the Verification and Validation processes. The scope of the QMS, mentioned above, includes clinical evaluation and post-marketing clinical follow up. Clinical Evaluation Reports (CER) will also be a critical compliance element as the deliverable of clinical evaluation. However, there is still some lack of clarity in the exact requirements of clinical evaluation process and CER – and their best practices. It becomes much more crucial for a medical device manufacturer to provide traceability between product requirements at the intended use environment, original design and verification and validation procedures both for analytical and clinical validation.

Automation of the capture, recording and traceability between these items not only cuts the time spent focused on regulatory compliance but can speed development time. It will help the medical device manufacturers to deal with the difficulties and challenges introduced via the clinical evaluation requirements. Adherence to a process that identifies requirements before implementation and then controls and manages requirements and requirement change throughout the design process is more efficient and requires fewer design iterations. When the requirements are identified, progress metrics and projection of completion dates are more objective and quantitative. Even when new requirements are identified mid-design or mid-implementation, the impact on the overall schedule is more quantitatively predictable when the requirements are properly captured and dependencies between requirements are maintained. Clients are often skeptical that following such a process can reduce time to market, but in addition to the efficiencies noted above, a good design control process followed by change and design reviews supported by change management allows problems to be identified earlier in the process while they are smaller, simpler, faster, and cheaper to fix.

Speeding the development time, is becoming a critical factor with the introduction of new EU MDR and IVDR. These new standards have exposed a shortage of certification bodies (could be as much as 50%) which will introduce a serious bottleneck in the certification process. Companies trying to achieve a time to market advantage will need to improve their internal development processes to offset potential delays in the certification process.

## How IBM Engineering solutions can help

IBM Engineering can help with implementing an effective design control process and a standard quality system process supported by best-in-class tooling to allow an organization to develop a corporate standard process which will provide efficiencies of scale. Developers can know what to expect and can easily develop compliant solutions incorporated with design control processes in line with FDA, satisfy QMS requirements imposed by FDA Quality Systems Regulations

# IBM ELM Solution

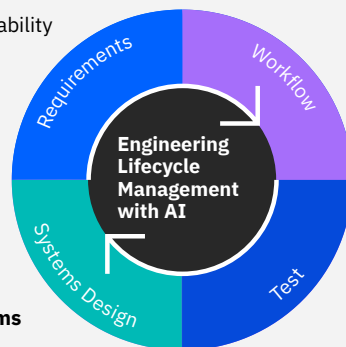
End-to-end product and software development management solution

## IBM Engineering Requirements DOORS Next

Manage all system requirements with traceability across the life cycle

## IBM Engineering Workflow Management

Collaborate across diverse engineering disciplines and development teams



## IBM Engineering Systems Design Rhapsody

Use modeling to validate requirements architecture and design throughout the development process

## IBM Engineering Test Management

Achieve “quality by design” with integrated, automated testing process

Collaborate

Automate

Improve

Best-in-class capabilities, integrated on a common platform

**Figure 1:** IBM Engineering solution to help manage regulatory compliance

or by the new EU MDR and satisfy Good Manufacturing Practice (GMP) guidelines. The IBM Engineering solutions for systems and software engineering supports collaborative tasks and linking of the life-cycle work products. Compliance can be made simpler with automated capture of design history, life cycle traceability and quality management processes required to manage compliance to regulations.

The solution offers, integrated, end-to-end traceability and fault and failure analysis that can improve processes, automate document generation, manage compliance to regulatory standards like IEC 62304, IEC 61508, 21 CFR 820.30, 21 CFR 11, ISO 13485 and ISO 14971.

Demonstrating compliance means control and documentation of the typical development tasks such as requirements gathering, analysis, system design, detailed design, verification and validation, risk analysis, project management and reporting.

The IBM Engineering software and systems delivery solutions offer visibility, control and automation. It is an open, proven, complete and modular solution comprising a comprehensive set of tools and best practices. IBM Engineering solutions offer all the tools that teams need to successfully define requirements, model, build, test, and deploy products.

