



ISO 13485:2016 is here

The world's most popular standard for medical device quality management has been revised for the first time since 2003.

The new ISO 13485:2016 standard is 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, 25 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 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, which can be found on this web page.

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".

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



Written by Bill Enos, Global Head of Microbiology, BSI Healthcare and Mark Swanson, President and Lead Consultant, H&M Consulting Group.

This paper introduces the proposed updates to ISO 13485, the quality management system standard that complements product specific directives.

> Register and download this whitepaper

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.

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

> Register today

ISO 13485:2016 is now available

Buy your copy of ISO 13485:2016 today and start your transition.

Buy ISO 13485:2016

Training

We have developed some training courses to help make the transition as smooth as possible. Click on the course links below to find our more.

- > ISO 13485:2016 Auditor Refresher Training
- > ISO 13485:2016 Transition Training
- > ISO 13485:2016 Transition & Auditor Training

Listen back to the webinar: ISO 13485:2016 publication

Watch the webinar from 09 March 2016 to learn about the newly published ISO 13485:2016 standard and how to plan for the implementation of the standard following publication.

Watch the webinar

Contact us

Find out how BSI can help you achieve excellence with Standards, Certification and Assessment.

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Your enquiry

Press releases

Read all press releases for the latest information on the ISO 13485 revision

- > Countdown begins for launch of the new ISO 13485:2016 standard
- > Final draft of Medical Devices Quality Management System Standard published

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