BSI Medical Device Newsletter

January 2015

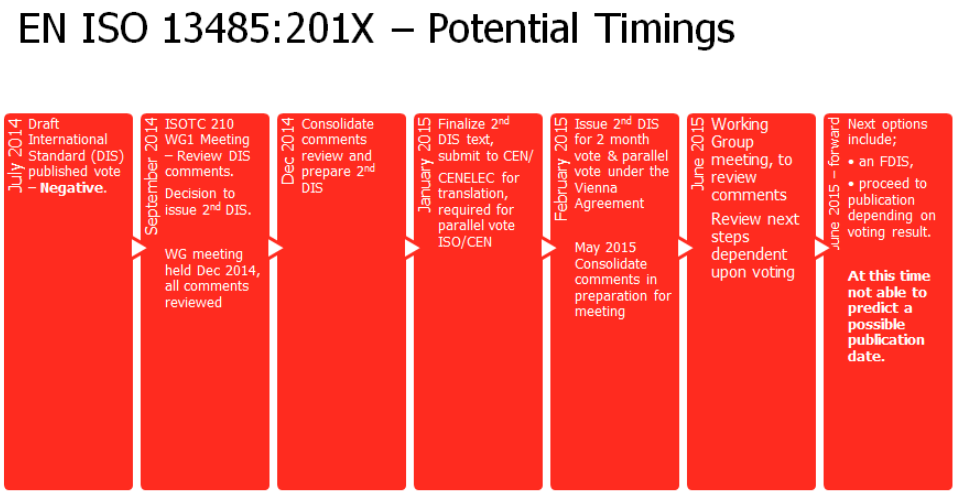
Welcome to the first Medical Device Newsletter of 2015.

The medical device regulatory world is facing unprecedented change over the next few years, with the revision of the three main Medical Device Directives, introduction of new requirements for Notified Bodies, including the focus on Unannounced Audits. It is important you stay up to date with the implications of these changes, and the newsletter aims to keep you up to date.

Changes to the Quality Management Standard.

The Quality Management Standard for Medical Devices, ISO 13485, is currently being revised. For the latest estimate of timings please select the image.

We are please to share with you a recording of a Webinar detailing the proposed changes. A further webinar will be run in May 2015, if you wish to sign up please see the next newsletter.



New for 2015: BSI Webinar Plan.

For 2015, to help you to keep up to date with a rapidly changing regulatory environment we are publishing an up front webinar schedule for the whole of 2015.

Explanation of Medical Device Single Audit Program (MDSAP) for Manufacturers

January 20, 2015 - 11:00 AM ET

The International Medical Device Regulators Forum (IMDRF) has recognized the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure patient safety. The IMDRF, at its inaugural meeting in Singapore in 2012, identified a Work Group to develop specific documents for advancing the concept of the Medical Device Single Audit Program (MDSAP).

The full list of webinars can be seen below. Registration will be available online for each one the month prior to presentation day.

- 20-Jan-15 MDSAP update
- 10-Feb-15 IVD regulatory update
- 13-Feb-15 Japan - New Legal framework
- 24-Feb-15 MDD and AIMD regulatory update
- 17-Mar-15 Unannounced audits lessons learnt.
- 14-Apr-15 IVD, how to build the clinical evidence required
- 28-Apr-15 ASEAN MDD
- 12-May-15 Will your product be reclassified under the new MDR?
- 20-May-15 ISO 13485 - the new revision
- 09-Jun-15 ISO 13485 AND ISO 9001, with both changing are you prepared?
- 23-Jun-15 Requirements for a 'Person Responsible for Regulatory Compliance'
- 07-Jul-15 Clinical evaluation, clinical investigations, do you have enough evidence?
- 15-Sep-15 ISO 14971: 2012 - Risk Management

LinkedIn Group

BSI Global Medical Device.

This group is for professionals who design, develop, manufacture or distribute medical devices or related services, or are involved in developing medical device standards or regulations.

We encourage you to start discussions about global medical device regulations, standards, directives and country requirements. Share your knowledge, challenges and opportunities.

How BSI can help you understand unannounced audits?

CE Marking Medical Devices - European Commission Recommendation of 24 September 2013 (2013/473/EU).

European medical device regulations are undergoing many significant changes that will impact manufacturers, suppliers, and Notified Bodies. One major and immediate change is the EU Commission requirement for Notified Bodies to conduct unannounced audits on manufacturers of CE marked products.

The BSI webpage has been set up for you to find all the relevant information in one place, we have FAQ's, Webinars and links to the relevant European Commission Documents.

- 13-Oct-15 You have launched your product, do you know your responsibilities now?
- 03-Nov-15 The New Radio Equipment Directive - are you ready?
- 20-Nov-15 Do you understand how software is regulated?

Do you understand the role of the Notified Body?

We have created a simple guide to help explain the role of BSI Notified Body.

Download the BSI Guide to Notified Bodies to find out the answer to these and many other questions:

- What is CE marking?
- Where does the CE mark apply?
- What is the role of the Competent Authority?
- What is the role of the Notified Body?
- How many Notified Bodies are there for the CE mark?
- Who decides on the content of the Directives?
- What is the process a manufacturer has to go through to get a CE mark?
- What does a Notified Body have to review as part of the assessment process?
- Does a Notified Body have to see the product as part of the certification process?

NEW Specialized Medical Device Training Courses

For 2015 we have created specialized medical device training classes. Courses in Q1 include:

Preparing for the IVD Regulation
Performance Evaluation (P/E) and Clinical Evidence for IVDs
Technical Files and Dossier Review
Medical Devices Risk Management: ISO 14971
Clinical Evaluation for Medical Devices

BSI Whitepapers

Download the latest medical device whitepapers help you perform better, reduce risk and make excellence a habit in your organization.

Engaging Stakeholders in the Home Medical Device Market
From devices designed for hospital use through to mobile apps that monitor sport and exercise – medical devices are steadily making their way into people's homes.

About BSI Healthcare
BSI Healthcare's mission is to ensure patient safety while supporting timely access to global medical device technology. We provide thorough, responsive, predictable conformity assessments, evaluations and certifications that are recognized and accepted worldwide. To learn more, visit medicaldevices.bsigroup.com

One Company, One Solution. By packaging assessment, training and a management system toolset, BSI delivers a business improvement solution that combines it all in a comprehensive service offering and allows us to provide an integrated approach to meet the needs of an organization and embed excellence across the business. BSI presents a one-stop value proposition from the decision to improve systems through to registration and continual improvement. From start to finish, BSI helps turn complexity into simplicity.