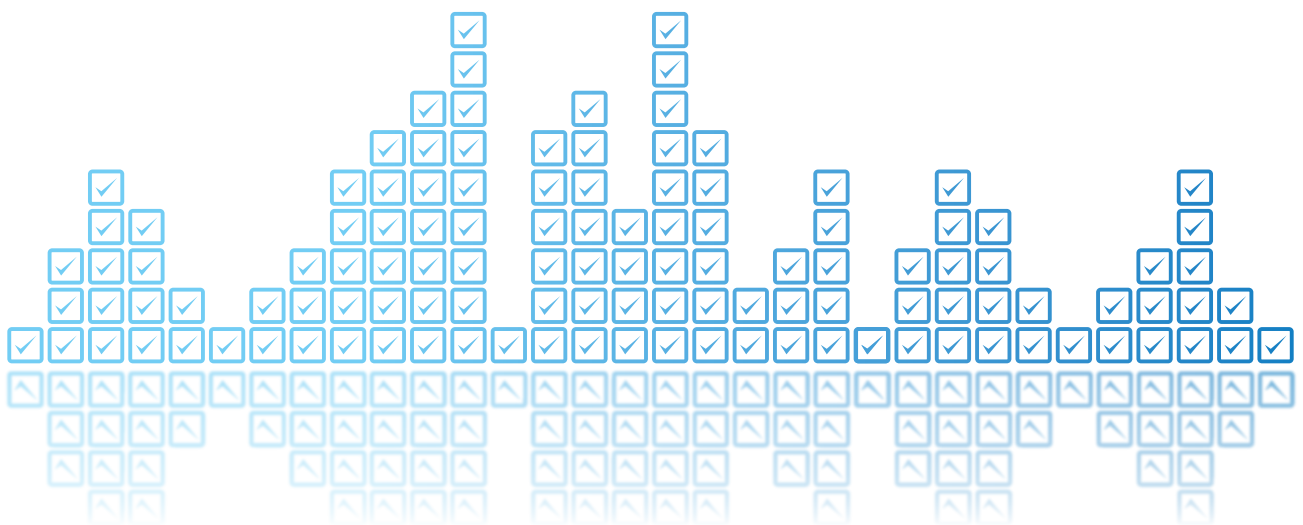


Life Sciences Product Development Artifacts Survey Results



About the Survey

Seapine Software conducted this survey over a six-week period during the first quarter of 2011. A total of 150 respondents provided a good cross-section of the life sciences industry, with over half of the responses coming from the medical device sector. The survey targeted those who manage product development artifacts, and greater than 70% had five or more years of experience in the life sciences sector.

Key Finding

Most traceability processes are manual and many life sciences organizations are still using outdated technology to organize and manage product development artifacts.

The State of Traceability

You might expect that, in 2011, life sciences organizations would be proficient at tracking core development artifacts like requirements, risk analyses, test cases, test records, issues, customer complaints, feature requests, source code, and other development assets. In reality, however, many organizations are still using outdated technology and forced to manage documents in a shared network directory or document control system.

Two main issues with manually managing documents, which can easily be hundreds of pages long, are being able to prove both the accountability and traceability required of most compliance standards. The majority of life sciences companies are manually tracking artifact relationships using spreadsheets, and cannot distribute specific sections for task-driven development or trace artifacts back to origination. Other industries have already adopted more automated ways of tracking and tracing development artifacts. Development teams in these organizations can collaborate more effectively, be notified automatically of changes, reuse content to reduce risk, and most importantly stay focused on their core tasks while continuing to meet quality control standards.

Traceability should be part of daily processes, but transparent and automatic. This is not unexpected news for life sciences organizations. In fact, we received several comments and questions about traceable product development solutions with this survey.

More than 32% of the life sciences companies that don't use Seapine products believe they are either under or over compliant when managing core development artifacts. The other 68% who believe they have a good mix of compliance likely don't understand the total cost to the organization to maintain these mostly manual compliance efforts.

Put simply, traceability is the ability to uniquely track, relate, and verify each step in a process. Traceability creates relationships between product development artifacts, and helps organizations manage these relationships and the impact that change has on them.

