DIGITAL INDUSTRIES SOFTWARE

Using Polarion for design control of medical devices

Enabling manufacturers to master compliance and mitigate risk while speeding time-to-market

Executive summary
Medical device product development is a highly integrated and regulated process. Implementing requirements management, risk management and mitigation requires attention to a variety of nuanced topics. Next-generation agile engineering solutions include tools that address the key challenges in developing and certifying medical devices for commercial use.

Siemens Digital Industries Software's Polarion™ portfolio for medical device design control represents a new type of platform designed to model the process relationships and provide a multidimensional, live-linked, relational database solution for today's complex development environments. The solution frees the development staff to establish relationships once so they can move on to more pressing tasks than constantly updating the project control paperwork.

Polarion is part of the Siemens Xcelerator business platform of software, hardware and services.

Introduction

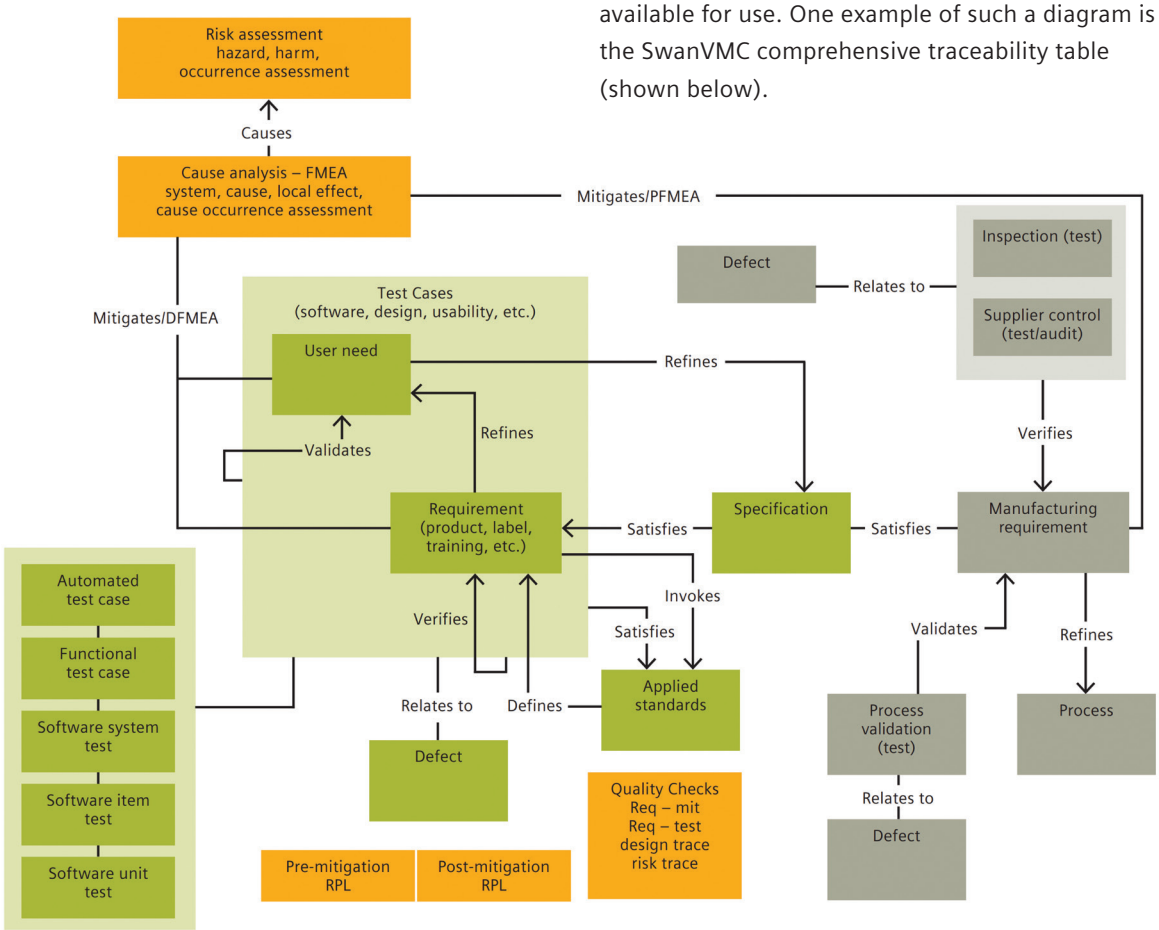
This white paper provides an overview of the nuances of requirements management, risk management and mitigation, and highlights the shortcomings of traditional tools to address these challenges to provide a solution for the complex nature of medical device manufacturing.

