

4 Best Practices for Requirements Traceability

Requirements change all the time. Whether due to evolving customer needs, regulatory updates, or other causes, these changes require corresponding impact analysis and informed decision-making, often on short notice.

With the increased technological complexity of the products developed, the ability to trace requirements to manage risk throughout the development process becomes mission-critical. **Why? Because ineffective requirements traceability is costly.**



The High Price of Ineffective Traceability

An average of **4,500 FDA-approved drugs and devices** are pulled from U.S. shelves every year.¹ Light vehicle recall campaigns also totaled 341 in 2018, a record.²

Just one recall can set a pharmaceutical or life science firm's **incremental innovations back by six months or more**, giving its competitors a major advantage.³

To curb these risks, teams need real requirements traceability. **Here are four tips for superior traceability:**

1. Connect contributors and stakeholders to requirements



Requirements aren't just words. Each one also has an entire universe of team members associated with it, from systems analysts and architects to developers and QA engineers.



Accordingly, **connect the relevant contributors and stakeholders to their requirements** via trace relationships, so that they can see updates and notifications and take action as needed.

2. Enable automated bidirectional traceability



When risks and requirements change, **the traditional approach is to update a traceability matrix.** However, this manual process is very error-prone and messy, creating problems in demonstrating compliance.



In contrast, **product development software can pull all relevant information** into one system that automatically alerts stakeholders of relevant changes and provides clear visibility into trace relationships.

3. Put all conversations and data in one place



Beyond seeing trace relationships and coverage gaps, **teams also need the ability to act quickly.** Doing so is easier when everything is stored on one platform.



Ideally, they will be able to easily see connections **between requirements and downstream test cases**, as well as all conversations and activities associated with each case.

4. Use built-in review and reporting for compliance



Proving compliance requires showing **traceable connections between requirements and test plans**, along with the status of verification and validation tests.



Built-in capabilities for review and reporting, such as exporting of data into common industry formats, help simplify this process and keep products on track.

The Outcomes of Better Traceability



RBC Medical reduced its average per-project time spent by 123 days.⁴ Similarly, Grifols **saved 80 hours per project**, to now use in more productive ways.⁵



3Shape used the traceability matrices in Jama Connect to streamline information access and simplify audit passage.⁶ Meanwhile, TOMTEC used full **traceability between requirements** and test cases to save time.⁷



We'd love to show you how the Jama Connect platform enables truly traceable product development. **Connect with us here**, or **learn more** about why traceability matters in this blog post.

SOURCES

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