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Saving money and making regulatory document management easy with Compliance Navigator

For SpineWelding AG, Compliance Navigator makes major savings in time and money and ensures they develop in the right direction. We spoke to Felix Kraeft about the difference the tool has made.

Background

SpineWelding AG is a Swiss medical device company that develops implant solutions for the human spine, using the patent-protected BoneWelding technology. This ultrasonic-based technology uses biodegradable liquid polymers that enable immediate bone stabilization and avoid the need for further operations to remove the implants.

Felix Kraeft is SpineWelding's Head of Quality and Regulatory Affairs. "Initially we were purely a small development company, almost a university spin-off," he explains. "We were making great strides scientifically, but had little formal regulatory structure."

But this changed from around 2018 as the company started looking at entering new markets. It plans for US market entry in 2021 and expects European market clearance in 2022.

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Spine Welding

"What an invention! I don't know how we managed before."

Felix Kraeft,
Head of Quality and Regulatory Affairs,
SpineWelding AG

Customer need

The challenge for Felix and his small team is not only to ensure their products are in line with the latest requirements, but also to find out about coming changes that could shape their product development. This is particularly important as SpineWelding looks to enter new markets. For example, the new European Medical Device Regulation (MDR) took effect in 2020, making significant changes to previous regulations that developers and manufacturers needed to know about well in advance.

Before using Compliance Navigator, it was hard for this busy team to find the time to keep checking standards and requirements. "With all the daily work and the big plans, it was too easy to fall behind on that," explains Felix. "We did our best, but it kept getting postponed. Every time we were set to do it, something more urgent would come up."

This had the potential to cause major problems, because standards are very important to product development. "How can we develop the right things if we don't know the latest state-of-the-art requirements?" asks Felix. "As developers, we come up with all sorts of great ideas, but it's essential for us to know if the requirements make them impossible or we just waste time and money on design and development. What's more, it's about being on top of requirements all the time – every week, not just two or three times a year. Otherwise we could be investing in the wrong direction for months, which would really hurt our small company."

"The training we received was very, very good."

Felix Kraeft, Head of Quality and Regulatory Affairs, SpineWelding AG

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The solution

With this situation preying on his mind, Felix looked for a solution and found Compliance Navigator.

The biggest attraction for him was the 'push messages' – the alerts that notify users of every relevant new development. "And soon as I tried the system, I knew it would save us a lot of headaches," he says. "We wouldn't have to think about checking requirements anymore; it would just be done for us."

It would also be very helpful to have their whole library of standards in one place, so it can be used across the organization. Although the regulatory team is small, the internationally-based engineers also need to stay completely up to date. Compliance Navigator was a way to equip them with their own one-stop source, while also alerting Felix to any training needs.

The SpineWelding team took advantage of the training offered by BSI, which is described by Felix as "very, very good." They needed a little practice, but before long they were familiar with the system and able to take advantage of all its tools.

"It alerted us when [key standards] were changing. That saved us tens of thousands of euros."

Felix Kraeft, Head of Quality and Regulatory Affairs, SpineWelding AG

Customer benefits

Compliance Navigator has transformed the lives of the team. "What an invention!" says Felix. "I don't know how we managed before."

For Felix, the best feature is the alerts. "It's an outstanding service," he confirms. "It's just so easy, and now we're always on top of the situation. It means we're always up to date without having to think about it."

But there are two other features that the team find particularly time-saving, and that also give peace of mind. One is the redlining that shows the difference between current standards and new versions, so users know they've picked up every change. The other is the expert commentaries; these are useful if there's any uncertainty on how to interpret a document, because they provide certainty and clarity.

The system has been designed to be as useful as possible to its users. One example is that users can put standards in different folders for different projects "At first we didn't think we needed to do this," admits Felix, "but very soon after using it we discovered that it was a good idea, because now the alerts we get are project-related and we can set up folders according to our project priorities."

The company has also seen a major financial advantage from the tool's early-warning system. "For example, it alerted us when the ISO standards for biocompatibility were changing," explains Felix. "We could read the draft versions and understand how on top of things we were. We could conduct testing in line with the new requirements, instead of finding out too late and having to retest. That saved us tens of thousands of euros."

The decision to use Compliance Navigator has paid dividends for SpineWelding. That's why we've just extended our subscription.

"Our development process is now more connected to upcoming regulations than ever before, which saves us time and money and stops us going in the wrong direction."

Felix Kraeft, Head of Quality and Regulatory Affairs, SpineWelding AG

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The Digital Revolution in Regulatory Document Management

Work smarter with the only platform designed by regulatory experts to manage your compliance process.

Digital tools that save time and money

Compliance Navigator holds over 5,000 documents essential for medical and IVD device compliance. With true multi-user access, it's available to your entire team, simultaneously.

- Alerts to changes

  Receive alerts as standards* change, so you can plan accordingly.
- Track changes

  Find it easy to see what's new, with 'red line' changes between versions.
- A comprehensive source

  Access over 5,000 internationally recognized Standards, the full text of the new Medical Device and IVD Regulations, MDSAP Regulations.
- Profiles and Templates

  Create and export regulatory profiles and templates, so you have the information you need in one place – right down to what's relevant to each aspect of development.
- Expert commentary

  Interpret new standards correctly and assess the impact of changes on specific devices as our experts provide context and guidance.
- MDR/IVDR and MDSAP Smart Support

  Understand how the regulations apply to your business and devices.

* All standards including third-party standards ASTM, AAMI, CLSI – alerts for current to withdrawn status.

In addition, for all BS and British-adopted standards – alerts on upcoming changes when a project for a new or revised standard is underway, from proposal to approval and publication. Access to the Draft version when the project is at the Draft for Public Comment stage.

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Find out more

To find out more, arrange a demonstration or request a quote: https://compliancenavigator.bsigroup.com/

T: +44 (0)20 8996 7029

E: cservices@bsigroup.com

bsigroup.com/complinav