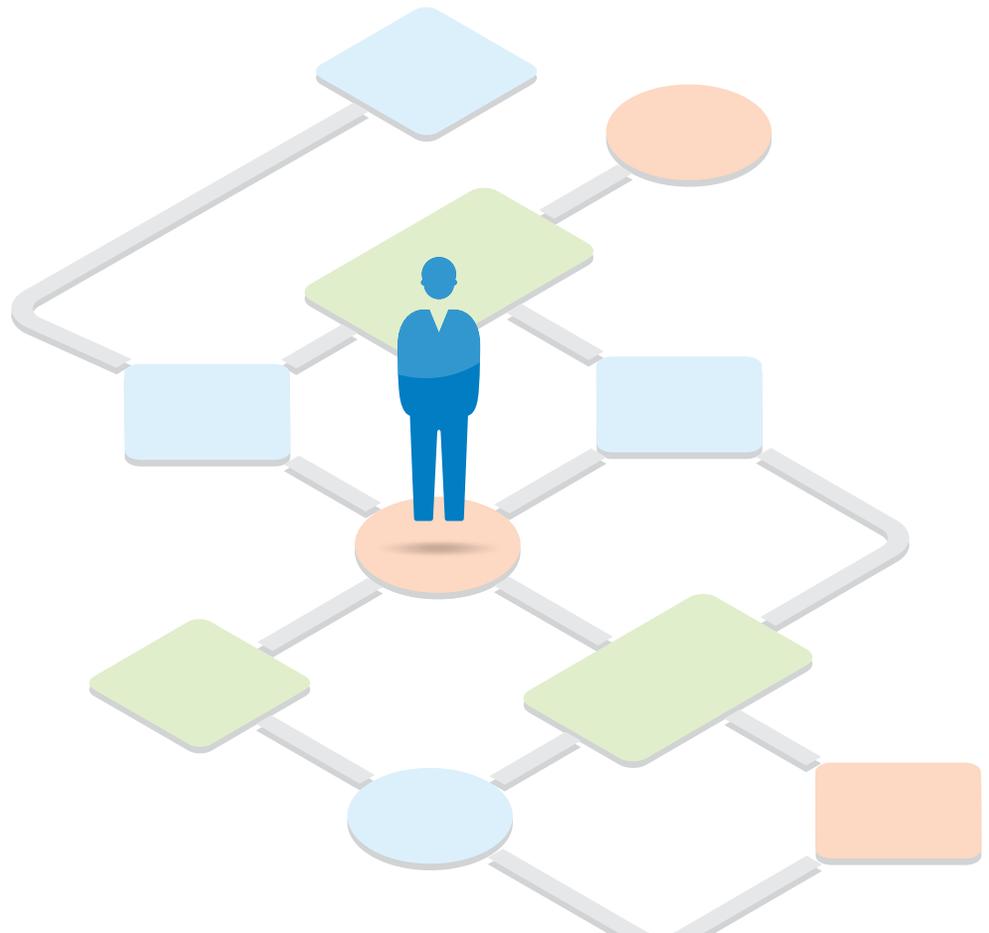


TRACEABILITY TOOLKIT

# What Is Your Traceability Strategy?



Many people don't think in terms of a traceability *strategy*. They track product development efforts in an Excel spreadsheet, a manual process that is time-consuming and prone to error. They stick with it, though, because they've always done it that way. But it's not the best way to track items.

An effective traceability strategy promotes and supports the sharing of changes and automates the approval process across teams. This is beneficial to companies in any industry, but it's particularly important for businesses that need to comply with quality standards and regulations.

Let's take a high-level view at developing a holistic traceability strategy.



## What Is Traceability?

At its simplest, traceability means two or more work items in the product development lifecycle are linked to one another due to a dependency. For example, you could link a hazard to the requirement for a feature that mitigates that hazard. Once that link is established, you can trace the relationship to verify coverage of requirements.

If you want to ensure the hazard was mitigated, you can trace the link forward to the requirement. If you want to know the reason for the requirement, you can trace it back to the hazard.

The requirement would also be linked to the resulting feature or code, which would be linked to a test case, which would be linked to a test run, and so on. You can then trace forward or backward from any work item, which provides tremendous insight into your lifecycle for both managerial and regulatory purposes.



## What Is a Traceability Strategy?

Your traceability strategy details the proactive approach you take to practice traceability, describing how you trace development items for the most effective results. It's what elevates traceability from an item on a compliance checklist to an essential solution for improving day-to-day operations.

A good traceability strategy provides better visibility of key data throughout the product development lifecycle. This allows for better analysis, reuse, artifact evolution, and notification when key milestones are met. In short, an effective traceability strategy delivers stronger traceability.



## What Are the Benefits of Stronger Traceability?

Traceability eliminates wasted time and money. When you follow a good traceability strategy, you gain the following benefits:

### Higher product quality

- Reduce product defects and risks.
- Avoid delays in a product's release.
- Improve risk management.

### Better visibility of product information

- Gain insight into the cost and impact of change.
- Ensure business goals are met.
- Decrease chances of project overruns.

### Reduced costs

- Decrease costly manual errors.
- Shorten timelines.
- Improve profitability.

