Medical Devices

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Countdown begins for launch of the new ISO 13485:2016 standard

ISO 13485:2016 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. The revision, completed under the provisions of the Vienna Agreement, recently saw the final stage ballot for both the ISO & EN versions concluded.

The working group met for the final review of the document in September 2015 and agreed final edits prior to issue by ISO/CEN for the respective FDIS ISO 13485 and FprEN ISO 13485 ballots. The documents were issued on 29 October 2015 for these final ballots with a straight YES/NO vote (no technical comments permitted), and the two month voting period ended on 29th December 2015.

Positive vote on the Draft ISO 13485

The standard received a positive vote in both the ISO and CEN ballots and will now be submitted for publication by the respective secretariats. A **three year transition period** has been proposed following publication which is expected **before the end of March 2016**. BSI will provide further information in relation to publication of both the ISO and EN versions, and provide updates on the progress of European Harmonization.

Start to plan your transition to ISO 13485:2016

With the final vote now confirmed as positive, users of this key medical device standard should start planning and obtain information from their Certification Agency or Notified Body in order to begin to develop suitable transition plans.

Whitepaper

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

bsi. ..making excellence a habit."

Our detailed 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.

Complementary ISO

The international working group has proposed a work plan for development of a mapping document to support users who chose to adopt new versions of both ISO 13485 and ISO 9001. There will not be an updated version of ISO 14969 - Guidance on the application of ISO 13485:2003. However, the alternative proposal is a handbook which would provide users with relevant guidance and interpretation of the requirements of ISO 13485:2016.

Where to find more information

BSI is developing a suite of materials, including webinars, whitepapers and training courses to help make transition as smooth as possible. Some of these are available now and will continue to be updated over the next few months. To ensure you view the most recent versions of the documents please refer to: http://medicaldevices.bsigroup.com/our-services/ISO-13485-Revision/

A transition course is currently being finalised and will be available to book onto from the end of January 2016, via our revision webpage.

Should readers have any further questions please email: UKISO13485@bsigroup.com.

Paul Sim
Chairman BSI CH210/1 Committee

13485 FDIS Webinar

On the 2nd 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.