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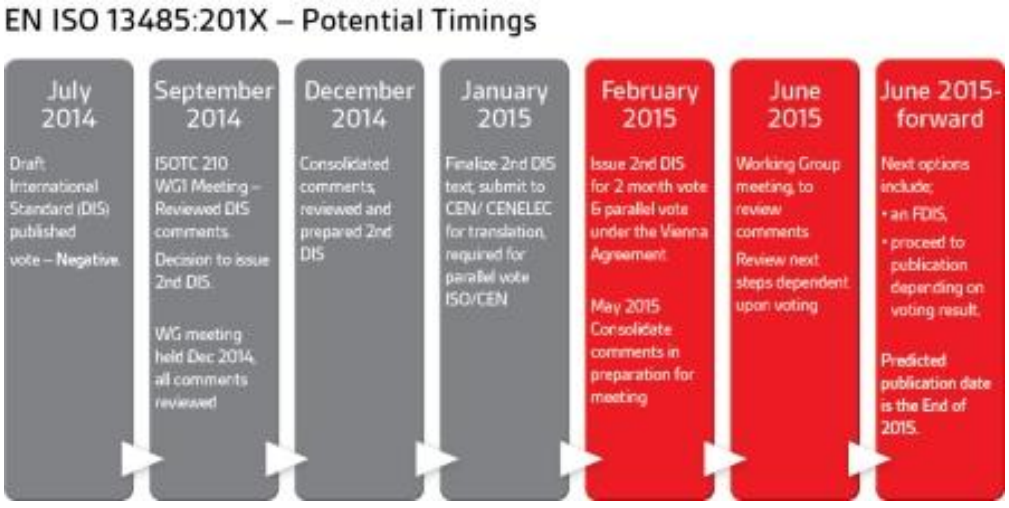
BSI Medical Device Newsletter April 2015

Welcome to the April Medical Device Newsletter 2015.

ISO 13485 Draft International Standard.

The text for ISO 13485 DIS2 (Draft International Standard) – Medical Devices - Quality Management Systems – requirements for regulatory purposes has been released by ISO for public comment. The voting period will close on the 5th May 2015. All comments must be submitted to ISO prior to this date.

We have created a dedicated webpage for you to keep up to date on the revision. The page includes details of webinars, details around commenting on the DIS2 and an updated potential timeline.



New BSI Webinars available.

For 2015, to help you to keep up to date with a rapidly changing regulatory environment we are publishing a webinar schedule for the whole of 2015. The full list of webinars can be seen on our website, and the following webinars are open for registration:

- Will your product be reclassified under the new MDR? Lessons you need to hear

Webinar Medical device unannounced audits, lessons learnt.

BSI have now completed a substantial number of unannounced audits and this webinar focused on the BSI experience to date with the unannounced audit program highlighting the challenges and learning points for both the Notified Body and the Manufacturers. Early experience indicates that Manufacturers with effective quality management systems with good control on sub-contractors, suppliers, and procedures/processes in place for dealing with unannounced audits fared better than others.

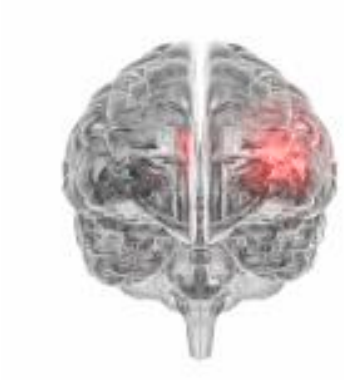
Listen back to the webinar.

- 12 May 2015 - 16:00 to 17:00 GMT
- ISO 13485 - the new revision
- 19 May 2015 - 16:00 to 17:00 GMT

If you missed the March webinars on the Revision of the MDD and AIMD, and the over overview on ISO 14971 Risk Management, you can listen back via the website.

Taster training courses.

We are proud to offer a selection of nineteen medical device courses, covering CE marking, ISO 13485 and a variety of specialized courses covering topics ranging from software as a medical device to process validation. To help you to decide which courses can help you we have some new tasters you review.



Medical Devices CE Marking

ISO 13485

Process Validation for the Medical Device industry

Drug-Device Combinations

Medical Devices Utilizing Materials of Animal Origin

Post market surveillance and vigilance

Full Details regarding these exciting courses are on our website, where you can also request a quote for In-company training.

Meet BSI in Person.

Some of the events BSI will talk at in April, for the full list of speaking events please see the events website.

Speaker	Date	Country	Event	Speaker Title
Bill Enos	02-Apr-15	US	ASQ Northern New Jersey quality conference	Proposed Changes to ISO 13485:2015
Neil Adams	14-Apr-15	France	DIA Euromeeting 2015	New Medical Device Regulations in the EU
Richard Stein	14-Apr-15	US	Design of Medical Devices Conference, University of Minnesota	Usability: From the clinic to the home to on the go.

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New BSI Whitepaper.

The growing role of human factors and usability engineering for medical devices

Written by Bob North, Human Centered Strategies.

By applying knowledge of human capabilities and limitations Human Factors and Usability Engineering (HF/UE) contributes to the design of intuitive displays, controls, and other interfaces that substantially reduce the risk of user error.

BSI Global Medical Device.

This group is for professionals who design, develop, manufacture or

Paul Brooks	20-Apr-15	US	Q1 Medical Device Supplier Quality	Unannounced Visits & Suppliers
Paul Sim	21-Apr-15	Germany	MEDTEC Europe 2015	Unannounced audits & ISO 9001 & ISO 13485 – where are we?
Sam Boyer	21-Apr-15	Germany	MEDTEC Europe 2016	Analysing the impact of a new proposed legislation on orthopaedic medical devices on European and global markets
Neil Adams Matthew O'Donnell	30-Apr-15	UK	Med-Tech Innovation Expo 2015	Medical Device Regulatory Affairs: Working with your Notified Body

distribute medical devices or related services, or are involved in developing medical device standards or regulations.