### Clearer proof of compliance

- Prove compliance with ever-stricter government regulations and other quality standards.
- Avoid warning letters, product delays, and substantial fines.
- Prevent quality and acceptance problems.



## Developing a Traceability Strategy

In order for your traceability strategy to be effective, it must document all the processes, tools, and best practices that help your business maintain product quality and regulatory compliance.

To successfully develop a traceability strategy, you need to be properly prepared. Include the right people in the meetings, get them to make the time, create a framework for the discussion, and—most importantly—follow through to the completion of the strategy.

### Include the Right People

It will likely take a few meetings to create and hone your traceability strategy. To make these meetings as productive as possible, you'll need to include the more than just the team managers.

Too often, managers believe they know what is best for their teams. In reality, they may lack knowledge about their team's daily activities and processes. This knowledge gap can negatively impact the effectiveness of your traceability strategy.

Rather than limiting participation in the strategy meetings to managers, include the following people:

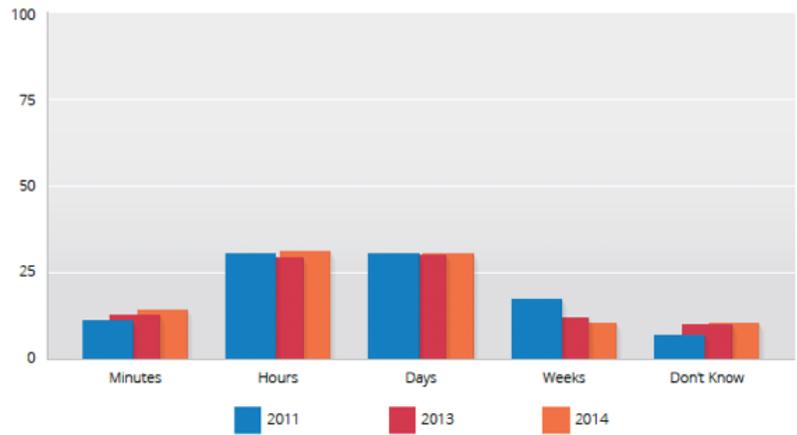
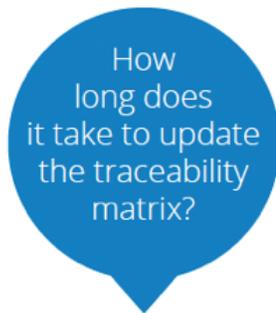
- Product experts from marketing, R&D, and product management
- Business analysts and project managers from design
- Developers and engineers from development
- Testers and QA managers from quality assurance
- Product documentation personnel
- Regulatory and compliance personnel

Be sure to include representatives from every team or department that will be affected by the new traceability strategy. If you don't, you may create animosity between groups and hinder adoption of the new strategy.

## Make Time

Some may balk at taking time away from their daily work to help develop a traceability strategy. You may be wondering if it's worth the time spent, too.

Consider this: According to the [2014 State of Medical Device Development Survey](#), 73 percent of businesses spend hours, days, or even weeks maintaining a traceability matrix. If the end result is ineffective or fails to satisfy the auditor, that's a lot of time wasted.



**SOURCE: 2014 State of Medical Device Development Survey Report**

By spending a few hours to create an effective traceability strategy, you can significantly reduce the excess time spent on the traceability matrix.

## Create a Framework for Discussion

Your meeting will go more smoothly and be more productive if you have a list of topics. The following framework can provide a starting point.

- Describe why traceability is important to the business.
- Cite examples of how the lack of traceability has negatively affected the business.

- Communicate the benefits of traceability to each department. The benefits may include:
  - Improved communication
  - Collaboration across departments
  - Specialization between departments
  - Continuous improvement
  - Reduced individual work
- Describe specific regulatory and compliance requirements.
- Assess current traceability practices.
- Develop repeatable traceability best practices.

## Follow Through

While all the preparatory steps we've outlined are important, the most critical part is following through—actually creating an effective traceability strategy.

Whether you follow Seapine's [6 Exercises to Strengthen Traceability](#) or use some other method, make sure you cover these basics:

- Identify key documents and items that need to be tracked and managed.
- Agree on common terminology and naming conventions.
- Analyze the impact of change between related artifacts.
- Establish traceable relationships and handoffs.
- Establish performance guidelines and tracking metrics.
- Examine your current methods and practices to ensure they are up to date and effective.



## Get Help

Many organizations find it difficult to dedicate the time or resources necessary to develop traceability strategies and implement best practices. As a result, they continue to scrape by with Excel spreadsheets, even though they know they could benefit from a change.

Don't be reluctant to get help formulating and documenting your traceability strategy. Seapine Software can assist you with creating a traceability solution that works for everyone in your organization. Our experienced professional services team has helped create effective traceability solutions for companies across a broad range of industries.



### **About Seapine Software**

With over 8,500 customers worldwide, Seapine Software, Inc. is the leading provider of quality-centric product development solutions. Headquartered in Cincinnati, Ohio, with offices in Europe, Asia-Pacific and Africa, Seapine's development solutions help organizations ensure the consistent release of high quality products, while providing traceability, metrics and reporting, and compliance.

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