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## Simpler, speedier management of regulatory information with Compliance Navigator



In an era of ever-changing international standards, it's very hard to run a manual compliance system. The Robinson Healthcare team are enthusiastic converts to Compliance Navigator. We spoke to the person who recommended it: Senior Regulatory Affairs Specialist, Jane Davies.

### Background

Robinson Healthcare, now part of the Vernacare group, has over 180 years' experience of working in partnership with healthcare professionals, pharmacists, retailers and consumers. It operates in three distinct market sectors.

Its Professional Healthcare range includes single-use instruments for surgical, gynaecological, podiatry and dental procedures. These are complemented by medical cotton wool and absorbents, patient and surface wipes, and professional woundcare products.

As part of the Personal Healthcare sector, it offers innovative first aid products for the

home, plus market-leading beauty and baby care cotton wool products, earplugs and continence care items.

Jane Davies is the company's Senior Regulatory Affairs Specialist. Her responsibilities include maintaining and creating technical files for medical devices, and approving promotional materials (IFUs, labelling etc.) She also contributes to the multifunctional effort to create new products, and she is responsible for surveillance of any complaints.

The team is small, with one other full-time employee and two people working part-time.

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**Robinson**  
Healthcare 



“The standards were always up to date. There’s no need to go looking, because it tells you when they’re going to be reviewed. To have the most recent standards to hand was absolutely brilliant.”

## Customer need

Historically, the Quality team had always looked after regulation. As a small team, they were often overstretched.

Buying standards on an ad-hoc basis, they would often have to buy a particular standard ‘just in case’, before knowing whether it was relevant to them. If the standard turned out not to apply, they had wasted time and money; if it was relevant, they had to buy further copies for each site where it was needed.

Keeping abreast of changes was another huge challenge. When Jane arrived at the company and started reviewing technical files, she had to trawl through standards and check that they were using the most up-to-date versions. This was time-consuming and tedious work: it involved searching through the websites of BSI and other standard-setters to see whether a newer standard had been issued, and if so, working out whether the changes had implications for her company.

## The solution

Before coming to Robinson Healthcare, Jane had trialled an early version of Compliance Navigator before it was even launched. “I was already convinced at that stage that it was going to be an absolute godsend,” she says.

So when Jane joined Robinson Healthcare, she suggested a demonstration and a trial of Compliance Navigator. The company instantly understood the benefits it could bring: everyone across the business would immediately have access to the most up-to-date standards, not just whichever one a particular department had bought.

“The Quality team completely bought into it,” confirms Jane. “They were absolutely gobsmacked by how easy it was.”

Implementation was straightforward. Jane recalls that “it wasn’t a problem at all. We got sent a link and we just accepted it. BSI came in and did the training for us and we just got on and did it. A few things like linking documents took a bit of explaining, but it’s pretty intuitive.”

## Customer benefits

Jane enthuses about the system. "If anything changes, we get notifications from Compliance Navigator saying that a standard is being reviewed. We get the opportunity to look at draft documents and comment on them. It's a great benefit because it's preparing us for what's likely to happen. That means we can get ready for it, which is much easier than trying to backtrack once a standard has been released."

Peace of mind about accuracy is also a major benefit. "Previously, it wouldn't always have been obvious that a standard was out of date. But now the team can be certain that they're using the most accurate and up to date information."

The majority of Robinson's products are fairly long-standing. But now that they have their own manufacturing facilities in China, they are improving some of these legacy products with novel designs and materials. One recent example is a mouth prop, used in dentistry and facial surgery to hold open the jaw. They replaced a metal version that had a detachable tether with a plastic one where the tether is integrated, and they needed to know the implications of the various standards. Compliance Navigator makes it easy to ensure compliance; the system is regularly consulted by teams in product development, manufacturing and marketing.

Compliance Navigator also helps with issues as diverse as risk analysis, bio-compatibility and labelling. In all these areas, standards have been changing recently, so the 'track changes' feature is very popular. Jane and her team simply pass on update notifications to the relevant teams. "No-one has to sit down with two documents and compare them side-

by-side; they can literally go in and see the changes highlighted. It makes it a lot easier and a lot quicker to do the comparison, because it's already done for you."

What else is useful? For some of the longer standards, there is an expert commentary which walks them through all the changes and explores how those changes might affect them. If they're not sure whether a particular standard is relevant, they can contact BSI through Compliance Navigator and get specific advice.

"And of course Compliance Navigator has improved since we had it," adds Jane. She gives the example of a recent enhancement: instead of having to update each product profile when a standard changes, users can update all the relevant profiles simultaneously. Again, this is a major time saver. Another improvement is that while at first Compliance Navigator contained just BSI and ISO standards, other international standards are being added to the system and Jane finds this helpful.

Robinson Healthcare is convinced: Compliance Navigator certainly saves time and – through its labour-saving – it also saves money. It helps with accuracy and compliance, and it makes handling audits easy. As a result, Compliance Navigator is now being rolled out to its sister company Vernacare.

"That's the beauty of it," continues Jane. "The licence is multi-site and we can have up to 999 users at any one time, with different levels of access. Everyone around the group can have sight of one standard, whereas before we had to purchase separate copies of each standard for every site."

# The Digital Revolution in Regulatory Document Management

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## 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

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