Application Management Reduced Testing Time from Days to Under One Hour

When a global leader in infusion therapy, pain management technology, and support was developing more complex systems, they required an effective design control solution to support those efforts. SPK stepped in to help the medical company implement Windchill RV&S.

> **THE AMOUNT OF PERSONALIZED ATTENTION AND DETAILED COMMUNICATION (WHETHER THAT BE ONLINE VIA ZOOM MEETINGS) OR THROUGH VERY IN-DEPTH AND WELL-THOUGHT-OUT EMAIL EXCHANGES, HAS BEEN PRETTY SPECIAL. ADDITIONALLY, THE ACCESSIBILITY OF SPK TEAM MEMBERS HAS BEEN IMPRESSIVE, AS HAS THE SPK'S FLEXIBILITY IN ACCOMMODATING THE NEEDS OF MY PROJECT.**
>
> *Business Leader*

CHALLENGES

Before they decided to implement PTC Windchill RV&S for design controls, this company had used a mostly manual system, based on Excel spreadsheets and Word documents. These manual processes required excessive effort to establish and maintain traceability across all the design artifacts, perform change management, and it did not provide adequate visibility into the state of the development for managers.

For one program, they had been using a partner's design controls system but found the tools to be inadequate. Additionally, the process of updating requirements, tests, and risk analysis through the partner was slow, error-prone, and cumbersome.

The company had also been using an older, on-premise installation of PTC Integrity Lifecycle Manager purely for source code control.

Furthermore, for bug tracking and change management of the source code they were utilizing an old on-premise PVCS Tracker system. Their IT department managed on-premise systems, but the engineering organization was frustrated with the poor support and slow response times associated with them.

SOLUTION

Due to the issues with the on-premise systems, one of the main objectives for the new design controls solution was that it should be cloud-based. At least three sites in North America would be using the cloud-based solution. Additionally, the goal was to create a new design controls solution that would integrate requirements management, risk management, test management, change management, and source code management. This would ensure that the company was fully compliant with the necessary medical device regulations such as ISO 13485, ISO 14971, and IEC 62304.

SPK implemented a tailored design control solution for this company that was based on the SPK Medical Device Solution TemplateTM. PTC Windchill RV&S is a highly configurable application lifecycle management platform, but out-of-the-box, it doesn't implement any processes. PTC provides its partners and application engineers with a standard solution template, which is good for demonstrating the potential of the product, but not necessarily a good starting point for configuring a customer-specific solution.

SHED WEEKS OFF OF THEIR DEVELOPMENT/RELEASE CYCLE.

ERRORS ON THE TEST FLOOR WERE REDUCED BY 50%

COMPLIANCE WITH ISO 13485, ISO 14971, AND IEC 62304

This is why SPK developed the Medical Device Solution Template as a streamlined configuration that was optimized for medical device development. It is a pared-down configuration without demoware or other extraneous features due to the computer system validation requirements for the Medical Device industry. By starting with a clean configuration that is optimized for Medical Device development processes, customer configurations can be developed and certified much more quickly than creating a custom solution from scratch or doing heavy reconfiguration of the PTC generic systems engineering solution.

SPK's implementation of the PTC Windchill RV&S customized medical device solution template provided end-to-end design controls and one-click full traceability via the SPK Report Engine™. Additionally, we implemented a customer test session adapter which enables efficient review of RV&S Test Session runs. Furthermore, SPK provided the company with a Validated Cloud Environment hosting PTC Windchill RV&S, Computer Systems Validation covering IQ, OQ, and PQ, and Application Management Support for the environment.

RESULTS

After implementing the Medical Device Solution Template, this medical company's product development efficiencies for Risk Management, Requirements Management, and Test Management improved. It worked so well that they shed weeks off of their development/release cycle. Furthermore, errors were reduced by 50% on the test floor due to the reduction of manual steps. Lastly, requirements and test management are completely integrated and traceable with a few clicks, with a traceability exception report available at the push of a button. This saves them several weeks of manual effort creating the report, as it can now be done within minutes.

With SPK's help, this medical company streamlined their processes, leaving them extremely happy.

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> **THE BIGGEST BENEFIT HAS BEEN THE ABILITY TO START ENTERING DESIGN INFORMATION INTO THE PTC ENVIRONMENT FOR A CRITICAL ON-GOING DEVELOPMENT PROJECT. THIS SETS MY ORGANIZATION ON THE PATH (ALBEIT PERHAPS A LONG ONE) WHERE WE TRANSITION OUT OF DOING SO MANY DEVELOPMENT TASKS IN SUCH A MANUAL FASHION AND START RELYING ON AND LEVERAGING A MUCH MORE EFFICIENT APPLICATION/SOFTWARE LIFECYCLE MANAGEMENT TOOL TO HANDLE REQUIREMENT DEFINITION, RELATIONSHIP TRACING, DOCUMENT AND REPORT GENERATION, ETC.**
>
> *Business Leader*

To learn more about how SPK can help you get started with Windchill RV&S, contact us today.