

## Transforming the management of compliance with Compliance Navigator

BSI spoke to Krupa Srivastava and Adam James from Smart Surgical Appliances Ltd to learn more about why they chose Compliance Navigator as their solution to manage compliance.

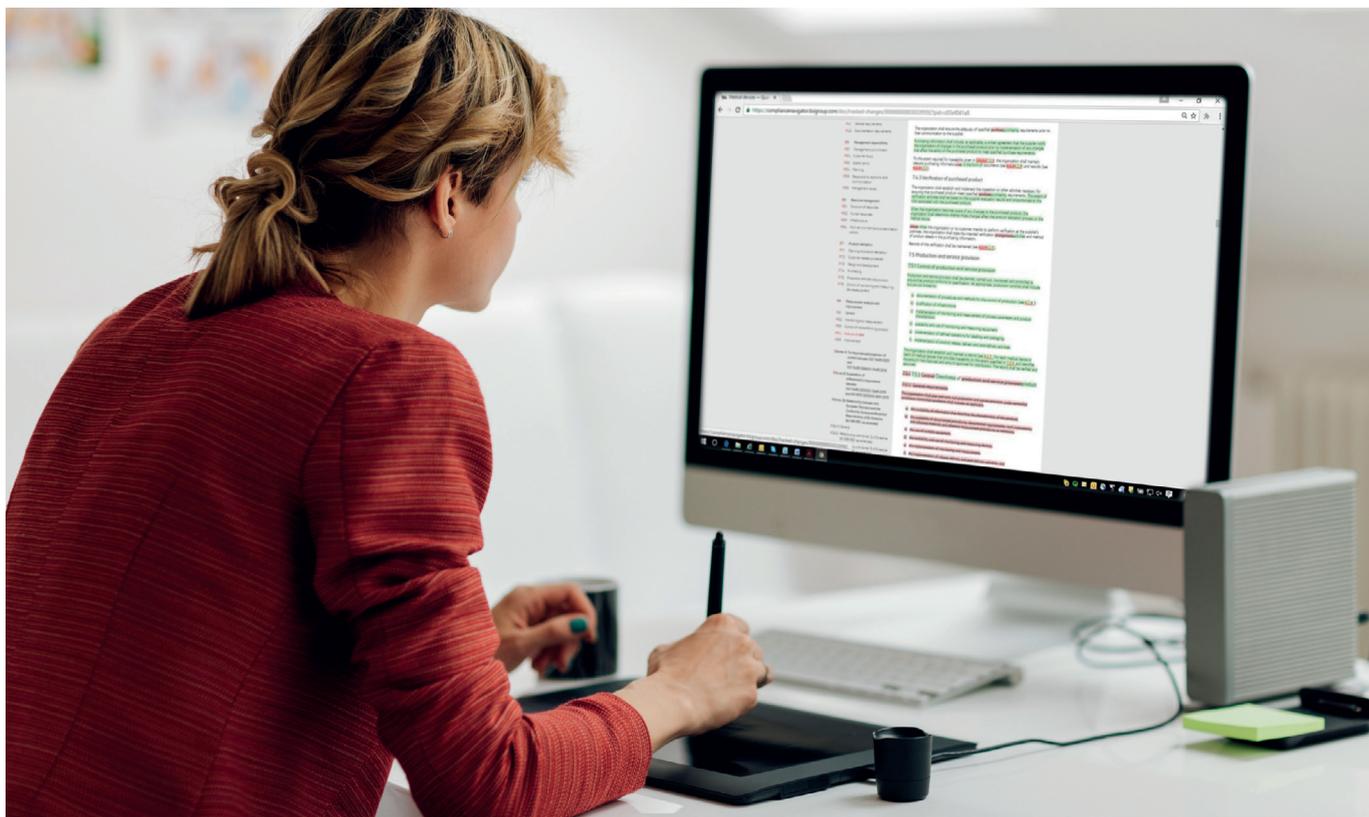
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### Background

As a start up, Smart Surgical know the importance of making every penny count. Ensuring risk is kept to a minimum is a fact that co-founders, Adam James and Dr Omer Aziz, know is key to success.

Born out of a concept the two co-founders developed while studying for their PhDs at Imperial College, London, Smart Surgical specialize in advanced sensor-enabled endosurgical instrumentation for keyhole surgery. The complex nature of the market in which it operates means that Smart Surgical need to be aware of all

upcoming changes to regulatory and standards information that will impact the design and development of their products. Krupa looks after their Regulatory Affairs and works with Adam, who has overall regulatory oversight. She has a varied role, but it mainly comprises supporting the development engineers with their work, such as organizing the technical file for the product and researching and reviewing relevant standards to make sure that everything the company does complies with all appropriate legislation.