Strong traceability helps ensure product quality. This is particularly important for products or projects that impact the public's health and safety, which is why traceability is often required by government agencies and industry standards such as the DOD, FAA, FDA, and ISO.

While the survey did include questions about other aspects of managing product development artifacts, like tracking requirements and issues, we are sharing traceability, risk analysis, and test case management findings.

Managing Traceability

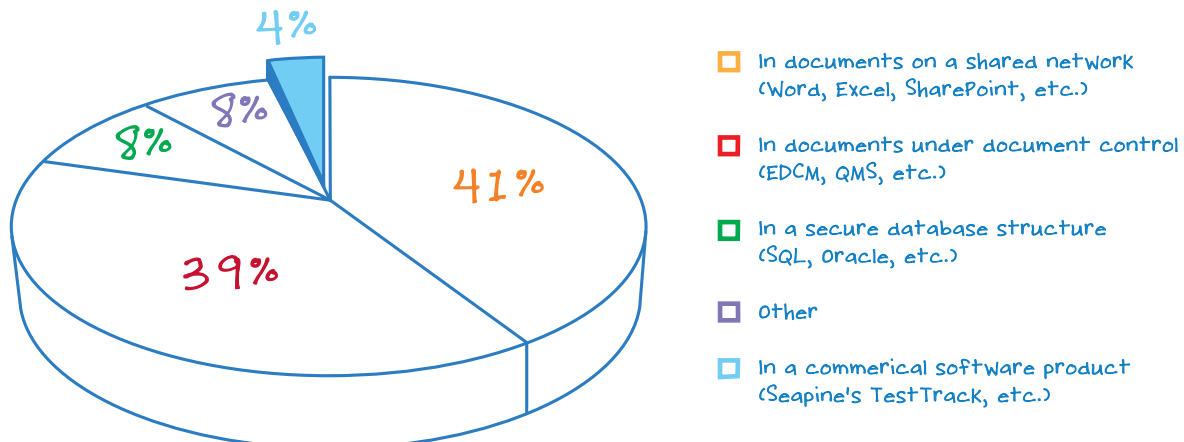
Managing and maintaining traceability is typically required of life sciences organizations, especially if they are developing a high-risk product or Class III medical device. Traceability is a required component of any good validation plan. Based on survey results, the most common artifacts tracked in a traceability matrix are requirements and test cases.

Please select all development artifacts that are tracked in your traceability matrix:

Requirements	89.4%	Customer Complaints	26.7%
Test Cases	80.2%	Development Tasks	25.6%
Test Results	57.0%	Feature Requests	24.4%
Issues/Defects/Anomalies	55.8%	Source Code	24.4%
Risk Artifacts	50.0%	User Stories	16.3%

We found that fewer than 4% of companies that don't use Seapine tools are using a commercial software product to manage core development artifacts.

How do you typically manage core traceable product development artifacts?