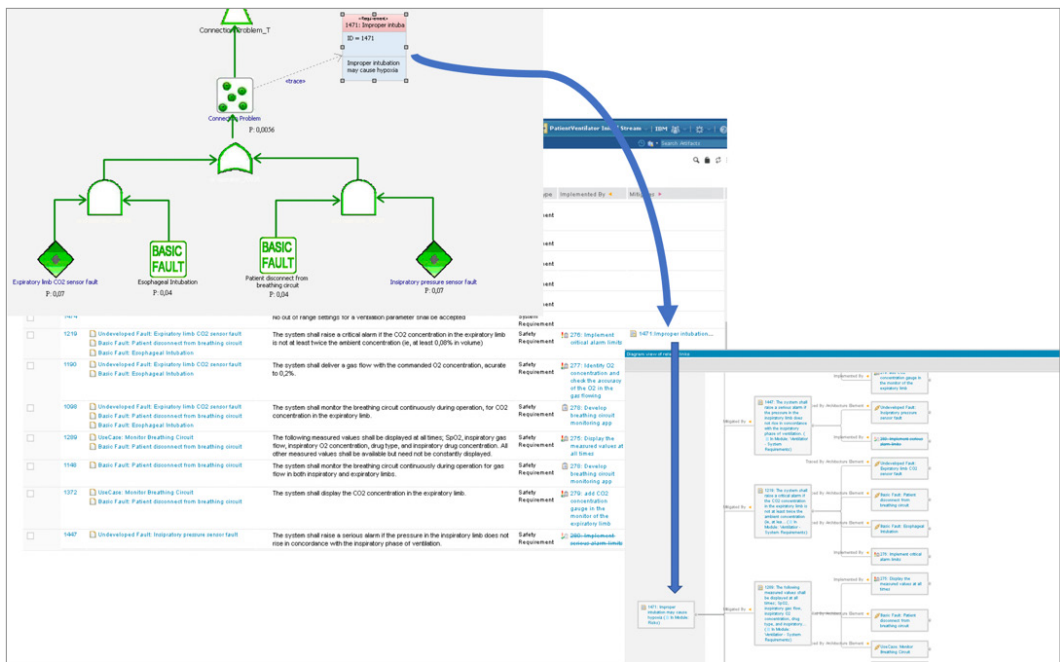
Without integrations across the systems delivery life cycle, systems and software teams are left to operate in silos. When silos form, product delivery effectiveness suffers. In order to deliver smarter products that respond to changing market needs, it is necessary to allow systems and software engineering teams to perform efficiently and to collaboratively manage all the life-cycle work products. The IBM Engineering solutions

for systems and software engineering provide complete life-cycle management—an integrated and collaborative environment for requirements analysis; architecture management; and work, change and configuration management for teams of systems engineers. The IBM Engineering solutions include:

- IBM Engineering Requirements Management DOORS® software for requirements management, traceability, and impact analysis capabilities
- IBM Engineering Systems Design Rhapsody® software for systems architecture, design and modeling
- IBM Engineering Test Management software for life cycle quality management from requirements, to build, to test cases and defects
- IBM Engineering Workflow Management software for integrated version control, automated work flows, and build capabilities enabling real-time visibility and complete project collaboration.

## Requirements management and definition

Solutions that help to define and manage requirements to reduce rework, demonstrate compliance, and minimize costs and risks. IBM Engineering solutions can help address concerns related to product innovation such as improving time to market and achieving return on investments. Through requirements traceability, development teams can trace requirements to (and from) system requirements to test and risk analysis results facilitating more accurate business analysis and



**Figure 2:** Demonstrate compliance by ensuring full traceability of requirements, design elements, risks, risk mitigation/contingency actions and verification and validation procedures using IBM Engineering Requirements Management DOORS, Systems Design Rhapsody, Engineering Workflow and Test Management

demonstration of compliance. In a recent industry study, organizations surveyed incurred a cost of as much as 60 percent on time and budget when they used poor requirements practices. Organizations with poor business analysis capabilities had three times as many project failures as successes.<sup>2</sup> When requirements are defined and managed properly, project overruns can be significantly reduced by lowering the number of inaccurate, incomplete, and omitted requirements.

