Medical Devices

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Medical Device Single Audit Program
February 2016 Newsletter

The Medical Device Single Audit Program (MDSAP) is an international initiative led by Regulatory Authorities (RA) to implement a program where Auditing Organizations (AO) can conduct a single audit of a medical device manufacturer that would be accepted by multiple regulators to address QMS/GMP requirements.

Health Canada announced on December 4th 2015, the requirement for medical device manufacturers to transition from CMDCAS to MDSAP to place devices into Canada. From January 1, 2019 Health Canada will **only** accept MDSAP for manufacturers who market their devices in Canada, hence, it is expected that manufacturers will need to transition from ISO 13485 Certification issued by a CMDCAS recognized registrar to MDSAP Certification issued by an AO.

BSI is working towards being a fully recognized AO and is already conducting MDSAP audits.

View the Health Canada announcement for more information.

Independent guidance on the MDSAP program and pilot can be accessed below:
International Medical Device Regulatory Forum (IMDRF) Guidance Documents
MDSAP Guidance Documents

Free MDSAP Webinar

Explanation of Medical Device Single Audit Program (MDSAP) for

New White paper

Following the publication of *The proposed EU regulations for medical devices: An overview of the likely outcomes and the consequences for the market*, a new white paper has been published by BSI to provide more detailed information to help manufacturers of medical devices understand the actions that are envisaged before, during and after the transitional period of the MDR.
How to best prepare for and implement the upcoming MDR – do's and don'ts discusses the

Manufacturers

18th February, 2016 at 4pm GMT.
This webinar will cover what is involved in the program, including what manufacturers can expect:

- Main differences in your current audits and audits conducted under MDSAP
- Explanation of grading of non-conformities
- Unannounced audits
- Audit structure / plan
- Submitting reports to the regulators and their role in MDSAP
- Opting out of Regulation
- Potential witness audits by the regulators
- Next Steps.

Sign up to our free webinar

Have you missed our comprehensive white paper or recorded webinar, covering usability engineering for 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 or listen back to our webinar from the 13th January 2016.

The webinar will help you to:

MDR on a chapter by chapter basis and outlines the changes that will impact manufacturers. The paper provides a useful checklist which outlines the actions required, by chapter, before, during and after the transitional period of the new Regulation.

Why is this paper important?

The new EU Medical Devices Regulation (MDR) is in the final stages of the legislative procedure. It is likely that it will be completed in 2016, allowing enter into force by the end of 2016 or early 2017.

Authored by Erik Vollebregt, a specialist in EU and national legal and regulatory issues relating to medical devices at Axon and Dr Gert Bos, Head of Regulatory & Clinical Affairs, Healthcare Development BSI, this new paper helps manufacturers understand the implications of the new MDR regulation on their business, enabling them to prepare to meet the requirements of the new legislation.

Download white paper

PPE Seminar

Preparing for the new PPE Regulation Seminar
19th April, 9:30am - 3:30pm
BSI Hemel Hempstead

- Learn about the new PPE Regulation and what it means for your business
- Understand main changes and how

- 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.

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these may impact your products
- Join our workshops and take part in practical scenarios
- Hear from industry experts BSIF
- Join us on a tour of our labs

If you would like to find out more please contact charlotte.broady@bsigroup.com