Ximedica Brings Products to Market More Quickly With Seapine

Ximedica's existing 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.

AT A GLANCE

Organization:
Ximedica

Web Site:
www.ximedica.com

Headquarters:
Providence, RI

Description:
Since 1985, Ximedica has enabled hundreds of organizations and businesses to innovate, execute and launch thousands of products successfully into the market.

Ximedica is a full-service product development firm with an exclusive focus on medical. 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 along 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 such as Conformité Européene (CE) and Underwriters Laboratory.

Choosing Seapine Software

Ximedica spent six months evaluating stand-alone tools from a variety of vendors, but soon found that most companies lacked experience in the life sciences industry. However, Seapine Software was different. The number of life science companies already using Seapine's products impressed Ximedica, and this convinced them that Seapine understood their needs.

Locating a right-sized solution that could be implemented quickly and still achieve FDA compliance was critical. Seapine's applications met those requirements perfectly, while offering an integrated solution for source code control, requirements management, and traceability analysis.

Implementing TestTrack and Surround SCM

Ximedica addressed their immediate regulatory needs by implementing Seapine's TestTrack for requirements, risk, test, and issue management. They also implemented Seapine's Surround SCM for change management. This integrated solution provided rapid development and control of their clients' complex software and hardware products while helping Ximedica manage projects that often involve designers, developers, and testers located around the world.

Ximedica also needed a way to tie everything together and a solution that gave them full traceability with requirements. Previously, Ximedica managed requirements with Microsoft Word documents, and traceability was done manually using an Excel spreadsheet. "This process was not only time consuming and labor intensive, but also made it challenging to make sure everything was covered," said Joseph Kralicky, Ximedica's Principal Software Engineer. Ximedica chose to implement TestTrack, which gave them full traceability with requirements and the ability to automatically generate traceability matrices.

"Seapine's suite of tools allowed us to bring all project artifacts together," added Kralicky. "TestTrack also gives us the ability to add or modify requirements by simply making the changes in TestTrack, then regenerating the supporting documents that we store in our document control system."

Taking Advantage of Seapine's Adaptive Technology

Ximedica works with medical device organizations, pharmaceutical companies, and consumer healthcare companies. The company needed to be able to adapt any solution to use the terminology of a specific client. With TestTrack, they use templates and workflows that can easily be configured for individual projects.

Throughout the normal course of design engineering,it is not uncommon for new requirements to emerge as the design matures. With TestTrack, Ximedica can easily go back and add requirements. "TestTrack gives us the ability to assess how much work needs to be done if something changes," added Kralicky. "And now we can provide the customer with a cost estimate to make the change."

TestTrack gives us the ability to assess how much work needs to be done if something changes.

Joseph Kralicky, Principal Software Engineer, Ximedica

Reducing Risk, Improving Reports

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.

"Implementing Seapine's suite of solutions has given us an integrated system that we can use to generate all of our documents from one data source," said Kralicky. "We don't have to fight with Microsoft products when we make changes. TestTrack is a perfect fit that allows us to bring everything together and fully document our design process."

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

Few full-system integration, design-to-manufacturing firms like Ximedica provide software development and verification/validation compliance. As a result of leveraging Seapine's solutions, Ximedica can now offer its clients a product development system to maintain FDA compliance and a transition plan that is affordable and backed by solid processes.

Implementing Seapine's suite of solutions has given us an integrated system that we can use to generate all of our documents from one data source.

Joseph Kralicky, Principal Software Engineer, Ximedica

Visit www.seapine.com/lifesciences.html to learn more about what Seapine can bring to your product development process.

Seapine Software™

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.

Learn more at **seapine.com.**