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Ingenuity for life

Mastering compliance for medical device solutions

Business best practices

Identifying risks and documenting mitigation is a daunting task for medical device manufacturers. Next-generation application lifecycle management solutions include test management tools that address the key challenges in developing and certifying medical devices for commercial use.

A white paper issued by: Siemens PLM Software

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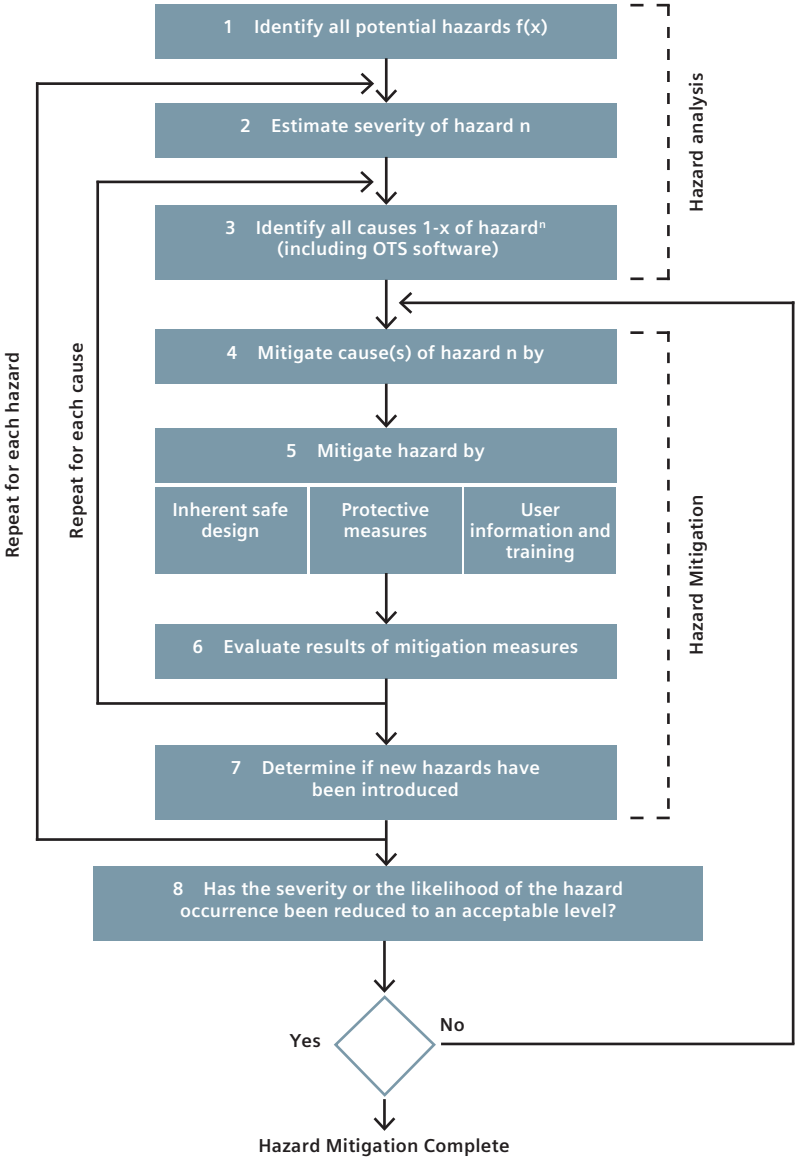
The challenge

A key milestone with any medical device organization is proving due diligence when identifying risks or what is commonly known as hazard analysis. These risks must be properly identified and the appropriate mitigation documented.

This requirement tends to generate a lot of documentation that is typically managed by multiple human resources. Software is commonly used to create the documentation, such as Microsoft® Word or Google Docs™ and spreadsheets for managing traceability between requirements (what has to be done to mitigate), test cases (how to verify the mitigation is met) and status (failed/passed).



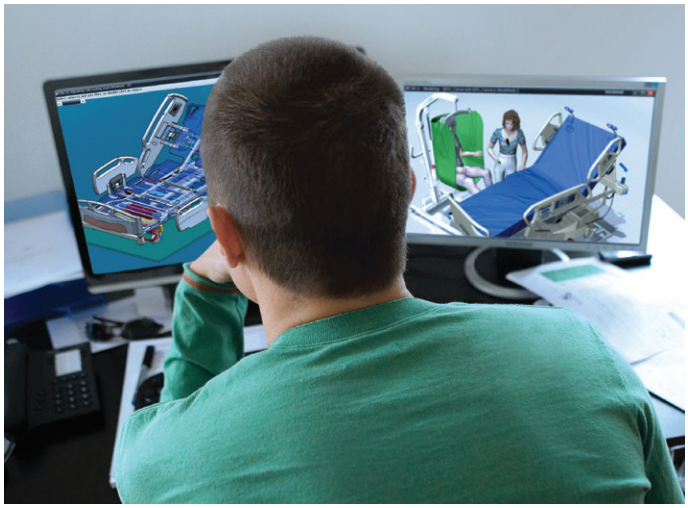
Traditional tools

Software tools that have traditionally been used to create and manage hazards when developing any software medical device are good for documenting requirements and issues in an automated fashion. However, there are several significant shortcomings:

1. Change management – When a requirement changes it is virtually impossible to notify or track the changes unless you manually do so.
2. Linking requirements to test cases – This is yet another manual and very cumbersome process.
3. Scalability – It is convenient to use Google Docs for managing several lines; however, this may not apply for managing several hundred line items.
4. Traceability – The most compelling reason for keeping track of hazards is to demonstrate to the Food and Drug Administration (FDA) that the medical device will not injure or harm anyone that uses it, and companies must show that they have done the necessary prevention and mitigation. This is accomplished using some sort of traceability from the identified hazard to the prevention and mitigation action, proof that the action took place, and the end result. This can be done with traditional tools; however, it is an exceedingly manual process requiring users to physically track, enter and publish the data to various documents. This leads to multiple human errors that cause unnecessary delays in the overall certification of the medical device product.

