



Medical  
Devices

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## ISO 13485:2016 Standard Published.

**Introducing the new ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes.**

The latest edition of ISO 13485, the internationally recognized quality management systems standard for the medical device industry, with over 27,000 certificates globally, has been published, 25th February 2016.

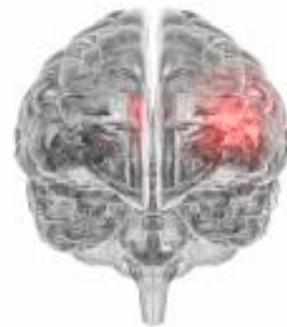
The standard provides an effective framework to meet the comprehensive requirements for a medical devices quality management system; for manufacturers and service providers to both comply and demonstrate their compliance to regulatory requirements.

The standard supports the design of a quality management system that establishes and maintains the effectiveness of a manufacturer's processes to ensure the consistent design, development, production, installation, and delivery of medical devices, or related services, that are safe for their intended purpose. The new edition is applicable across the whole supply chain and seeks to address the entire lifecycle of a medical device.

The requirements in ISO 13485 are used by suppliers or other external parties providing products or services to medical device manufacturers. By using ISO 13485, organizations will be able to demonstrate compliance with regulatory requirements, manage risk, ensure best practice for quality and safety, improve processes and provide confidence to patients.

The publication concludes over four years of work by experts around the world, to bring the standard up to date with the evolving European requirements and other international regulatory changes that have occurred since

### New ISO 13485 Training



### ISO 13485:2016 Transition

This comprehensive course introduces you to the new requirements and explores the changes between ISO 13485:2003/ EN 13485:2012 and the latest standard.

With greater attention on the organization's ability to meet applicable customer and regulatory requirements, ISO 13485:2016 focuses on the entire supply chain of the medical device industry, with added emphasis on risk management.

You'll be able to identify the

the previous revision in 2003.

Some of the key changes to ISO 13485 include:

- Alignment of global regulatory requirements
- Inclusion of risk management and risk based decision making throughout the quality management system
- Additional requirements and clarity with regard to validation, verification, and design activities
- Strengthening of supplier control processes
- Increased focus regarding feedback mechanisms
- More explicit requirements for software validation for different applications.

Anne Hayes, Head of Market Development for Governance and Risk at BSI said, "The regulatory landscape for medical devices is a rapidly changing one, and with that comes the evolution of ISO 13485. Today, we have to consider the supply chain and associated risks, so it is necessary to have transparent pathways in place - where all the development stages of a medical device can be observed, and any issues managed correctly."

Existing BSI certification customers have three years to transition from ISO 13485:2003 and the associated European Standard EN ISO 13485:2012. BSI has developed a suite of materials, services and courses to help make the transition as smooth as possible, details can be found on our [transition website](#).

BSI has proposed plans for the process of certifying customers to ISO 13485:2016 including customers who need to transition from the 2003 version of the standard. BSI is in the process of confirming these plans with the appropriate accreditation bodies and will communicate certification arrangements in the near future.

[Order ISO 13485](#)

gaps in your current Quality Management System (QMS) and start planning your transition and certification to comply with ISO 13485:2016.

### **ISO 13485:2016 Auditor Refresher**

Are you an existing auditor with knowledge of ISO 13485 wishing to update your audit programme in line with ISO 13485:2016?

This course will refresh your auditing techniques and help you prepare to audit against requirements.

With a transition period of 3 years, it's important to get up to speed so you can ensure your organization is ready to comply with new requirements. Through audit scenarios, you'll identify opportunities for improvement and build on your reporting skills.

To book your course visit: [bsigroup.com/training](http://bsigroup.com/training)

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**BSI White paper**

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## **NEW ISO 13485:2016 Webinars**

[Publication of the Medical Device International Standard, ISO 13485](#)

**09 March 2016, 4pm GMT.**

The published standard is now available, and this webinar will introduce you to the final standard and guide you through the BSI transition plans. BSI, the UK National Standards Body has participated by providing technical input and commentary throughout the full standard development.

The webinar will highlight the actions you should be taking now and how to plan for the implementation of the standard.

[New Versions of ISO 13485 AND ISO 9001, what do you need to consider.](#)

**23rd March 2016, 4pm GMT.**

The new revision ISO 13485:2016 does NOT align with the revised high level structure, Annex SL, used in ISO 9001:2015. For those medical device manufacturers who hold dual certification, you will need to be aware and start to consider and develop transition plans to allow for a smooth migration from previous versions of the standards to the two newly released versions.

Cross referencing material will be available within the standard which will correlate the clauses of ISO 9001:2008 to the clauses of ISO 9001:2015. As with previous versions of ISO 13485, the standard will also contain cross referencing tables, i.e. ISO 13485:2016 with ISO 9001:2015.

This webinar will discuss the considerations needed to transition to the new standards within your organisation taking into account the now different structures.

[All registrants will be sent a link to the recorded webinar and presentation slides after the event.](#)



ISO 13485

The proposed changes and what they mean for you  
Bill Enos, Global Head of Microbiology, BSI Healthcare  
Mark Swanson, President and Lead Consultant, ISOI Consulting Group

**bsi.**

...making excellence a habit™

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

Our new 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.

[\*\*Download White paper\*\*](#)