The challenge

Traceability – design V&V

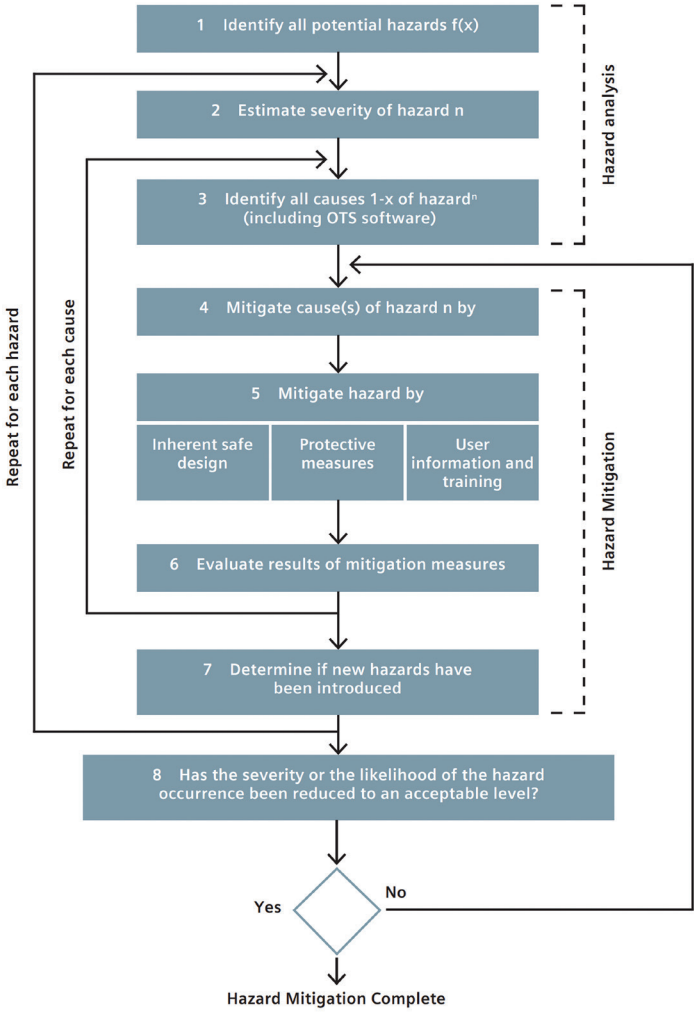
The first task in any product development process is to discover, define and link the items of interest for that product. This is typically done in a logic flow diagram and provides the basis for developing the design verification and validation (V&V) test plan. In complex development environments, it can be a daunting task.

The good news is Polarion offers templates for typical setups that have been completed and made available for use. One example of such a diagram is the SwanVMC comprehensive traceability table (shown below).



Risk management and mitigation

Conceptually, risk management is not difficult to describe and understand. We have hazards that lead to harms. These hazards should be documented and mitigated to control the outcome and make the device predictable and safe. However, implementing such a system is complicated. This is due to a variety of factors, including: the number of variables needed to describe the relationships between the various system components, options for whether to make these concepts unique and re-usable and the many-to-many database relationships and sometimes vague or confusing regulatory expectations.



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. Documentation is commonly created using software such as Microsoft Word, Google Docs and Microsoft Excel to manage traceability between requirements (what must be done to mitigate), test cases (how to verify mitigation is met) and status (failed/passed).

A new approach to managing requirements, risks and hazards

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 impossible to notify or track the changes unless you do so manually.
2. Linking requirements to test cases – This is another manual and cumbersome process.
3. Scalability – It is convenient to use Google Docs for managing several lines, however, this may not apply to managing several hundred line items.
4. Traceability – The most compelling reason for keeping track of hazards is for companies to demonstrate to the U.S. Food and Drug Administration (FDA) the medical device will not injure or harm anyone that uses it, and to show they have done the necessary prevention and mitigation. This is accomplished by tracing the identified hazard to the prevention and mitigation action, proving the action took place and describing the result. This can be done with traditional tools; however, it is a manual process requiring users to track, enter and publish the data to various documents. This leads to multiple human errors that cause unnecessary delays in certifying the medical device product.

Next-generation agile engineering solutions

Unlike traditional methods and tools, with modern agile engineering solutions such as Polarion you can not only create software requirements and test cases, but you can also easily track any changes using various built-in collaboration methods. For example, when a product manager makes a change to a set of requirements, the appropriate team members are notified of what was changed via email with a hyperlink to the requirement. Subsequently, these members can take appropriate action in real time with full transparency and an understanding the: who, when, what and why for every change.

Polarion provides automated designed history records so you can audit changes at any time. With Polarion, you are not only tracking changes at the document level, but also on individual objects. This is important for regulatory audits because it includes configuration and process definition changes.

Polarion enables the user to create and manage documents and effectively author, link and track ideas and concepts. The tool can be used by any company department that manages complex information throughout lifecycles and across projects spanning teams. Examples include designing and implementing V&V testing, quality management systems (compliance with federal registers) and manufacturing processes (compliance with internal company operating procedures).

