



Why IceCure will never go back to their old ways of working

When they listed all the hidden costs and frustrations of trying to purchase and manage standards, the IceCure team realised that Compliance Navigator was exceptional value. We spoke to the company's VP Shay Levav to find out more.

Background

IceCure Medical is an Israeli medical device company founded in 2006 to advance treatment of cancerous tumours. IceCure's core technology is based on cryoablation, using freezing temperature (liquid nitrogen) to destroy tumours safely, quickly, and painlessly without the need for surgery.

Their next generation cryoablation technology, the ProSense™ system, enables rapid, minimally-invasive, safe and effective treatment of breast lesions.

IceCure's Vice President of Regulatory Affairs, Quality Assurance and Clinical Applications is Shay Levav. He has nearly 20 years of healthcare management experience.



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Customer need

Like any other medical device company, IceCure not only has to comply with a wide range of standards: it also has to demonstrate that compliance. That's challenging enough, but of course the standards change over time. Even though IceCure had bought a particular standard, they had to actively check and research any changes to it.

Shay says: “it was a very manual process. We did subscribe to some websites to get updates, but even so we had to dig into the data and look for it. And then after we found a change, we had to go and learn more about it to see if it was applicable to us or not. Sometimes the changes are transparent; sometimes they are more complex and require us to do testing and other activities.”

IceCure is a relatively small company, with around 65 people. So it had very few people who could monitor these changes from a quality or design perspective – and doing that was taking them away from the more added-value parts of their jobs. It became clear that they had to find a way to automate the work with a higher-quality solution.

The solution

Shay's team calculated the costs of buying the individual standards, but then they looked at all the indirect costs: managing the library of purchased standards, making the relevant standards available to the right people, monitoring changes and trying to understand them.

"And all of those brought us to the decision to look for a tool to do it, specifically BSI's Compliance Navigator," says Shay. "We'd heard good things about it. And of course, we received demos and researched the capabilities of the system, and that is why we decided to go with BSI."

The implementation was straightforward. "For us it was fairly easy because we had

a file with all the applicable standards that we used to manage manually. And what we did was to find those standards in the library and put them in the right place so everyone can access them. Once we did that, we just extracted the information from the system and made the comparison to check that we'd uploaded everything properly. And from that point, we were working with Compliance Navigator."

They arranged two BSI training sessions and went through all the capabilities to show the team how the system works. "It's very simple and very straightforward – there's not too much need for refreshment. Our R&D team is working very closely with this tool; in fact they work with it on a daily basis."

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Customer benefits

"The crucial benefit is that we're up to date," explains Shay. "This is vital because it then helps me with audits, and with time planning and implementation."

He continues: "One of the auditors' questions is always 'how do you follow online standards?' With Compliance Navigator, you can present it to the auditors and show them that you have access to the right library. It immediately addresses the question. They realise that you're professional about this and it helps the rest of the audit go better as well."

On the topic of time planning, Shay thinks back to the previous way of working. If there was a change to a standard on January 1st but he only looked for it in April, then he would potentially lose three months of implementation time. This would have knock-on effects in wasted effort and late changes.

He cites a real example: IEC 60601 is one of the main standards in terms of electrical safety.

When the fourth edition was issued, IceCure analysed the changes. But they originally missed a specific detailed change, and then had to go to the lab to plead with them to conduct an urgent test so that they could hit a deadline. This incurred additional costs and led to questions from a registrar in one particular country.

We asked Shay whether Compliance Navigator would have avoided this problem. "Yes, such things will not occur now. We are getting notifications from the system, and supportive documentation every time there is a change. This is very helpful – instead of looking for the data, it is being pushed to us. And this is a big difference... We will use the experts' notes and get more details about each change."

Overall Shay is clear that the new way of working is here to stay. "Although the direct costs of the service are higher than the costs of the standards, we have saved all sorts of indirect costs that are more complicated to evaluate. But I can tell you that the decision to go with the tool wasn't so complex, because there is the understanding that it brings a benefit. The organisation understands the benefits."

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