Streamlining Design Controls For A Leading Medical Device Maker

SPK helps this global enterprise to boost product development efficiencies, increase compliance reliability, generate reports with a single click, and shave weeks off their development/release cycles.

The Client

A respected global medical device powerhouse, with more than 50,000 employees in scores of countries worldwide, had hit a wall when it came to product development. The company—which develops, manufactures, and markets innovative medical products and services to the healthcare industry—was developing more and more complex systems. Yet their controls for this process were limited. In fact, they were largely manual.

They knew it was time for a change: from clunky Excel sheets (and Word docs!) to an advanced PTC Windchill PLM (product lifecycle management) solution, and from antiquated on-prem systems to a robust and always-available cloud setup—and from taxing their internal IT department to freeing them for core, keep-the-lights-on tasks.

A Kluge That Was Past Its Time

Prior to this company's decision to implement PTC Windchill RV&S (Requirements, Validation & Source) for design controls, they had used a primarily manual system, based on Excel spreadsheets and Word documents. All of these manual processes required excessive effort for basic daily requirements such as:

- Establishing and maintaining traceability across all the design artifacts
- Performing change management
- Providing managers with adequate visibility into the state of development

(Indeed, when SPK and Associates was called in, the usually rapid initial requirements definition-and-review phase of our engagement dragged on for a full eight months. The reason? These people were simply so bogged down with all of the manually-intensive processes they wanted to streamline, that they simply lacked the time!)

Other Parts Of The "System" Were Equally Creaky:

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

Accelerated product releases by 4 weeks

Risk Managment available

One-click Traceablity Reports

- PVCS Tracker system for bug tracking and change management of the source code. The Integrity system was several years old; the PVCS Tracker was so old that it had already been deprecated (read: "no longer supported") by its manufacturer.
- The company's internal IT department was over-burdened with the prospect of trying to manage outdated on-premise systems; this underscored the need for a migration to the cloud.

A Multitude Of Requirements

Clearly, there was a lot of room for improvement—but there were numerous considerations:

- The new design-controls solution 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, the Quality Management System standard for Medical Device manufacturing; ISO 14971, the Risk Management standard for Medical Devices; and IEC 62304, the Software Development Lifecycle standard for Medical Devices.
- Speaking of compliance, the new solution would need to meet FDA requirements, and those of the company's own internal Quality Management and Regulatory auditing teams.
- Importantly, 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 a standard solution template which is very generic. But it's loaded with demoware, which is good for demonstrating the potential of the product, but not necessarily a good starting point for configuring a customer-specific solution.

How, then, did SPK and Associates rise to meet these manifold challenges?

Better, Faster, Cheaper

Today, the new cloud-based Jira system is working wonders for this IT team. It adds the flexibility that their previous system lacked. It handles both the routine and one-off requests. Importantly:

- SPK and Associates saved this client some 16 hours of configuration time which they lacked the bandwidth to perform.
- We advised them on best practices and how to "future-proof" the setup.
- Even with its many advantages, the new system actually costs them less than their old system, especially with their nonprofit discount.

The Solution

SPK and Associates implemented a tailored Design Control solution that was based on the SPK Medical Device Solution TemplateTM. This is a streamlined configuration that's optimized for medical device product development.

It starts with the out-of-the-box PTC Windchill RV&S platform. But it then pares down the configuration, leaving out all of the demoware and other extraneous features. This is because the computer system validation (CSV) requirements for the medical device industry would require that any such extraneous features be either removed or disabled—and then their removal or disabling verified.

Thus by starting with a clean configuration that's optimized for medical-device development processes, the customer configuration could then be developed and certified much more quickly than by creating a custom solution from scratch, or by attempting heavy reconfiguration of the generic PTC systems-engineering solution.