IBM Engineering Requirements Management DOORS software is a leading requirements management solution that can help reduce costs, increase efficiency and improve quality by managing requirements collection, control, communication, collaboration and verification. The use of its integrated requirements design environment can help manage traceability of your compliance and regulatory needs throughout the design and implementation life cycle.

IBM Engineering DOORS software design control templates built against FDA design control inspectional techniques can jumpstart projects subject to FDA regulations. Engineering DOORS software attributes can be used to properly classify and manage risks and hazards as required by the FDA. Engineering DOORS software maintains requirement and specification records of the design process which can demonstrate how your design and development plans are met by verification and validation plans and how risks can be mitigated.

Using Engineering DOORS software, traceability reports and matrices can be produced in a fraction of the time that it would take to produce them manually. Most importantly, Engineering DOORS software maintains a full audit trail on all changes: what was and what is, user

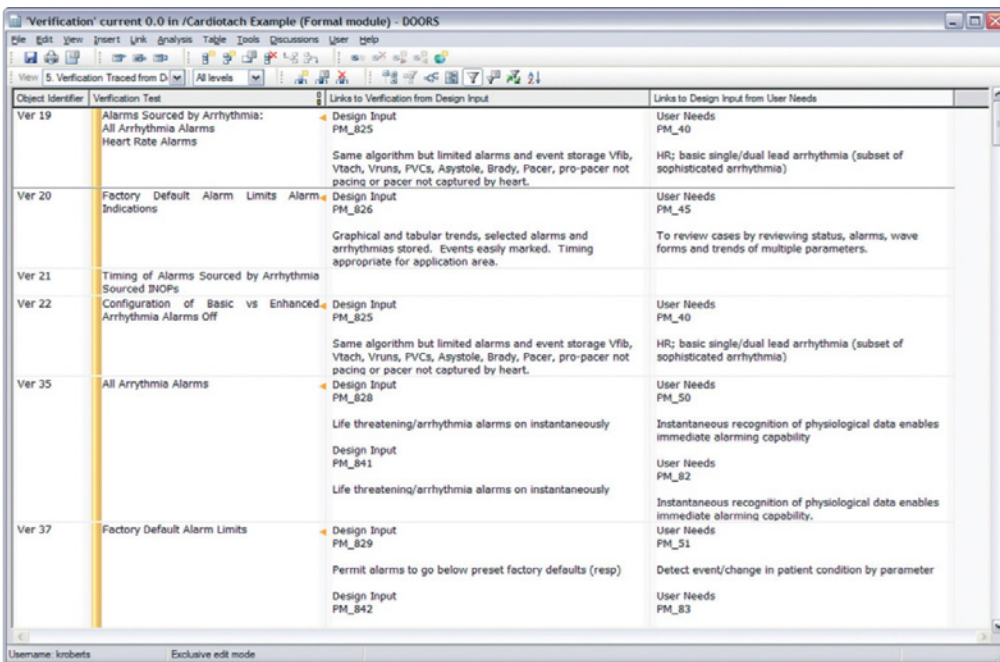
ID and date/time stamps of changes so that the design history file is created automatically as users go about their work of entering data and creating links. Electronic sign off is also available.

## Integrated collaboration, change and configuration management

Integrated change and configuration control, and automated work flows enabling real-time cross-team communication and collaboration for rapid response to change. The solution is integrated on the IBM Jazz™ platform which is suited to global and distributed teams. The Jazz platform can help transform systems and software delivery by making it more collaborative, productive, and transparent. IBM Engineering Workflow Management software is the collaborative engine of the solution, coordinating the system engineering tasks and workflows; all governed by a customizable team workflow process. Requirements from IBM Engineering DOORS software can be linked to work items in the IBM Engineering Workflow Management tool: this linkage helps developers or stakeholders review the requirements linked to a work item. The work item type may be a requirements change request, an implementation task, a defect, or other standard or custom work item type.

