

Industry:
Life Sciences

Seapine Products:
Surround SCM, TestTrack Pro, TestTrack TCM

Ximedica

A part of the Item Group, Ximedica, LLC helps life sciences companies that need to bring products to market quickly while still meeting U.S. Food and Drug Administration (FDA) compliance requirements. Ximedica's process for artifact submission was labor intensive and costly. With Seapine Software's help, Ximedica created an integrated solution that allowed them to manage compliance artifacts and easily transfer management of that data to clients at the end of a project.

Situation

Ximedica offers outsourced design, development, and market research for medical device and pharmaceutical companies. As part of every project, they must track requirements, test cases, and other artifacts for FDA compliance. After completing a project, they need to deliver the artifacts to their clients with the finished product. Ximedica's main goal was to acquire a compliant, procedure-based product development system and an efficient tool to maintain the data required by the FDA and other third party testing agencies (e.g., Conformité Européene (CE), Underwriters Laboratory, and International Organization for Standardization (ISO)).

Solution

Ximedica spent six months evaluating stand-alone tools from a variety of vendors, but they were disappointed with most company's experience in their industry. However, Seapine Software was different. "During the evaluation process, we realized that we had clients in common," says Ximedica's Douglas Kornbluth. "We were impressed by the variety of companies using Seapine's products, and this convinced us that they understood our needs."

Ximedica addressed their regulatory challenges by implementing Seapine's TestTrack Pro, TestTrack TCM, and Surround SCM. This integrated solution provides rapid development and control of their clients' complex software and hardware products and helps Ximedica manage projects that often involve designers, developers, and testers located around the world.

Locating a right-sized solution that could be implemented quickly and still achieve FDA compliance was critical. Seapine's applications met those requirements perfectly. According to Kornbluth, "The applications we reviewed were difficult to implement with our limited IT resources.

"We now have a unique capability that other companies our size do not. Our integrated development solution gives us the confidence to undertake more sophisticated software projects. I don't know where we would be without the solution Seapine provided."

Douglas Kornbluth
Ximedica LLC

In addition, many low-cost, open source tools did not offer integrated solutions for source code control, requirements management, and traceability analysis or the remote collaboration we needed."

With the new system, Ximedica creates a requirements document and stores it in Surround SCM so they can track the revisions. Individual requirements are stored as records in TestTrack Pro and test cases based on those requirements are created in TestTrack TCM. All of the test cases, test runs, and defects are tied back to the requirement record so it is easy to determine the status of the project and track every action taken on the requirement record.

"With the new comprehensive system, we reduced our final reporting and traceability reconciliation work by two to three person months."

Douglas Kornbluth
Ximedica LLC

Because Ximedica works with both medical device and pharmaceutical companies, they needed to be able to adapt any solution to use the terminology of a specific client. With TestTrack Pro and TestTrack TCM, they use templates and workflows that can easily be adapted to individual projects. They also use audit logging and electronic signatures to improve their compliance tracking.

Results

"Not many full-system integration, design-to-manufacturing firms like Ximedica offer software development and verification/validation compliance," says Kornbluth. "As a result of leveraging Seapine's solutions, we can now offer our clients a product development system to maintain FDA compliance and a transition plan that is affordable and backed by solid procedures."

Ximedica can now easily manage requirements and generate status reports in a timely manner, both of which reduce risk. They have improved their ability to create the required reports, which improves compliance and reduces unbillable hours. "The improved reporting efficiency has translated directly to increased project profitability." By eliminating manual tracking and streamlining reporting, Ximedica also reduced their project turn time and recouped their investment on their first project.

Another valuable result is employees' improved understanding of the value of well-defined requirements. "Because we can trace requirements from design to implementation, developers, project managers, and testers can see how requirements and test cases relate to one another," Kornbluth adds. "We now write requirements with an eye on testing, which produces clearer expectations, more efficient testing, and improved quality throughout the entire process."