The solution – next-generation software

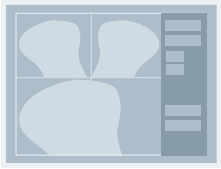
Software technology has come a long way since word editors and spreadsheets became mainstream. Several software solutions are available; probably the most important are web-based platforms that use open source and allow companies to easily integrate with various other applications. One particular solution that lends itself well to the medical device industry is application lifecycle management, or ALM.



Unlike with traditional methods and tools, with ALM you can not only create software requirements and test cases, you can easily track any changes using various built-in collaboration methods. For example, a product manager makes a change to a set of requirements, and the appropriate team members are notified of the change via email with a hyperlink to the requirement and what was changed. Subsequently those same members can take appropriate action, all happening in real time.

What really distinguishes ALM is the concept of test management. Software requirements can be written and documented almost anywhere; however, outside stakeholders and of course regulatory bodies are only concerned about whether the medical device behaves accordingly and does not cause injury or death.

Coming of age for test management



Test management is the process of managing all testing activities and is most commonly performed using a software application. This isn't solely defect tracking, test automation or any single testing-related activity, but a software system that manages all of those activities in a web-based ecosystem.

For medical device solution providers, test management, if used correctly, can benefit your teams in these ways:

1. The team can continue to write software requirements and test cases in a familiar format while leveraging all of the functionality of test management software.
2. Testers can physically link all test cases with requirements and view the relationships at any time.
3. Testers can manage multiple scenarios using multiple operating systems, multiple web browsers, and other infrastructure stack changes with confidence and ease.
4. Internal controls can be set up and managed with workflow, limiting the need for manual oversight by team leadership, project managers and quality analysts.
5. Review and approval comments workflow, in some cases critical for corrective and preventive action (CAPA) responses, are accessible and traceable to the underlying problem. If configured, connections back to the original customer incident management ticket can also be achieved.
6. When auditors arrive, you can show complete traceability between requirements, hazard analysis and end results: what needs to be done to mitigate the hazard, how the mitigation needs to be tested, and whether the action was completed and successful in preventing, mitigating or completely eliminating the identified hazard. A closed-loop system is accomplished and can be demonstrated for internal and external inspection with limited preparation time.

The Polarion solution

Several test management solutions are available; however, Polarion QA from Siemens PLM Software is one of the premier offerings that addresses the key challenges in developing and certifying medical devices for commercial use.

Requirements – All software requirements can still be created using existing Word or Google documents, while readily managed and linked to all the key artifacts used to develop your solution, such as testing and software source control.

Testing – Existing testing tools can easily be integrated with Polarion QA to manage all the results in a central location that visibly links back to your requirements while allowing all team members to gain access and collaborate in real time on what needs to be done and what is done.

Regardless of development methodology, your testing team spends more hands-on time testing with the product and less time proving that testing has been completed.

Individual templates for different classes of medical devices can be used to manage these products under a unified quality management system.

Traceability – Using Polarion will enable you to establish traceability from requirements, regardless of software used, to the specific actions (test cases) created for mitigation and resulting actions (test results). This provides a forensic level of traceability from the creation of requirements to the actions used to develop and mitigate any and all hazards. Regardless of the source of your test results – manual, automated or external – with Polarion you can consolidate and report on them all.

Time-to-market

Customers rely on Polarion to help accelerate time-to-market for medical device innovation. Polarion's proven ALM technology, combined with thorough knowledge of medical industry standards, not only reduces time-to-market, but also ensures that solutions are regulatory-ready, helping medical device manufacturers manage and mitigate risk.

Polarion provides the software toolset to navigate through the arduous world of medical regulatory compliance, specifically for IEC 62304 and FDA 21 CFR Part 820/11, by tracking all activities in single repository that can be accessed from any web-enabled device.

Ask Polarion customers
Siemens PLM Software has many customers using Polarion to develop medical devices, and several have shared their experiences. Contact Siemens PLM software to discover the key benefits that these customers have realized using a complete test management system.

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About Siemens PLM Software

Siemens PLM Software, a business unit of the Siemens Digital Factory Division, is a leading global provider of product lifecycle management (PLM) and manufacturing operations management (MOM) software, systems and services with over 15 million licensed seats and more than 140,000 customers worldwide. Headquartered in Plano, Texas, Siemens PLM Software works collaboratively with its customers to provide industry software solutions that help companies everywhere achieve a sustainable competitive advantage by making real the innovations that matter. For more information on Siemens PLM Software products and services, visit www.siemens.com/plm.

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