bsi. Compliance Navigator
for Medical Devices

The Japanese market discovers the benefits of Compliance Navigator

We asked a leading Japanese medical devices manufacturer about the background to adopting Compliance Navigator and the benefits it has brought them.

Background

The client is a leading Japanese medical devices company that develops, manufactures and sells medical devices all over the globe.

It uses Compliance Navigator to help with acquiring and updating licenses and permits in countries around the world; obtaining and sharing information about laws and regulations; and monitoring and sharing technical standard trends.

Customer need

The company operates globally, so the process of obtaining and sharing information about standards and regulations takes an enormous amount of time.

There is also a language barrier. Although information is available in English in many markets, in certain markets (such as the Chinese-speaking world and Asia), official documents are sometimes in the local language – and this makes the team's work more difficult. In the past, they had to take a slow and steady approach to researching regulations by accessing the websites of the regulatory authorities in each country and gathering information from local sales bases.

The solution

Compliance Navigator has been rolled out in the Japanese market, and this company was quick to act as an early tester. The team was seeking a high-quality solution to the challenges of gathering and sharing information about standards. In particular, they wanted to be able to track revisions to standards and access Expert Commentaries wherever they linked to the company's various initiatives.

Customer benefits

"What appealed to us was that Compliance Navigator covers not only medical devices standards but a wide range of other standards," said a key team member. One example is the EMC standards. IEC 60601-1-2 is the EMC standard for medical devices, but it's also necessary to check details in individual

EMC standards. “Other services we tried that the team were limited to medical device standards only, but with Compliance Navigator we can view reference standards in the IEC 61000 series as well, which is extremely convenient”.

The tool also includes Expert Commentaries about key standards, which the team found useful for interpreting the standards. One such example, ISO 14971, was revised in December 2019 – and because the Expert Commentary was posted immediately, they were able to read it first to gain a general understanding before reading the official text of the standard.

Another popular feature is the Tracked Changes function for key standards. This compares the new standard with the old standard, making it easy to see which parts have changed or been deleted and added, and helping the team to grasp the changes to standards.

Compliance Navigator also allows the team to confirm the status of revisions to reference standards straight away. For instance, before ISO 14971 was revised in December, Compliance Navigator showed that revisions were in progress. Furthermore, simply by opening the relevant page, the team could tell immediately that there were moves to revise the standard.

With Compliance Navigator, the team can work faster and more accurately, giving them a competitive edge in the market.

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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 4,900 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 4,900 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:

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