What distinguishes Polarion is the concept of integrated test management. Requirements can be written and documented anywhere; however, outside stakeholders and regulatory bodies are only concerned about whether the medical device behaves as it is designed to and does not cause injury or death.

Coming of age for integrated test management
Integrated test management is the process of managing all testing activities, which is not solely about defect tracking, test automation or any single testing-related activity. Instead, it is about managing all these activities in an ecosystem that is natively linked to requirements in a single tool. For medical device solution providers, integrated test management, if used correctly, can benefit teams in many ways:

1. The team can continue to write requirements and test cases in a familiar format while leveraging all 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 confidently manage several scenarios with ease using multiple operating systems and web browsers and other infrastructure stack changes.
4. Internal controls can be set up and managed within the workflow, limiting the need for manual oversight by team leadership, project managers and quality analysts.
5. The 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, you can also connect back to the original customer incident management ticket.
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 eliminating the identified hazard. With limited preparation time, a closed-loop system can be demonstrated for internal and external inspection.

Polarion

Using Polarion enables you to address the key challenges in developing and certifying medical devices for commercial use. Using Polarion allows the entire team to collaborate with a single solution while providing different tools for different people.

Engineers appreciate working in our LiveDocs interfaces because like in Word, they can edit the requirements. Using Polarion allows you to access third-party data with LiveDocs. All 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. Furthermore, you can access the MATLAB Simulink model from the design specifications for impact analysis. However, the same data can be accessed by the project managers using Excel like tree table views. There is no data duplication, just different tools and views designed for different roles.

Collaboration is the easy part as Polarion allows you to keep a track of every change. It guarantees the safety of processes (process adherence) but without disturbing the ease of use.

This is done with the Polarion native workflow engine, which helps you save time and increase quality:

- Workflow automation – Helps reduce routine manual work and prevents errors
- Workflow conditions – Guides users and makes sure the process is followed

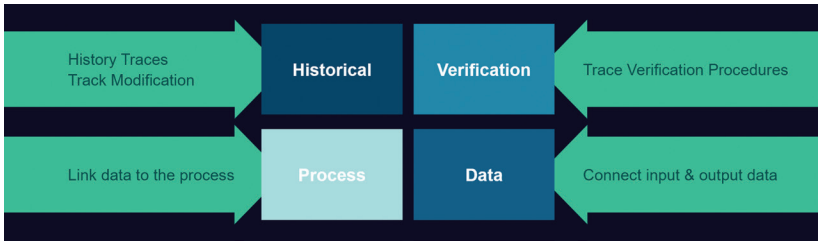
You (almost) do not need to document and train the standard operating procedures (SOPs), but rather configure the workflow functions and conditions that enforce or guide people through their activities.

For example, you can make sure the requirement is approved for implementation only if the test case was created and linked and the functional safety engineer has signed off on it.

Or you can automate the creation of documentation tasks when requirements get accepted, so users do not need to create such tasks manually.

Traceability can be grouped into a few major categories and Polarion supports each of them. Traceability refers to every step in the process:

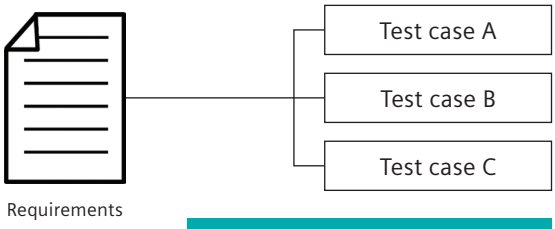
- Historical traceability – Every change is tracked, however, Polarion supports other forms of traceability as well
- Process traceability – Provide proof the process was followed by linking the evidence in the software design specification from the design tasks
- Verification traceability – It can be considered part of process traceability, but it is important it is listed separately as it provides evidence the requirements, design and user stories were verified and validated
- Data traceability – This is the ability to decompose your data and navigate from higher level objects, from business case, epics, user stories or work packages to user level tasks



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 creating requirements to the actions used to develop and mitigate all hazards. Regardless of the source of your test results – manual, automated or external – with Polarion you can consolidate and report on all of them.