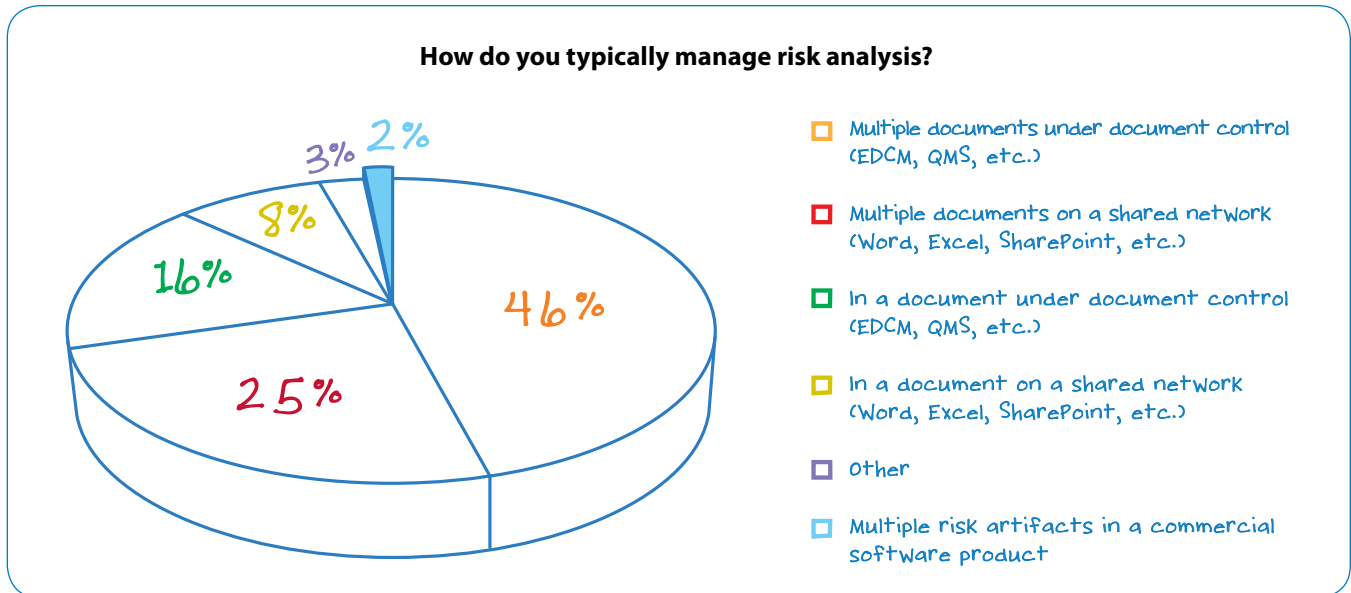


Over 80% of respondents manage core traceable product development artifacts in documents, such as Microsoft Word. Using document-based traceability is a time-intensive process that can severely inhibit productivity.

Ironically, less than 24% believe the entire organization is responsible for traceability. Most indicated that quality control or a specific regulatory group was responsible. If the entire organization isn't responsible for managing and maintaining traceability, it's no wonder it becomes an afterthought and not part of the daily process.

Managing Risk

According to the survey results, risk artifacts are the toughest items to manage and trace. And, less than 2% of responding organizations that don't use Seapine tools are managing risk with a commercial software product.



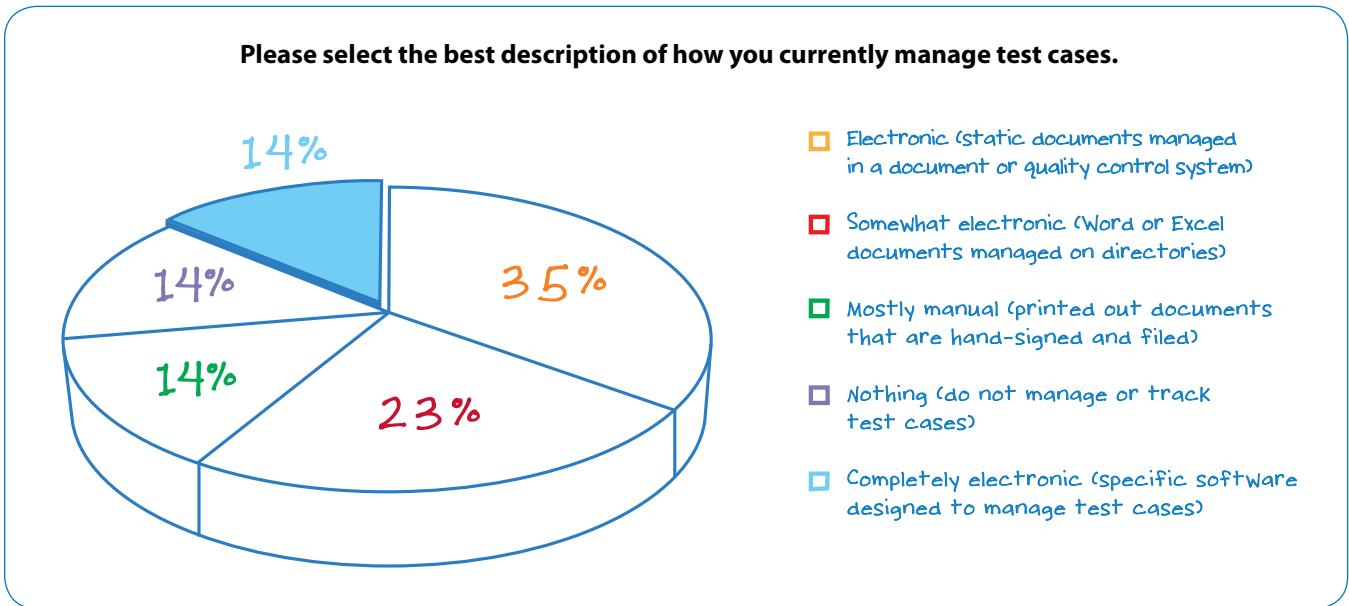
Another compelling survey result was the fact that over 66% cannot easily create relationships or traceability with other product development artifacts. Many companies that can trace risk artifacts are doing it manually, which is prone to human error.

