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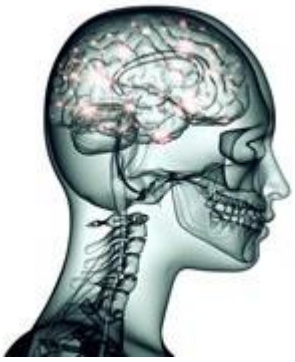

Regulatory review

Your monthly medical device update

April 2018

The EU General Data Protection Regulation: Don't miss any key communications from BSI

The EU General Data Protection Regulation (GDPR) mandates that companies handle and store personal data in an appropriate way, giving individuals more power over how their personal information is used. This includes how companies communicate with you, outside of any contractual obligations they have to get in contact. The Regulation will apply from 25 May 2018.

We are taking this opportunity to make our databases GDPR compliant, so **you must re-register if you wish to continue to receive regular updates from BSI Medical Devices.** These newsletters and our notifications of new resources such as webinars, white papers and other guidance documents. Don't miss out during this critical transition period.

Re-register today

"We improved our overall quality awareness by training colleagues about the changes to ISO 13485."

The ISO 13485:2016 transition period ends in less than a year. It's vital that you understand the changes to the standard so that you're prepared to complete your transition.

In our new case study, Chinese Orthopaedic device manufacturer Trauson discuss how they used BSI training to ensure they were aware of the changes to the standard, allowing their team to effectively implement the necessary changes for their transition.

BSI has a series of training courses designed to provide information on the content of ISO 13485:2016, allowing you to interpret the requirements for your business.

Read the case study

Book training with BSI

Join AAMI and BSI for our joint International Conference on Medical Device Standards

Join AAMI and BSI on 19-20 June 2018 and hear from European and US government and industry leaders as they explore developments in international standards and regulations that are key to global market access and regulatory compliance.

The two-day conference will be conveniently held at London Heathrow, making it accessible for an

international audience. Find out more about the conference and agenda, and register online today.

Find out more

Stay up-to-date with the MDR and IVDR through our weekly Compliance Navigator blog

The BSI Compliance Navigator blog provides information on key topics of the two new Regulations. Weekly posts keep you up to date with some of the latest developments and provide guidance to explain some of the complex issues facing medical device manufacturers in these changing times.

Some recent titles include:

- What is the future of harmonized standards?
- Digital health innovation
- Updated guidance on medical device borderline and classification issued

Visit the Compliance Navigator website to register for the blogs or to learn more about the tool.

Find out more

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