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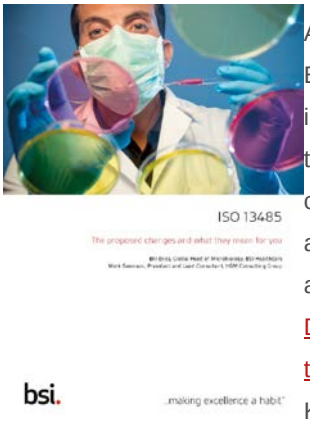
BSI Medical Device Newsletter: September 2015

Welcome to the September Medical Device Newsletter 2015

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



Authored by Mark Swanson and Bill Enos, the new white paper introduces the proposed updates to ISO 13485, many of the changes are current best practice and can be immediately addressed.
Download our latest white paper to find out more.
Keep up to date with the development of the standard via our revision website.

ISO 13485 AND ISO 9001, with both changing are you prepared?

The 3rd revision of ISO 13485 will not align with the revised structure of ISO 9001:2015 when published. For those medical device manufacturers who hold dual certification, you will need to be aware and start to consider and develop

Downloadable BSI White papers

The proposed EU regulations for medical and in vitro diagnostic devices

Generating clinical evaluation reports: A guide to effectively analysing medical device safety and performance

Effective post-market surveillance

What you need to know about the FDA's UDI system final rule

Engaging Stakeholders in the Home Medical Device Market

Negotiating the Innovation and Regulatory Conundrum

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

transition plans to allow for a smooth migration from current versions of the standards to the next. If you missed our webinar in July discussing the considerations needed to transition to the new standards, listen back to the webinar.

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:

You have launched your product, do you know your responsibilities now?
13th October

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

Missed any of our previous webinars? Listen back to these on our website. Two of our most recent webinars are below:

ISO 13485 and ISO 9001, with both changing are you prepared?

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

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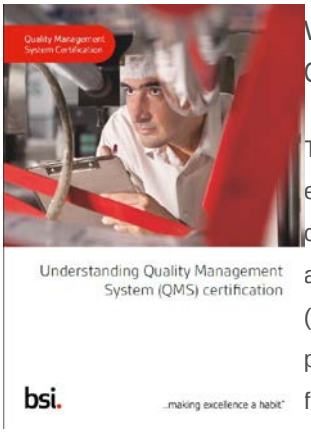

What is ISO 13485 Certification?

The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a Quality Management System (QMS). Adopting ISO 13485 provides a practical foundation for manufacturers to address the medical device directives,

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Medical Device Single Audit Program

The Medical Device Single Audit Program (MDSAP) is a foundational international initiative led by Regulatory Authorities of the International Medical Device Regulatory Forum (IMDRF) to implement a certification program where recognized third party Auditing Organizations (AO) can conduct a single audit of a medical device manufacturer that will be accepted by multiple regulators to address various QMS/GMP requirements.

Four of the Regulatory Authorities (Australian TGA, Brazilian ANVISA, Health Canada and US FDA) have decided to proceed with a three year MDSAP pilot. BSI is fully supporting the MDSAP pilot and participating in the process as an AO. Japan recently announced its participation in the MDSAP pilot; Europe and the WHO are officially participating as observers.

For further details please visit our new MDSAP webpage.

BSI Global Medical Device LinkedIn

Make sure you sign up if you haven't already to keep up to date with latest news and updates.

regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices.

With over 150 BSI QMS assessors globally supported by BSI product experts, our ISO 13485 certificates are known and trusted in the medical device industry by authorities, suppliers and manufacturers around the world.
Whether you're starting the certification process, looking to transfer or just need to discuss options for your business, contact our expert team who will guide you through the process.

Medical device training

We run online, public or inhouse training courses. For training at your place of work, call us on +44 (0) 845 086 9000.

View all training courses

Meet BSI in person

Some of the events BSI are attending and speaking at in June are below. For a full list of event we will be speaking at please see our events page.

BSI Shop

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

Find out more ▶

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other than the NSB activity that help businesses worldwide to improve results through Standards-based best practice (such as certification, self-assessment tools, software, product testing, information products and training).

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