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Medical
Devices

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February Medical Device Newsletter, 2017



Are you familiar with the new Unannounced Audit Visit Schedule?

January brings the implementation of changes to the audit cycle for Unannounced Audit Visits; first introduced in European Commission Recommendation 2013/473/EU.

Visit our website to read about Unannounced Audits and the changes to the schedule.

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New Senior Management Briefing in ISO 13485:2016

Are you a senior manager for a company certified to ISO 13485? As a leader, your commitment and support is crucial to the success of your organization's ISO 13485:2016 Medical Devices Quality Management System (QMS) transition.

The [Senior Management Briefing](#) allows you to understand your role and your wider organization's obligations and actions in the transition to the new version of ISO 13485.

[Find out more](#)



A knowledgeable Notified Body with an expert team - BSI case study.

"BSI are reputable and experienced... [and]"

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are at the cutting edge of regulations; they also have a variety of different resources including webinars about upcoming changes which gives us more confidence in our Notified Body.”

Samantha Neilson, Regulatory Affairs Manager,
Smith & Nephew Medical Ltd

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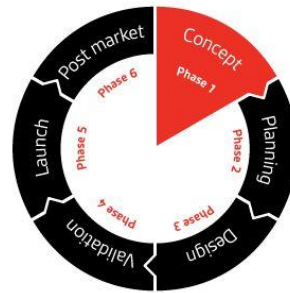
New webinars: Learn more about the EU regulatory requirements

Our upcoming webinars cover a range of topics, including Post Market Surveillance and Vigilance, and roles and responsibilities under the new Regulations. Sign up now to access our expert commentary on these topics.

[Post Market Surveillance and Vigilance - do you know the requirements? - 22 February 2017, 4pm GMT](#)

[Roles and responsibilities in the Medical Device and IVD Regulations – 15 March 2017, 4pm GMT](#)

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