



A new approach to managing standards with Compliance Navigator

We spoke to Louise Hollywood, Quality and Regulatory Associate, at medical device company Tissue Regenix, about the impact of Compliance Navigator on their use of standards.

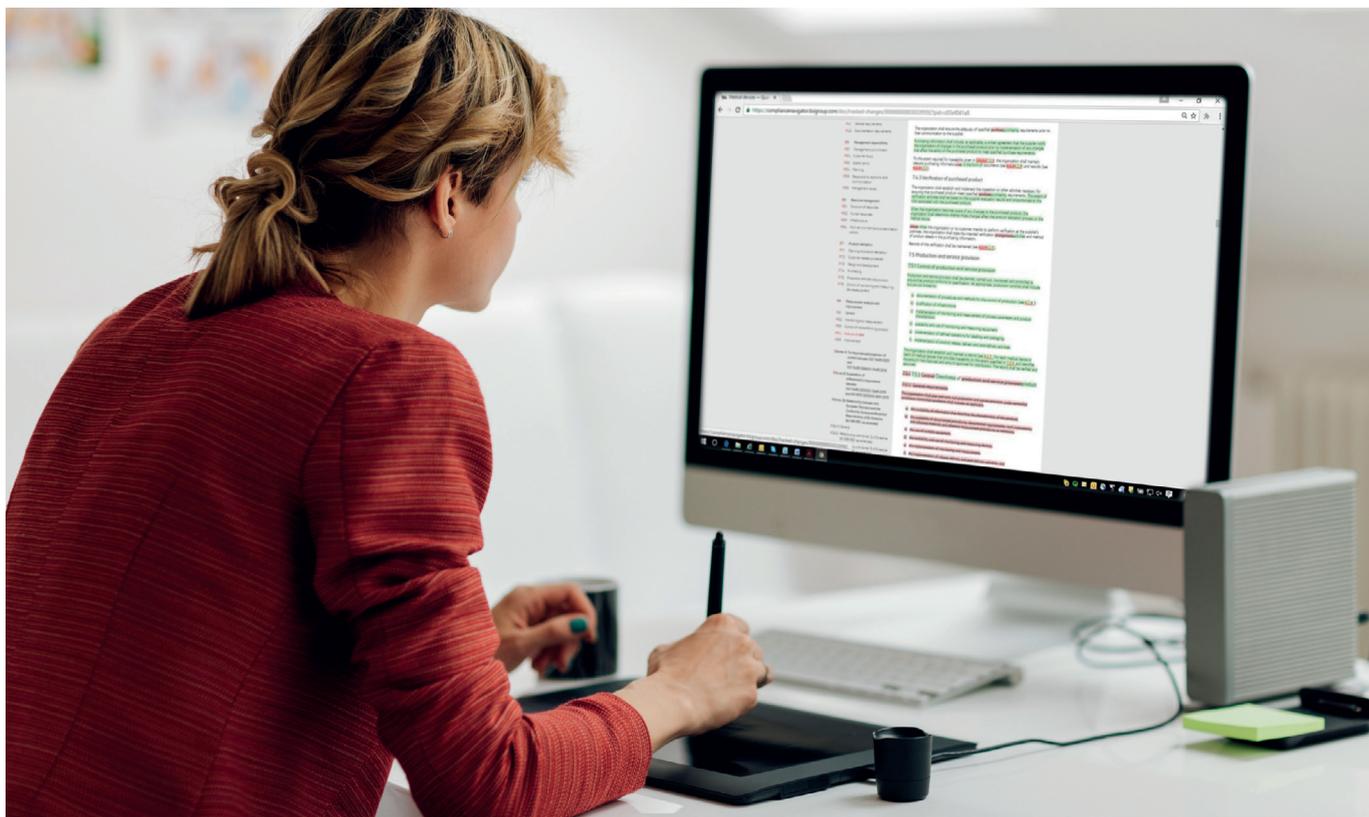
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Background

Tissue Regenix were spun out of the University of Leeds in 2006 to commercialize academic research conducted by partners around the world in the field of regenerative medicine. Louise moved from the manufacturing side of the business to regulatory affairs two years ago and began a thorough review of the way standards were used throughout the organization.

