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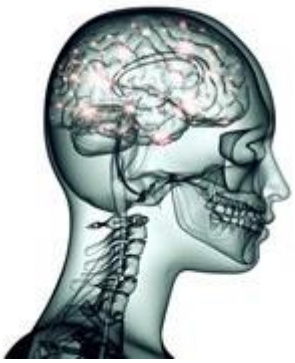

Regulatory review

Your monthly medical device update

June 2018

FDA Announcement: Harmonizing and Modernizing Regulation of Medical Device Quality Systems

On May 9 2018 the US Food and Drug Administration (FDA) published the Spring 2018 “Unified Agenda of Federal Regulatory and Deregulatory Actions” (Unified Agenda), which provides federal agencies with the opportunity to update the public on US government’s regulatory priorities.

FDA announced that it intends to harmonize and modernize the Quality System regulation for medical devices. The revisions will replace the existing requirements with the specifications of an international consensus standard for medical device manufacture, ISO 13485:2016. The revisions are intended to reduce compliance and record-keeping burdens on device manufacturers by harmonizing domestic and international requirements. The revisions will also modernize the regulation.

Hear from FDA about global regulation, harmonization and transformation at the upcoming International Conference on Medical Device Standards and Regulations, 19/20 June, at London Heathrow, UK.

View the full agenda

Read the full insight from BSI Compliance Navigator to find out more.

Read the article

Find out more about Quality Management System (QMS) certification and BSI certification services to ISO 13485.

Find out more

The regulatory impact of Brexit: Listen back to our latest webinar

Hear from BSI CEO, **Howard Kerr**, and Senior Vice President Global Medical Devices, **Gary Slack**, as they discuss the status and implementation of Brexit and its impact on the MDR and IVDR. During the webinar, Howard and Gary explained BSI's commitment to the medical devices industry, and gave more detail on our progress with our contingency plans.
Listen back now to dispel the myths, get the facts and learn more about our position.

Listen back

BSI is proud have achieved accreditation for ISO 13485 under the Dutch Accreditation Council (RvA)

This accreditation is another successful step in growing our Netherlands-based business. We are currently working towards Notified Body designation under the MDD, AIMDD and IVDD, allowing us to offer full medical devices certification services for CE marking.

Visit our dedicated Brexit page to get more information on Brexit and our position in the EU, and to stay up-to-date on the latest developments.

Visit the webpage

Don't miss your chance to hear from three of the world's top regulatory bodies

Join us on 19 & 20 June to hear from **FDA, MHRA** and **BSI** on some of the biggest topics in regulation at the joint BSI and Association for the Advancement of Medical Instrumentation (AAMI) conference. Conveniently located at London Heathrow, UK, we'll be discussing developments in international standards and regulations that are key to global market access and regulatory compliance.

This will be a rare opportunity to hear from these prominent organizations all together at one conference. Find out more about the conference and agenda, and register online today.

Find out more

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