- Failure Mode Effects Analysis (FMEA) was practiced by about 67% of respondents.
- Fault Tree Analysis (FTA) was practiced by about 38% of respondents.
- Hazard Analysis and Critical Control Points (HACCP) and Failure Mode, Effects, and Criticality Analysis (FMECA) were equally practiced by about 25% of respondents.
- Hazard Operability Analysis (HAZOP) came in last with only 7% practicing this method of risk management.
- A few respondents don't practice any formal method of risk analysis, even though they indicated they do track risk artifacts.

Assessing, managing, and tracing risk is a huge issue in the life sciences industry, especially because risk scores seem to be isolated in documents outside of daily product development tasks. Ideally, life sciences companies would benefit from having this information readily available and more integrated with their daily tasks, because these artifacts share and reuse key components of risk or risk scores as related artifacts are generated and updated.

Managing Test Cases

Regarding companies that manage test cases but don't use Seapine products, the survey showed that only 14% use software designed to manage test cases.



Another interesting finding is that more than 68% still use manual signatures for approving test cases, which makes building and maintaining a traceability matrix difficult and time consuming. Test cases and executed test results (test runs) were second and third, respectively, as items most managed in a traceability matrix.

Clearly, some life sciences organizations believe they are tracking traceability electronically by managing static, signed documents in an outdated document or quality control system. Within the last 10 years, however, most other industries have started to manage and integrate verification activities and artifacts into their overall product development lifecycle.

Objective evidence is also a concern in life sciences organizations. The survey showed that only 23% of respondents track the pass/fail status and attach the actual screen shot at each step of test case resolution, which may be one reason why many organizations don't use a commercial software product to manage their testing efforts.

Ready for an FDA Submission?

Of the medical device companies that have submitted 510(k)s or Premarket Approvals to the FDA, the survey indicated that less than 12% could quickly provide an updated traceability matrix. In addition, more than 60% indicated it took days or even weeks to update their traceability matrix.

Proving traceability is a core requirement of an FDA premarket notification process. The surveyed companies also believe that risk analysis, validation, and audit trails are among the toughest items to prove to the FDA.

Future Trends

Once life sciences companies catch up with technology and trust that traceable, integrated software systems are compliant, they can begin adopting development methodologies that help reduce time to market, such as Agile. Based on our survey results, less than 17% of organizations track user stories in their traceability matrix.

Conclusion

It appears that the life sciences industry has taken a literal definition from the FDA's use of the word "document." However, the FDA also considers digital artifacts tracked in a secure electronic system (assuming the system meets 21 CFR Part 11 and 820) to be "documents," as long as they can be provided and proven in a digital format. An excerpt from 21 CFR Part 820.3 in definitions, "(k) Establish means define, document (in writing or electronically), and implement."

The FDA's intent is not to waste reams of paper just to record signatures in ink. Instead, the FDA merely seeks proof that good processes were followed and core product development artifacts are accountable and tracked. Most importantly, the FDA wants to ensure these artifacts are traced during the development phases, not created outside of development in a spreadsheet or only shared internally with management and the FDA.

About Seapine

Seapine Software has helped many life sciences organizations achieve product development compliance. More importantly, Seapine has helped regulated companies deliver higher quality products to market faster. We appreciate everyone who participated in this survey and welcome any additional feedback, as we strive to deliver the highest value in managing product development artifacts in the life sciences sector. To learn more, visit www.seapine.com/lifesciences.html.