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BSI Medical Device Newsletter: December 2015

Welcome to the December Medical Device Newsletter 2015

The new ISO 13485 - will you be ready?

ISO 13485, the world's most popular standard for medical device quality management, is now under review.

There have been two public consultations, which saw close to 1,500 comments, and elicited collaborative input from trade associations, manufacturers, academia and individual experts. The standard is expected to be published in spring 2016, following publication of the FDIS in October 2015.

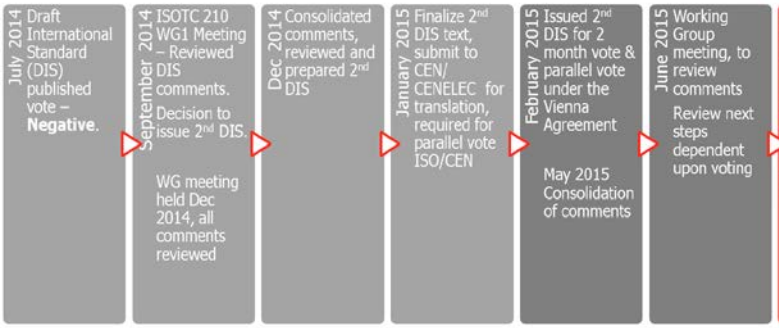
The new ISO 13485 is applicable across the whole supply chain and seeks to address the entire lifecycle of a medical device. Some of the key changes include:

- Harmonization of regulatory requirements
- Inclusion of risk management throughout the QMS
- Additional clarity with regard to validation, verification, and design activities
- Strengthening of supplier control processes
- Increased focus regarding feedback mechanisms
- Software for QMS, manufacturing and the medical device

Featured whitepapers

ISO 13485: The proposed changes and what they mean for you

Our new whitepaper by Mark Swanson and Bill Enos, introduces the proposed updates to ISO 13485, many of the changes are current best practice and can be immediately



Existing certification customers will have three years from the date the new edition publishes, to transition from ISO 13485:2003 and the associated European Standard EN ISO 13485:2012. BSI has developed a suite of materials, services and courses to help make the transition as smooth as possible: ISO 13485 Revision.

Complementary ISO 13485 FDIS Webinar

On 2 December BSI ran the webinar: An update on the published Final Draft International Standard of ISO 13485.

The webinar, from Vicky Medley, Head of QMS at BSI Medical Devices and Stewart Brain, QMS Certification Lead at BSI Medical Devices covered the details of the FDIS and the expected timings moving forward, including the BSI transition plan.

The webinar highlighted the actions you should be taking now and how to plan for the implementation of the standard following publication. Listen online.

The growing role of usability engineering for medical devices

addressed.

The proposed EU Regulations for medical and in vitro diagnostic devices

As the trilogue process is indicative of the last key step towards the reform on the EU legislation on medical devices, the earlier version of this paper, published in March 2014, has now been updated and reflects the position as of 5 October 2015.

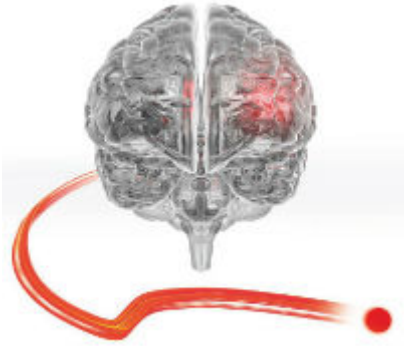
BSI Medical Device LinkedIn

Make sure you sign up if you haven't already to keep up to date with latest news and updates.

Medical Device Training

We run public or in-house training courses. For training at your place of work, call us on +44 (0)345 086 9000.

What is Usability Engineering in Medical Devices?



The ability for a human to interact easily and relatively error-free with a system, product or procedure. Manufacturers are increasingly expected to provide a safe product that the user understands thus errors are minimized. Terms such as ‘user-friendly’ and ‘intuitive’ have emerged as descriptors of usability which translate to subjective attributes regarding whether a system or device works and acts in the way the user expects, therefore avoiding frustration and annoyance in carrying out an intended action.

The expectations from both European Notified Bodies and FDA are increasing in this area and should now be considered a vital part of the medical device design process.

Read more about the role of usability engineering in our comprehensive whitepaper.

Upcoming BSI Webinar, 13 January 2016

This webinar will help you to:

- Identify the relevant directives, standards, and guidance documents recommended to incorporate Usability into your design process
- Overview of basic concepts from the key Usability standard IEC 62366-1:2015, and how you should be using this to improve your products, reducing risk
- Apply your best usability practices by understanding the experiences of others through the examples presented

No matter what stage of development you are in, this webinar will help you to plan and launch your product efficiently according to the necessary requirements.
The webinar will be run by Richard Stein who has 20 years of experience in medical devices, from the entire development process of concept, design, hazard analysis, evaluation, regulatory submittal, market launch and ongoing product support. Much of his experience in medical device development is the basis of his usability contributions.

View all training courses

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Purchase a range of documents and training products from the BSI Shop.

New BSI webinars available

The full programme of webinars completed this year have been positively received and we are currently working on a full plan for 2016. This is based around regulatory changes to the global market place and feedback from customers. If you have any feedback on our communications, including our webinars please email our Global Product Manager, Jane Edwards.

The following webinars are open for registration:

The growing role of usability engineering for medical devices, Richard Stein, 13 January 2016

Did you miss any of our previous webinars? Listen back to these on our website.

An update of the published Final Draft International Standard of ISO 13485
2 December

Medical Device Software - do you understand how software is regulated?
20 November

ASEAN Medical Device Directive (AMDD) A brief overview
11 November

Organizational Resilience: Is your business ready for change?

A new report released by The Economist Intelligence Unit (EIU) on behalf of BSI identifies a worrying gap in the capability of firms to maintain long-term growth.

To find out more about Organizational Resilience, and the key features of resilient organisations, download a copy of the report.