FDA regulation guidelines require identification of the major development tasks to be undertaken, deliverables for each task, and individual or organizational responsibilities (staff and resources) for completing each task. The IBM Engineering Workflow Management





**Figure 3:** Effective test management using IBM Engineering Test Management, integrates test planning and execution with requirements

tool integrates stakeholders, project leads, and systems engineers to facilitate compliance to FDA requirements for a quality design control process. It offers the collaborative task environment and automated change control process required by medical device developers and life sciences teams to manage FDA quality systems regulations and design control change management guidelines. Project dashboards in the IBM Engineering Workflow Management software can help further improve project tracking through transparency and reporting of team status and project health. Dashboards present live project and plan information in tabular or graphical form further facilitating the control over the development process while also providing flexibility and agility in team workflows. The team build component in IBM Engineering Workflow Management software implements a standardized and controlled build process and provides build awareness, control, and traceability to the software engineering team and the software test team. Teams can also expect improved configuration management to control product content as required by the FDA controls for design documentation and artifacts.

## Design and development

Solutions that help model, design, and build resilient architectures for today's most innovative products, systems, software and systems of systems. Architectural decisions and design activities are supported by IBM Engineering Systems Design Rhapsody software. IBM Rhapsody software offers capabilities for modeling system and software requirements, as well as developing and delivering

the software components. It provides an easy-to-use yet rigorous environment for the creation, management, and execution of both SysML and UML models.

IBM Rhapsody software is a visual development environment for systems engineers and software developers creating real-time or embedded systems and software. IBM Rhapsody software helps diverse teams collaborate to understand and elaborate requirements, and abstract complexity visually using industry standard languages. IBM Rhapsody software provides medical device engineers with a collaborative development environment with simulation for early requirements, architecture and behavioral validation, fostering better understanding of complex requirements and trade-off analysis of complex systems.

The intent of the FDA quality system requirements is that the product's conceptual description be elaborated, expanded, and transformed into a complete set of design input requirements which are written to an engineering level of detail. IBM Rhapsody software can facilitate meeting the intent of this regulation. FDA regulations require procedures for the formal review and documentation of the evolution of the design and identification of concerns and potential design issues. IBM Rhapsody software helps capture design evolution and its powerful simulation abilities support design reviews and help in the early identification and capture of potential design issues.

# Quality management

Solutions that help teams advance productivity and quality across the entire life cycle. IBM Engineering Test Management software provides a collaborative environment for test planning, construction, and execution, supporting continuous testing as well as test management of system validation and acceptance testing.

FDA regulations are very much focused on verification and validation (V&V). A defined and controlled process is required. V&V planning, reviews, methods and results all must be documented and linked to changes or corrective actions that result from testing. IBM Engineering Test Management software links test artifacts across the life cycle so that traceability to and from requirements, change requests, development tasks and development artifacts may all be traced. And IBM Engineering Test Management software also facilitates effective workflow control, tracking, and traceability features for test and verification. Using the Engineering Test Management software dashboards (Figure 3), testers can review the systems quality metrics and project status, which may include tasks assigned in Engineering Workflow Management software, requirements defined in Engineering DOORS software or software integration builds ready to be tested.

## Summary

The IBM Engineering solutions for systems and software engineering can assist with reaching compliance goals through integration, collaboration, automation and reporting. The solutions support the creation and management of life-cycle work products necessary to fulfill FDA or EU regulations and guidelines as well as safety and / or quality standards like IEC 62304, ISO 13485, ISO 14971. The solutions provide a core set of best-in-class tools and processes for

systems and software engineering teams, facilitating engineering collaboration with unprecedented high level of transparency of project progress, control of artifacts, traceability with audit trails, task management and change control.

The IBM Engineering solutions help address the FDA identified lack of design controls as one of the major causes of device recalls by:

- Maintaining design control specifications in a central, automated repository
- Providing design control specifications using customizable document templates
- Facilitating the design control process models, attributes and reports
- Maintaining up-to-date traceability matrices
- Facilitating change impact analysis and capturing design history
- Managing compliance.

## For more information

To learn more about the IBM Engineering solutions for the healthcare and life sciences industries, contact your IBM representative or IBM Business Partner, or visit: [https://www.ibm.com/internet-of-things/solutions/systems-engineering?lnk=hpmp\\_r\\_&lnk2=learn](https://www.ibm.com/internet-of-things/solutions/systems-engineering?lnk=hpmp_r_&lnk2=learn)

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