Q&A With Seapine Software

Traceability Optimization for Medical Device Developers

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Introduction

Medical device manufacturers are subject to increasing regulatory scrutiny, ambiguity surrounding reimbursement levels, and the need to produce substantially differentiated clinical offerings. The increasing pressure of this evolving environment has elevated the need to bring new devices to market as fast as possible (without sacrificing quality, compliance, or design).

Regulatory bodies such as the FDA require medical device manufacturers to document and track huge amounts of information to ensure device safety and demonstrate that safety in the event of an audit. Traceability, however, is still an area that a number of device developers and manufacturers struggle with.

Seapine Software's integrated life sciences solutions help companies manage regulatory compliance initiatives by tracking and linking product development artifacts, verification and validation artifacts, internal validated IT systems, and other mission-critical activities—all without interrupting daily activities. As specialists in this space, we sat down with Seapine Software to gather their insights into the traceabilty challenges medical device manufacturers face, and how they can be overcome.

Why do medical device developers and manufacturers struggle with R&D traceability?

There are a few reasons why medical device companies struggle with traceability in their research and development processes. A big reason is how they interpret FDA guidelines on traceability; they may understand the guideline one way, while the auditor has a different view of it. Interpretations can even vary from auditor to auditor.

The class of the medical device also has an effect. The more complex the device and the greater the risk of harm, the more important traceability becomes. Class I devices must comply with only general regulatory controls, while Class II and Class III devices are more strictly regulated.

But the biggest reason companies struggle with traceability is information overload. The FDA and other regulatory bodies require medical device companies to track and document a huge amount of data about their development process. Companies must track changes to a variety of development assets, including requirements, specifications, risks, test cases, test records, issues, customer complaints, feature requests, source code, and more.

Many companies try to track all of these assets in disparate systems, or with basic tools like Microsoft Word and Excel. The problem? If there's a change to a single requirement, for example, the entire requirement document needs to be updated, and the updated copy shared with everyone on the team.

This kind of labor-intensive, manual traceability can lead to duplication of effort, change management problems, misinformation, and confusion among stakeholders. It also adds risk to the process, drives up costs, and makes regulatory approval more difficult to attain.

To compound the challenge, it's common for each stakeholder group to store and manage information in different ways, using different tools. The requirements team might be using Word documents, while the risk team uses spreadsheets, and the testing team uses yet another tool. None of these tools are linked, so when one team updates information, that update has to be manually made by the other two or three teams. You can see the potential for inefficiencies and errors.

For companies using manual traceability methods like these, creating a trace matrix can take days or even weeks.

What are the biggest traceability challenges that medical device manufacturers face?

The biggest traceability challenge medical device companies face is a lack of visibility into the key data about their development assets. Most often, this is due to the document-centric, manual traceability method described above, but it can also happen because there's no real traceability strategy in place.

You'd be surprised at how many medical device companies lack a documented traceability strategy. Generally, these are the companies that are struggling with excessive rework, communication problems, change management, and related issues. They think their traceability is strong enough, but they have trouble producing satisfactory proof for auditors.

So the two biggest traceability challenges center on improving the traceability strategy, and then supporting that strategy with the proper tools.

What options do medical device manufacturers have when looking at ways to overcome these challenges?

If a company is committed to using Word and Excel to manage traceability, one option (but not a good one) is to devote more time and resources to that process. They should have a traceability manager on each project—someone highly skilled with Word and Excel, whose only job is to create and maintain that project's traceability matrix and reports. We don't recommend hiring people to make such a bad system more productive, though, because it just makes it harder to improve the process.

For companies using separate systems that don't communicate with each other (QMS, PLM, etc.), additional software tools can be added to connect them together. Several tools have been developed recently to tie older front-end and back-end systems together. It can be challenging and costly to integrate a number of disparate systems this way, however. And when you upgrade one of the tools in the chain, will it break the system?

The best results can be obtained by using an integrated toolset that is designed to cover the entire R&D process. Integrated tools enable companies to begin tracing artifacts in the very early stages of their development process, and automate the linking of each artifact as it evolves from requirement to test case, and so on. Some integrated tools, like TestTrack, can generate a trace matrix at any point in the process with just a few clicks.

Are there any best practices that medical device manufacturers can adopt to improve their traceability processes?

Develop a traceability strategy. Document it. It's going to take a lot of work, but it's an essential step toward strengthening traceability. Executive management must make it a priority and dedicate the time and effort needed to do it right.

If the process proves to be too political or contentious, they may need to bring in a neutral third party to facilitate the discussions and planning. There are consultants who can help, and many of them used to work for the FDA, so they can help clarify what auditors want to see.

What are the benefits of using traceability software?

Traceability software provides enhanced visibility of key data, keeping important information in front of the team throughout the development process. This is extremely valuable for managing risk items. When risk is managed separately and not linked into the development process, it can get overlooked easily. Traceability software links mitigations to the affected requirements, test cases, and other artifacts, so they are constantly in front of the team at every stage.

Traceability software also gives stakeholders access to a live stream of data for better decision-making. With the ability to more fully analyze all development items, the team can perform deeper impact, gap, risk, hazard coverage, and requirements analysis.

Another big benefit of using traceability software is the reusability and modularization it provides. This can cut costs and save significant time when working on existing and future projects.

And again, a major benefit of traceability software is its ability to automate tedious and redundant tasks, like linking and communication. With an integrated tool like TestTrack, even the traceability matrix can be automatically created and maintained.

What advice would you give to medical device company struggling with their traceability?

A good starting point to learn more is our white paper, Six Exercises to Strengthen Traceability. The exercises in this paper are based on training we've done with Seapine customers to help them discover where their traceability is weakest and how to strengthen it.

As previously mentioned, an outside consultant may help move this process along. If the team has already tried self-directed exercises and is still struggling, they may need to engage a neutral third party.

Finally, they need to find a toolset that matches how they want to work. Don't let the tool dictate the development process; that road leads to more traceability problems, rather than solving the current ones.

Seapine's medical device customers have found TestTrack to be ideal for providing end-to-end traceability.

Additional Resources:

Six Exercises to Strengthen Traceability

Webinar Recording: Struggling with Word or Excel to Manage Traceability?

Find out more about end-to-end Traceability With Test Track

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