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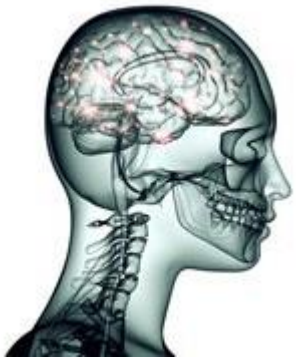


Regulatory review

Your monthly medical device update

May 2018

Last chance to register for BSI Medical Device updates

You will no longer receive BSI Medical Device updates after 25 May 2018 if you have not signed up to continue hearing form us. Don't miss out.

Sign up now to continue receiving these regular updates

New guidance mapping ISO 13485:2016 to MDR and IVDR now published

CEN TR 17223 - Guidance on the relationship between EN ISO 13485-2016 (Medical devices. Quality management systems. Requirements for regulatory purposes) and European Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation

The newly published guidance will be key to understanding the

changing requirements for Medical Devices. This document maps the clauses of EN ISO 13485:2016 to the Articles and Annexes of the Regulations, and will serve as the basis for the standard's Annex Zs.

We're currently one year into the MDR and IVDR transitions, and less than one year from the end of the ISO 13485:2016 transition deadline. A robust understanding of the requirements and sufficient planning is essential for successful transitions. Ensuring conformity to the standard will support manufacturers in their MDR and IVDR transitions by satisfying some of the Regulations' QMS requirements.

You can get more information about the transitions and access our comprehensive resources, including Frequently Asked Questions, webinars and white papers, on our dedicated web pages:

CEN TR 17223

ISO 13485

MDR

IVDR

Don't miss out! Register now for the joint AAMI and BSI conference

BSI is teaming up with the Association for the Advancement of Medical Instrumentation (AAMI) to bring you the International Conference on Medical Device Standards and Regulations. Join us on 19 & 20 June 2018 at London Heathrow, UK, to hear about developments in international standards and regulations

that are key to global market access and regulatory compliance.

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

Find out more

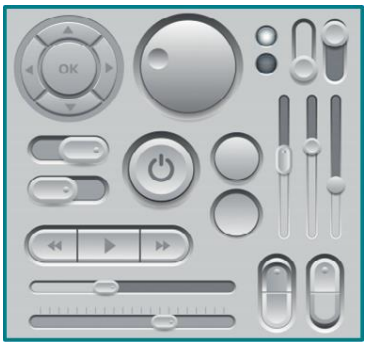
BSI's David Adams provides key update on Human Factors

New article featured in TOPRA (The Organisation for Professionals in Regulatory Affairs) magazine.

Human Factors, or Usability Engineering, is about how usable or ergonomic a product is. While this hasn't always been a key focus in the European regulatory environment, in the US there has been a much bigger drive on usability. This is, in part, because of the high number of errors or potentially avoidable deaths from misused devices.

Authored by David Adams, Global Head of the BSI Active Medical Devices team, the article explores the topic of usability, its regulatory history and what's changing under the new Medical Devices and IVD Regulations. David has over 35 years' industry and regulatory experience, and is an expert on usability in medical devices, making this article an important resource for any device manufacturer.

Visit the TOPRA website to access your copy of the article.



Want to know more about usability?

You can learn more about usability by listening back to our recent webinar with BSI usability expert Richard Stein, or by downloading our most recent whitepaper on human factors.

Watch the webinar

Read the white paper

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