### The customer need

The decision to purchase Compliance Navigator was a relatively straight forward one. Through previous roles, the company was aware of British Standards Online and from the start took the view that an all-encompassing solution to locate and research relevant standards would be more appropriate and cost effective. Krupa explains:

*"The first and foremost thing is that it is a mandatory requirement for our product to meet with harmonised standards and to meet compliance with the directives. I was aware of the BSOL subscription, which I've used previously, but rather than buying standards separately and working to those, the business decided to look at an option where all staff members can easily get access to the standards we need – and that all standards are kept in one place."*

*"A solution such as Compliance Navigator provides that confidence that you are not missing anything that you may do if using other solutions or workflows. It's that peace of mind that we're not going to veer off track."*

As well as ensuring compliance with current regulations, another key aspect for Smart Surgical was being kept informed of changes to standards and when those changes were coming into effect. Other solutions were looked at prior to purchasing Compliance Navigator, but the company found that even though some offered information about standards that have changed, it was very difficult to get information about when standards are due to change. *"In most solutions, you will typically just buy a standard,"* says Krupa. *"You might not be actively following up on any subsequent changes or be aware of the transition period for that change to come through. When you do learn of the changes, it can make it really difficult for a company to cope with implementing them within the timeframe."*

The final key requirement was visibility. Smart Surgical work with third parties and contractors, as well as having their own development staff, this meant it was essential that anyone requiring access to standards could view them. They needed a robust online solution that offered easy access to all relevant standards.

## The solution

With these requirements in mind, the team explored available solutions and quickly found that Compliance Navigator met these needs and more.

Standards are organised by device type which streamlines the research process in locating relevant information. As Krupa comments, *"You can get lost trying to find the right standards and guidance documents applicable to the product and in some cases end up researching documents that are not necessarily right for your product, which wastes more time"*.

Of particular use to Smart Surgical is the expert commentary. It helps the team correctly interpret the meaning of standards and track changes, which helps

the team quickly identify the areas of a standard that have changed and assess the impact for their own product. Krupa has also set up notifications to stay informed of when standards will change, *"Being notified of changes that are upcoming is particularly useful. I get notifications on a weekly basis, which means I can make sure that we are compliant. Because the notifications tell me what is changing and what has been changed, I can quickly go into the system and see how it will impact the product. This also helps me understand how it will impact our timelines."*

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## Customer benefits

Set up and implementation of the solution is also quick and easy, comprising a simple 3-step process of creating product profiles, setting up notifications and receiving alerts to keep compliant. *"A big area for us in terms of criteria was the learning curve. There are a lot of software tools out there to support the regulatory process and often you can invest a significant amount of time in just learning how to use them. From that perspective Compliance Navigator was easy to set up, understand and then start to use."*

Another major value of Compliance Navigator was having constant vigilance of the standards. As anyone working within product development will know, ensuring that the design of your product meets all relevant standards is not only mandatory, but also essential in keeping costs and risk to a minimum. For small companies in particular, working to an out-dated standard not only wastes time, but also can be very costly, resulting in having to re-do everything from developing to building to testing. As Adam comments, *"A solution such as Compliance Navigator provides that confidence that you are not missing anything that you may do if using other solutions or workflows. It's that peace of mind that*

*we're not going to veer off track – or if we do, we're not going to be far off track. For large corporations if they are working to the wrong standard, they'd probably have the capacity to absorb that slightly but when you're a start-up, any major deviation particularly in regulations, can have an impact in both time and money."* Compliance Navigator mitigates this risk and helps companies to keep on top of the changes across all areas of the product lifecycle from developing to testing to manufacture and stay on track.

But while Compliance Navigator was developed to provide a solution that transforms the way in which compliance is managed, its ultimate aim is to help developers of medical devices save time, effort and money across the product development lifecycle – so has this benefit been realised by Smart Surgical? The indicators are positive. *"From our side, it gives peace of mind, which adds a lot of confidence to what we're doing and how we move forward. In terms of quantifying how it's affected productivity, it's too early to get a true sense of that, though my thoughts are that it will, and it has. There is an underlying feeling that Compliance Navigator will support 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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