Navigating the regulatory landscape for medical devices

Chrissi Jackson, BSI Standards
BSI participates in all of the international standards bodies wherever we can, working to shape standard development, policy, strategy and outputs.

- Shaping best practice knowledge for medical devices manufacture including safety, efficacy and performance.

- Building on UK’s strength in creating new business standards, and working to support innovation through new and emerging technologies.

- Supporting and growing our community of 10,500 experts and 1,200 committees to help them deliver the codes and standards needed for global application.
BSI – two perspectives on Medical Devices

- Conduct conformity assessment against relevant sections of applicable Directive
- Audit of quality system
- Assessment of technical documentation
- Issue CE certificate
- Perform product testing

- Development of standards through technical committees
- Publishing
- Information solutions
- International projects
- Private/sponsored standards and specifications
Access to information is a central component of compliance strategy
“It's all frustrating as there are so many sites and sites within sites, even when you go to a site you trust.”
Medical devices — Quality management systems — Requirements for regulatory purposes

Regulatory framework

Legislation
Based on the New Approach, rules on medical devices were harmonised. The framework consists of 3 directives for active implantable medical devices and Directive 90/385/EEC for medical devices. They aim at ensuring the health and safety of medical devices and have been supplemented by Directives 2007/47/EC and 2007/47/EC.
The Big Issues
“It’s difficult to identify what exactly applies to a specific product.”

“A lot of time is wasted assessing the credibility of information gained through internet research.”

“The single largest challenge is understanding which standards are directly or indirectly applicable to the products the company manufactures.”

“Information from outside can be thought of as the morass through which we navigate, but also upon which we must travel to reach the destination.”
“The sharing of documents across the organization would be of huge benefit, and cost effective.”

“Compliance Navigator is 1000 times better than what I have now in terms of keeping things organized.”

“Any functional group – Document Control, Research and Engineering, RA, Technical, QA – would be able to access the information pretty straightforwardly.”
“Most of us are so limited for time, yet many people ask us for our impression as to changes to a standard. Compliance Navigator would save us time and provide the feedback we need to give.”

“Today the most common question is: there's a new standard, what's changed?”
How Compliance Navigator helps
Staying informed of standards and regulations is challenging...

but it doesn’t have to be time-consuming
Compliance Navigator delivers the right information...

at the right time...

to help you make the right decision
Trusted and authoritative
So managing risk and staying compliant is easier
Easy as...

“what I am seeing is very straightforward, not cluttered. It’s just the information that you need. Makes it very easy to go through.”

“the key benefit of using the service is our ability to manage external standards, and to be notified when they are changed, and have access to those changes.”

“it didn’t take too long to get familiar with it – it’s not intimidating. Other services can be clunky and difficult to navigate.”

“not intimidating … kind of fun … really efficient”
Let Compliance Navigator do the hard work for you
The service
See us today for a demo

bsigroup.com/complinav

christina.jackson@bsigroup.com
gino.vassallo-todaro@bsigroup.com

@BSI Standards