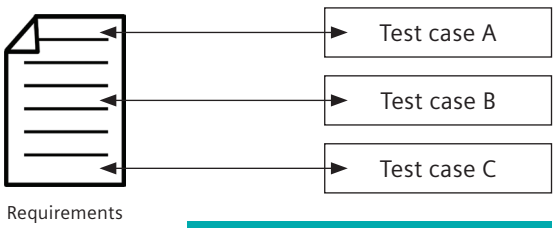
Testing and test case coverage – Very often, when dealing with traceability, people target the goal of establishing and measuring traceability coverage to see if all requirements are covered by test cases, if all the requirements are implemented by development tasks and if all the fixed issues are covered by automated tests. This isn't necessarily the best approach. For example:

- If your objects are large, you can have complete coverage and still fail miserably. This is where granular traceability comes in



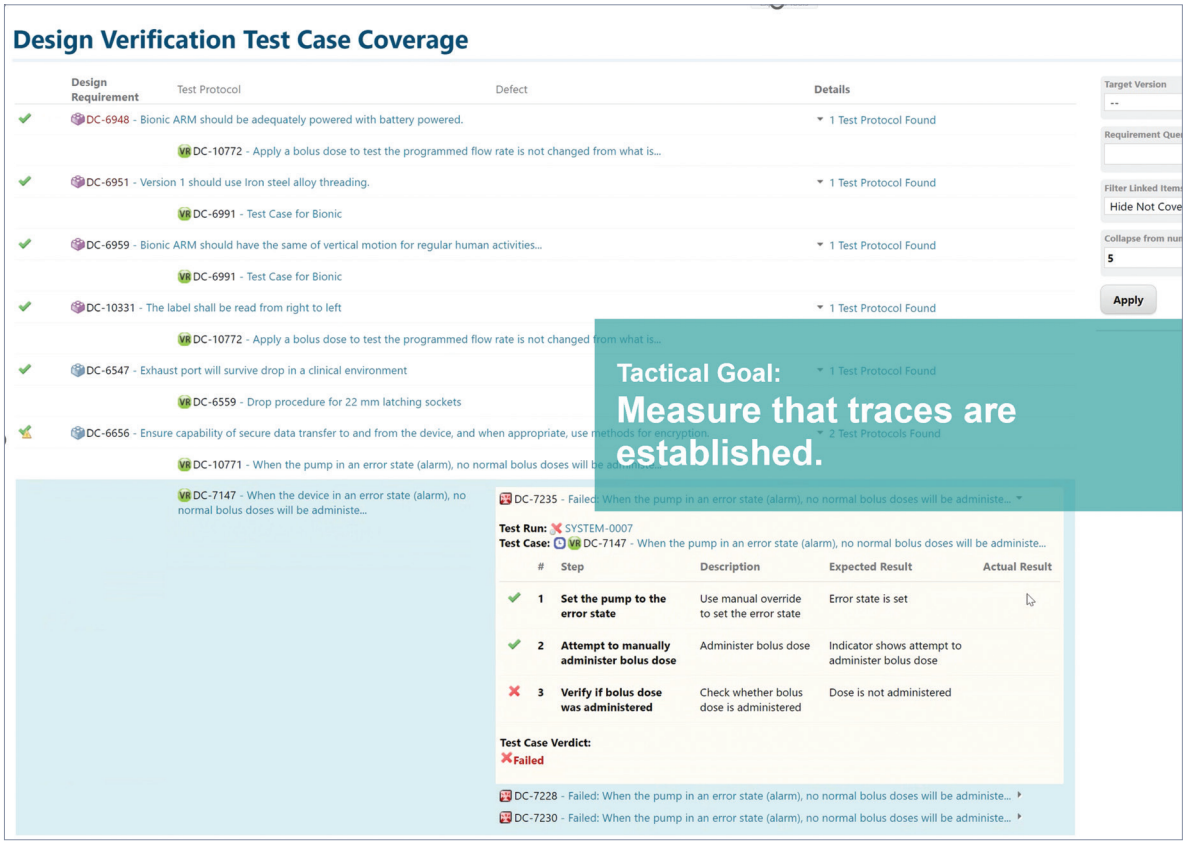
Good coverage + large items = still bad

Using Polarion supports granular traceability in a document. This enables running a test case against any specific requirement by going through just about every paragraph in a requirements document



Granular traceability

Existing testing tools can easily be integrated within Polarion 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. Regardless of development methodology, your testing team spends more hands-on time 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 in a unified quality management system.



Conclusion

Customers rely on Polarion to help accelerate time-to-market for medical device innovation. The application lifecycle management (ALM) technology in Polarion combined with thorough knowledge of medical industry standards not only reduces time-to-market, but also provides solutions that are ready for regulatory scrutiny, 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 International Electrotechnical Commission (IEC) 62304, International Organization for Standardization (ISO) 14971, ISO 13485, IEC 82304-1, IEC 60812, ISO 60601, European Union Medical Device Regulation (EU MDR), FDA Title 21 CFR and more by tracking all activities in a single repository that can be accessed from any web-enabled device.

Siemens has many customers using Polarion to develop medical devices, and several have shared their experiences. Two of the customers are Sonova, a leading provider of innovative hearing care solutions, and iThera Medical, a leading manufacturer of opto-acoustic imaging equipment for laboratory and clinical applications. Contact Siemens to discover the key benefits that these customers have realized using a complete test management system.

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