bsi. | Medical Devices

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

BSI Medical Device Newsletter: November 2015

Welcome to the November Medical Device Newsletter 2015

Final draft of Medical Devices Quality Management System Standard published

ISO 13485 Medical devices -- *Quality management systems -- Requirements for regulatory purposes*, the internationally recognized medical device industry quality management systems (QMS) standard, has been under revision since 2010. A final draft of the standard has now been released incorporating changes made following feedback from users and experts around the world. In accordance with the consensus-based approach, BSI, the UK National Standards Body has participated by providing technical input and commentary.

There have been two public consultations, which saw close to 1500 comments, and elicited collaborative input from trade associations, manufacturers, academia and individual experts. The standard is expected to be published in spring 2016.

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:

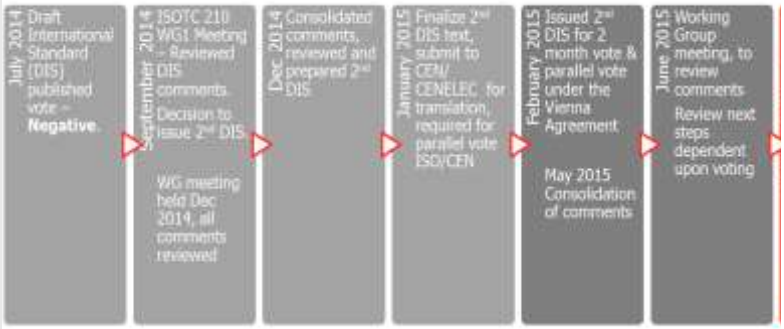
- Harmonization of regulatory requirements
- Inclusion of risk management throughout the QMS
- Additional clarity with regard to validation, verification, and design activities

Latest whitepaper from BSI

The 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 addressed.

To download this and other white papers please visit our

- Strengthening of supplier control processes
- Increased focus regarding feedback mechanisms
- Software for QMS, manufacturing and the medical device



Gary Slack, Senior Vice President of Global Healthcare Solutions at BSI said: "The regulatory landscape for medical devices is a rapidly changing one, and with that comes the evolution of ISO 13485. Today, we have to consider the supply chain and associated risks, so it is necessary to have transparent pathways in place - where all the development stages of a medical device can be observed, and any issues managed correctly."

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.

For more information, sign up for our upcoming webinar, where industry experts will provide an update on the published final draft and its implications.

BSI and CSA at the International Medica Exhibition

website.

Trilogue update

As the first of the EU trilogues on the MDR and IVDR is concluded, the medical device industry is one step closer to the adoption of the new Regulations. This will bring with it changes effecting processes and procedures across the supply chain; not only within your business, but also the relationships with suppliers and customers, too.

To understand how the changes will impact the industry, and what this means for your business, download your complimentary copy of BSI's updated whitepaper.

Authored by Dr Gert Bos, Head of Regulatory and Clinical Affairs at BSI, and Erik Vollebregt, Partner at Axon Lawyers, the whitepaper provides insight into the likely outcomes of the Regulations consequences for the market. Don't delay in understanding
the consequences of these significant, mandatory changes on your business.

Book your meeting today online.

The alliance between one of the world's leading medical testing organizations in North America and one of the world's leading Notified Bodies in Europe brings together an unrivalled mix of expertise to offer a fast, efficient global market access service that you can be confident in.

At BSI, we provide rigorous quality management reviews and product certifications for medical device manufacturers around the world. Our clients range from established globally recognized brands to new innovative companies in 150 countries worldwide.

With more than 90 years of experience, CSA group is a leading testing and certification organization in Canada and the USA. CSA group is an official testing and certification body, accredited and accepted by ANSI, OSHA and SCC. CSA group is also a member and national CB scheme certification body of IECEE.

BSI and CSA will be exhibiting at the world wide Medical Trade Fair from November 16 to 19 2015, Hall 10 booth 10E03 in Düsseldorf, to arrange a meeting please visit our joint site.

New BSI webinars available

Want to keep up to date with a rapidly changing regulatory environment? A full list of our upcoming webinars can be seen on our website, and the following are open for registration:

ASEAN Medical Device Directive (AMDD) A brief Overview
11th November

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

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 inhouse training courses. For training at your place of work, call us on +44 (0)345 086 9000.

View all training courses

---

bsi. | shop

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

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

Missed any of our previous webinars? Listen back to these, including our most recent webinar, on our website.