Email not displaying correctly?
View it in your browser.

bsi. | Medical Devices

Talk to us
+44 (0)345 080 9000
eu.medicaldevices@bsigroup.com

September Medical Device Newsletter, 2016

The 'Person Responsible for Regulatory Compliance' - Do you understand the requirements?

New complimentary webinar from BSI

The role of the 'Person Responsible for Regulatory Compliance' in the future Medical Device Regulation (MDR) and In Vitro Diagnostic Device Regulation (IVDR) - 28 September 2016 - 4pm BST

The new European Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) feature requirements of the 'Person Responsible for Regulatory Compliance', borrowed from the concept of the Qualified Person from the pharmaceutical industry. The MDR and IVDR describe the minimum expertise required to be held by Regulatory Affairs teams to meet the requirements relating to the 'Person Responsible for Regulatory Compliance'.

The requirements have been adapted for the medical device industry, although have been diluted down since the original MDR and IVDR proposals, with requirements on training, qualification and registration having eased.

However, the basic principles remain. This change may appear minor compared to some of the drastic ones that the MDR and IVDR will bring. Nevertheless, it is crucial that medical device manufacturers take these aspects into consideration as part of their transition plan.

Listen to our webinar to understand more about the requirements.

ISO 13485:2016 Transition Tools

NEW! Sign up for our new ISO 13485:2016 webinar

In a period of immense change for the medical device industry, preparing for new regulatory requirements for both your product and system certification requires thorough planning.

Find out more about alignment between the new medical devices standard and regulations by signing up to our webinar on October 6th, to ensure an efficient transition.

ISO 13485:2016, the Medical Device Regulation and the IVD Regulation- How aligned are they? - 6 October 2016 - 3pm BST

ISO 13485:2016 Readiness Review

When preparing for your transition, it is important that you understand the new requirements that you will need to meet.

Sign up now

Overcoming regulatory challenges by embedding excellence in practice

Learn more about how BSI's expertise in specific technology areas can support your business.

The diverse range of products and technologies in the medical device markets requires a deep yet diverse knowledge base from the Notified Body. Learn more about BSI's expertise in animal tissues, and the benefits of working with an experienced Notified Body.

Download your copy

What has changed in the Clinical Evaluation Guidance, MEDDEV 2.7.1 Revision 4?

Key changes and clarifications

The new revision of the MEDDEV guidance 'Clinical evaluation: A guide for manufacturers and notified bodies under Directives 93/42/EEC and 90/385/EEC', was released by the European Commission on 1 July 2016. This revision, Revision 4, contains some new requirements, although principally has been revised to include clarification of the existing requirements. Guidance on how to undertake a clinical evaluation is now much more robust and explicit.

BSI has identified what it thinks are the top ten changes to MEDDEV 2.7.1. Find out more about the key changes and clarifications with our new guidance brochure.

BSI has developed a Readiness Review, to support you in your pre-transition gap analysis. The Readiness Review should be used in conjunction with the standard.

While not mandatory for transition, this useful tool can help you prepare for the next step.

Download now

Learn more about ISO 13485:2016 - BSI Expert Commentary

The BSI Standards team have developed an Expert Commentary to take you through the new version of the medical device QMS standard, ISO 13485:2016.

Download your complimentary copy now.

Download now

Stay informed on key updates

Keep up to date with the latest changes, information and new resources on ISO 13485:2016 by bookmarking our transition webpage.

Download your copy

ISO:13485 2016 Transition page

New complimentary BSI webinar: New version of MEDDEV 2.7.1 Revision 4: Key changes and clarifications - 18 October 2016 - 4pm BST

Revision 4 of the MEDDEV Guidance on clinical evaluations has been designed to provide more instructive and explicit insight into the requirements of manufacturers.

Join Global Head of the BSI Orthopaedic and Dental team, Monisha Phillips, and Product Technical Specialist, Amie Smirthwaite, as they explore the new requirements and clarifications in more detail.

Sign up now

Do you need the latest standard?

bsi. | shop

Visit the BSI Shop to purchase the latest standards and related guidance relevant to your product, including the new ISO 13485:2016.

BSI Medical Devices LinkedIn

Join the BSI LinkedIn Group to stay informed and updated with the latest news.

For all general enquiries call +44 345 080 9000 or visit the BSI Medical Devices website

Our mailing address is:
BSI
Kitemark Court, Davy Avenue
Knowlhill
Milton Keynes, MK5 8PP
United Kingdom

You have received this email because you have purchased a product or service from BSI, opted-in to a third party list or opted in to marketing emails. If you wish to unsubscribe please click on the 'one-click unsubscribe' link located below. Some of BSI's services include a customer newsletter/eshot as part of that service. This ensures that you are made aware of any changes to that particular services.

Please note that this inbox is not monitored so don't use "reply to" or "reply all" in your email. Should you wish to talk to us, please call +44 345 080 9000 or email eu.medicaldevices@bsigroup.com.

The British Standards Institution (BSI, a company incorporated by Royal Charter), performs the National Standards Body activity (NSB) in the UK. BSI, together with other BSI Group Companies, also offers a broad portfolio of business solutions other than the NSB activity that help businesses worldwide to improve results through Standards-based best practice (such as certification, self-assessment tools, software, product testing, information products and training).

We respect your right to privacy - view our privacy policy

Unsubscribe from this list | Update subscription preferences

Join us