

Lean Process Transformation in a Medtech Organization

Challenge

The customer is the US subsidiary of a global European technology group from the medical engineering industry. Strict market regulations require compliance with FDA, IEC 62304, and many other standards. Very high-quality standards also apply to the product, process, and tool verification and validation.

The company moved to Agile a decade ago and launched successfully two Agile Release Trains (ARTs) according to the Scaled Agile Framework (SAFe 4.0). These ARTs were a great success, however, the company was not able to replicate their success on a larger scale and to clearly prove compliance to regulated requirements. There was a great amount of discussion back and forth to discuss the actual, and concrete implementation of SAFe. The used QMS was not able to cope with endeavor-specific configurations, user responsiveness, changes due to further development of the SAFe and finally to prove compliance in there environment.

Solution

It was decided to start a pilot with Applied SAFe as Lean QMS. Applied SAFe is an interactive and tool-agnostic framework of how to achieve business agility in a regulatory compliant way. The internal LACE team was trained to lead the further customization of Applied SAFe.

The concept was to adjust just as little as absolutely necessary which resulted in a Reuse-Rate of almost 90 %. Defined roles, their interaction, and supporting artifacts, enabled a clear and common understanding for all participants. Roles were used as is in Applied SAFe and enhanced with specialized responsibilities, the concept was to keep number of additional roles to the existing roles as low as possible.

Existing process assets like 'SOP's' were integrated into Applied SAFe. With the use of Applied SAFe's organizational processes assets, agility and compliance of activities could be established as self-proving evidence.

Existing Tailoring as from Applied SAFe, was used in it's basic possibilities. Further tailoring was built in later for better adjustments of endeavors, e.g. Hardware-/Firmware endeavors vs. pure software endeavors. With that, Design Controls were established in an agile manner.

"When we discovered Applied SAFe we were relieved! This solution makes it possible for us to adopt SAFe to deal with the complexity within our organization, even though it's regulated and has compliance challenges. This platform helps our organization reduce waste and do what is really needed, which allows us to have lean processes so we can bring our product to market."



Daniela J.,
Medical Device Industry

Benefit

With these measures, the company has reduced the complexity of its processes by around one-third. Today, the departments collaborate much more closely, enabling them to permanently reduce their error rate in the field to "almost zero". The successful certification of products in the USA proved the correctness of the chosen scaled agile way of working for the medical device organization.

Applied SAFe was such a success that it was soon rolled out on the ARTs and later as an enterprise-wide solution. While the SAFe transition is still ongoing, assessments show that the general knowledge base on SAFe practices had improved considerably. Furthermore, thanks to the Applied SAFe platform, the organization was able to gradually integrate teams who were out of scope into the SAFe transformation.

Results

The new process flows were optimized and harmonized in a series of workshops together with practitioners. As a result, the customer has achieved cross-department process understanding and has also harmonized and simplified workflows significantly.

- ✓ Process complexity reduced by over 30%
- ✓ Design controls were identified and defined
- ✓ Successful certification and validation of products
- ✓ Tool validation to regulatory needs
- ✓ Established compliance in scaled agile processes
- ✓ Reuse rate of 90% in the Lean-QMS achieved.
- ✓ Ready for compliant pilot within 6 weeks.
- ✓ Organization executes lean-agile process engineering by themselves after 5 days of training and 2 months support by PEDCO.

Talk with us!

We are well aware that this anonymized case study may not include enough details as expected, but it's hard to provide the right content without flooding you with too many details. As you have read this case study, we assume that you are interested in a pragmatic solution. So we would love to find out what you are looking for in reality, to show you your information wanted and to see if we can be of any help towards your goals.

Let's start talking in a free session: pedco.appointlet.com