Like many small companies, different stakeholders and

departments had different access to standards. Some had come to the company with new staff as standalone PDFs, some were purchased online. There were different formats, including paper, and no visibility on what the company had access to overall. The company found out about Compliance Navigator from BSI, and immediately saw that the product could simplify the use of standards.



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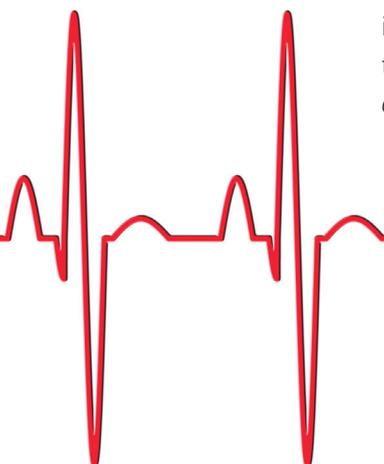
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The customer need

The purchase of Compliance Navigator was part of a larger, strategic approach to the way standards were used throughout the company. The aim was to make the same, up-to-date standards available to all departments:

“... it was the way that the company wanted to access standards that led to the decision to purchase Compliance Navigator. I don't think people would've used it if it had been a file in a room and they had to go in each time to find a standard. Online, universal access was a big point.”

Tissue Regenix wanted colleagues to be able to access critical standards information from home, and to standardize access from their UK base and US office. Providing resources that could be used across the organization, rather than by a few specialist users, meant the resource had to be robust and easy to use. The easy set up and implementation of Compliance Navigator coupled with its online, universal access to standards influenced the decision to purchase. *“Overall it was just what we needed; a place that was controlled where people could access standards in a really easy way.”*



The solution

When developing new medical devices, it's vital that standards are built in to the conceptualization and design stage, so teams know they can get a device all the way to market.

Tissue Regenix have three products at present and have set up product profiles, linking relevant standards to each profile to make it easier to track all applicable information. *"This feature has been particularly useful to us... Our staff is split into teams across different areas of the business and are based in different locations. Knowing they can go into Compliance Navigator, open the relevant product profile and access everything they need to be looking at is not only a real benefit but provides a level of confidence that they will not be missing vital information that may impact the work they are doing."*

With a lengthy development and testing process for many devices, it's also important to have visibility on future changes to standards. Compliance Navigator won't only inform teams at Tissue Regenix that standards have changed, but it will also let them know what is going to change. A particular case in point is the upcoming revision of 13485. Compliance Navigator's redlining of documents feature means all the changes to the standard are clearly highlighted, a benefit the teams have said that is invaluable in saving time. *"This is a really great feature as we can use the marked-up document to carry out the audits, see where the changes are and what we need to be working to."*

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Customer benefits

Tissue Regenix received two training sessions when they purchased Compliance Navigator, one for the team who needed to build and maintain the product profiles and one for colleagues who needed to view standards. The sessions were tailored to the specific needs of Tissue Regenix: *"It was really useful that the BSI training team came in and tailored the sessions to our specific needs. The sessions helped us to understand how we could integrate Compliance Navigator in our workflows."*

The training, product profiles, search tools and 24/7 access to the same up-to-date, compliance information has made the teams much more enthusiastic about referring to standards at every stage of their workflow. Before the company invested in Compliance Navigator, it was necessary for a researcher to work out who owned a relevant standard and request it

to be sent to them or even go and photocopy it as appropriate, adding more time to an already time-pressed process. With Compliance Navigator, Tissue Regenix researchers have individual logins and passwords, this ensures they have access to essential standards all day, every day.

Making standards easy to access has also driven usage, embedding this vital information in all areas of the workflow and meeting the company's key strategic aims. In a final comment, Louise said, *"We're really pleased with Compliance Navigator. While we've only been using it a short while, we've already experienced the benefits and made time-savings in our processes. We look forward to exploring how the new features of Compliance Navigator, such as template management for managing multiple product profiles from one place, will help us to further improve our productivity."*

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:

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