Axonics

Accelerated workflow and a 50% cost saving with Compliance Navigator

'It was easy to purchase, because I could see immediately that our company spent more on individual standards per year than we would pay for Compliance Navigator, with access to many more standards, so it was a simple decision to make.' BSI spoke to Rinda Sama of Axonics Modulation Technologies to learn more about why they chose Compliance Navigator as their solution to manage compliance.

> "It's not just the direct time saving of locating information quickly, it's a much faster, accelerated workflow."

Background

The Axonics Modulation team brings over 15 years of medical device design and development experience to their products, which include an innovative new implantable system to treat urinary and bowel dysfunction. The Axonics Sacral Neuromodulation System™ is the first CE-marked rechargeable SNM system designed to improve the experience of both clinicians and patients suffering from Urinary and Fecal dysfunction.

Biomedical engineer Rinda Sama comes from a medical device design background and as VP for Operations, Quality and Regulatory Affairs now heads up the team responsible for design, engineering, and manufacturing compliance. He's worked with BSI's notified body for 15 years.

bsi.

...making excellence a habit.™

The customer need

'It's an additional burden on the company to keep buying individual standards. Moreover the standards are not static, new updates and revisions are released almost every other year.' As part of a team that has developed and sold three medical device start-up companies, Rinda had experience of the different methods of purchasing standards. He found that the large database model could be very expensive and so prior to investing in Compliance Navigator, Axonics Modulation Technologies were purchasing single standards.

Rinda's team experienced the drawbacks of the single standards model. Licences for single standards were available only on a single computer, and it was difficult for the start-up to justify the cost of multiple licences. '*This was a problem,*' says Rinda, '***because determining the applicability of a particular standard, and appropriate test methods is a collaborative effort. The whole team had to be able to see the standard, particularly colleagues from engineering, and decide whether to test to a certain requirement, or meet that requirement.***'

With such a brand new innovative product, the question of applicability was particularly difficult.

> "The applicability of a particular standard is a collaborative effort. The whole team had to be able to see the standard."

Both cardiac and neuro medical device products have leads which are placed inside the body. As the patient moves, the leads need to move with them. So the lead is subject to the mechanical stresses of movement. As neuro is an area of innovation, neuro standards don't specify the number of cycles needed to test bending of the leads and establish that they can move safely. The team needed access to standards in order to assess applicability, so even though a specific standard may not be applicable to a particular product line, they needed to be able to determine that this was indeed the case.

Equally, there could be testing and validation methods described in some standards that were relevant to the R&D and compliance process for new products. For instance, standards in the neuromodulation space are not as mature as cardiac standards, because implantable systems are a relatively new product in this area, so the team needed information from a wide variety of standards to help them develop test methods that would qualify the new products, and ensure they are safe from a patient perspective.

As developers of an innovative new product, Rinda's team also needed to know when standards were changing, to make sure they were ahead of the game, and could take the product through testing and compliance all the way to sale, without being tripped up by changes to standards that they hadn't been aware of.

The solution

A BSI roadshow offered Rinda the answer to these workflow issues, when he saw a demonstration of Compliance Navigator. He followed up with a live demo and made a purchase. As Rinda notes; '*Everyone can now access and review the standards. And for applicability, **I don't have to buy single standard only to find out it is not applicable to the product I'm developing.***'

Compliance Navigator offers Axonics Modulation Technologies an enormous amount of standards covering many different aspects of medical device design, but without the cost burden of a large database.

'It's not expensive like the old fashioned databases used to be,' he says, 'and that's another reason we like it so much.'

The team were therefore able to use Compliance Navigator to search, review and determine the most appropriate tests for developing brand new products. For example, they were able to review several different standards and found that the cardiac standards had the best and most detailed information on how to ensure the lead would be safe. The cardiac standards were used to qualify the implantable lead on the new neuro product and make sure it was safe for patient use.

A couple of months after initial purchase, the entire company had moved to using Compliance Navigator. *'There's no-one who would want to go back to the old system now,'* Rinda explains. Soon after mastering the basics, they began to explore the additional features of the product, and were particularly impressed with the ability to group individual standards together and then share the different groups with different teams and colleagues according to the product they are working on.

After being tied to one computer that contained standards, the ability to share information with different team members is one of the strongest features, but most important is the notifications feature: *'It's a great tool, especially when we are in the middle of testing or the middle of regulatory review.'*

> "I immediately subscribed because I could see all the problems with single standards were solved with one subscription."

Customer benefits

Axonics Modulation Technologies have experienced a direct time saving as a result of switching to Compliance Navigator. But more powerful than this saving is the accelerated workflow they experience now that they have access to the information they need:

'If someone asks me something in a meeting, I can quickly check the information. Before, I would have to note it down, go away, check at the computer that has access to all the standards and report back at the next meeting, which might be a week later. Now I can provide an answer straight away. It saves a tremendous amount of time. So it's not just the direct time saving of locating information quickly, it's a much faster, accelerated workflow.'

Compliance Navigator makes standards more immediate, not only for Rinda, but also for the people who work for him. *'They don't have to come to me for standards advice; they can access it, and come to me for clarification. They are empowered to review it for themselves.'*

Compliance Navigator saves time, and '***time always turns into money***', as Rinda points out. He estimates a 50 – 60% cost saving on compliance in the R&D phase, by eliminating the time spent searching for applicable standards. The team can now spend their time more efficiently; using their general medical device and specific product knowledge on reviewing and evaluating standards.

> "Now, everything we need is at our fingertips."

Take the smart route to compliance

There is no room for error in medical device standards. You need all your team working with the same information, wherever they are. You need them to know when it is going to change, the instant it changes and to know what those changes mean for your devices. BSI's Compliance Navigator is the smart, simple way to manage your medical device compliance with UK and EU requirements – helping you to get to market faster and maximize your ROI.

Smart tools that save time and money:

- **Alert notifications** – discover when standards are due to change and have changed
- **Track changes** – easily assess and review revisions between documents
- **Expert Commentary** – understand the correct interpretation of new standards
- **Product profiles** – store information by relevance to each medical device
- **Search by device** – quickly view each documents applicability by device type
- **Universal access** – unlimited company-wide access to view, share and review over 2000 UK, European and Internationally adopted standards and regulations

Make the change

Use Compliance Navigator to help you avoid risk, stay competitive and maximize profitability.

Find out more

To find out more, arrange a demonstration or request a quote:
T: +44 (0)20 8996 7029 E: cservices@bsigroup.com
bsigroup.com/complinav

BSI Group
389 Chiswick High Road
London, W4 4AL
United Kingdom

T: +44 845 086 9001
bsigroup.com