July 2016

ISO 13485:2016
Frequently asked questions

This FAQ document is designed to answer some key questions around ISO 13485:2016 and EN ISO 13485:2016. Questions are grouped by key theme. The document accompanies two BSI Webinars covering the scope of the new standard, and a discussion of both ISO 13485:2016 and ISO 9001:2015.

For more information, please see the ISO 13485:2016 revision webpage.

Transition period

Validity of ISO 13485:2003 and EN ISO 13485:2012

What is the date of withdrawal for ISO 13485:2003?

The previous version of the Standard, ISO 13485:2003, and the European version, EN ISO 13485:2012, will be withdrawn on February 28th, 2019. This allows a three year transition period.

Will certificates issued to ISO 13485:2003 or EN ISO 13485:2012 during the transition period have limited validity?

Yes, certification to ISO 13485:2003 or EN ISO 13485:2012 will be limited to the end of the transition period. From February 28th, 2019 onwards, only ISO 13485:2016 or EN ISO 13485:2016 will be accepted.

Note: New certificates and re-certifications to ISO 13485:2003 or EN ISO 13485:2012 will not be issued in the final year of transition.

EN ISO 13485:2016

When will EN ISO 13485:2016 be published?

EN ISO 13485:2016 was published on 1st March, 2016. The Standard has been submitted to the European Commission for harmonization to the European Medical Device and In Vitro Diagnostic Directives.

Auditing

How will BSI assess us during the transition?

The transition assessments can be conducted during several surveillance audits or at a recertification audit. BSI will assess you against ISO 13485:2016 once you begin to transition.

If you choose not to transition before your next routine audit, you will be assessed against the requirements of ISO 13485:2003 during that visit.

Which version of the Standard should I use for internal audits prior to certification?

You will need to ensure that your QMS effectively meets the requirements of ISO 13485:2016 in order to assure successful completion of the transition process. This includes the need for internal audits to address the requirements of the 2016 version.

Is additional review time required only for the transition audits, or for all audits against ISO 13485:2016?

Additional time is required on transition from ISO 13485:2003 to ISO 13485:2016, to allow auditors to ensure the new standard has been met. Once certification to ISO 13485:2016 has been achieved, future audits will not require the additional audit time.

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Alignment with other regulations

Canadian Medical Device Conformity Assessment System (CMDCAS)

Will Canada recognize ISO 13485:2016 for CMDCAS or MDSAP certification?

Yes, Canada will adopt ISO 13485:2016 for its CMDCAS and MDSAP assessments. Timelines for this have not yet been announced.

Note: Health Canada has announced plans to only accept MDSAP certificates from January 2019. This date was chosen to align with the transition of ISO 13485:2003 to ISO 13485:2016.

Medical Device Regulation (MDR)

Will EN ISO 13485:2016 be updated on publication of the new Regulation?

Once the text of the proposed EU Medical Devices Regulations has been published, the normative text of the Standard will be reviewed to ensure the content is aligned with the requirements. Revised Annexes Z will then be compiled to cover the relationship between the Standard and the Medical Devices Regulations.

Medical Device Single Audit Program (MDSAP)

Will MDSAP require demonstration of conformity to ISO 13485:2016?

Yes, MDSAP will adopt the new version of the Standard for its assessments. The Audit Model Companion Guidance will also be updated to include ISO 13485:2016. Timelines for this have not yet been announced. For more information about MDSAP, please visit our website: bsigroup.com/MDSAP

Are our obligations for MDSAP met if we are certified to ISO 13485:2016?

MDSAP requires audits to be carried out by designated Auditing Organizations (AO). These audits include an assessment of conformance with regulatory requirements specific to the program. Therefore, whilst ISO 13485:2016 forms a good foundation to meet the requirements of MDSAP, you must ensure that your Quality Management System (QMS) meets all of the applicable regulatory requirements.

ISO 9001:2015

Are medical device manufacturers required to maintain both ISO 13485:2016 and ISO 9001:2015?

No, ISO 13485 is the harmonized standard for quality management systems for medical devices. ISO 9001 is a quality management standard and is not specific to the type of product or service. Some countries require ISO 13485 certification to support regulatory approval. BSI is not aware of ISO 9001 being required to support regulatory approval in any country.

Good Manufacturing Practices (GMP)

Does compliance to ISO 13485:2016 demonstrate GMP?

No, GMP are separate requirements.

Guidance

Is there any guidance on the implementation of ISO 13485:2016?

CEN ISO/TR 14969:2005 – Medical devices. Quality management systems. Guidance on the application of ISO 13485:2003 – is in the process of being withdrawn, and will not be updated for ISO 13485:2016. A Handbook similar to that created for ISO 9001:2015 is being developed, and is expected in 2017.

Are there any guidelines about the validation of software?

EC 62304:2006/AMDI:2015 Medical Device Software - Software Life Cycle Program is the medical device software lifecycle standard.

We have developed a range of materials, including whitepapers, webinars and a transition webpage to support you through the transition.

Visit: **bsigroup.com/iso13485revision**

To purchase ISO 13485:2016 and other standards, please visit the **BSI Shop**.

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Risk

Will the Risk Management Standard ISO 14971 now be updated?

ISO policy requires international standards to be subject to a systematic review every 5 years, in order to determine whether revision, amendment or withdrawal of the standard is required. ISO 14971 has been reviewed by the National Committee as part of its systematic year review; a decision on whether to update this Standard is expected later in 2016.

Does ISO 13485:2016 now require risk mitigation, without economic consideration, as in ISO 14971?

ISO 13485:2016 does not specifically refer to the mitigation of risks. However, you need to ensure that you comply with the applicable regulatory requirements. EN ISO 14971:2012 remains the recognized harmonized risk management standard under the European Directives.

Validation

Do we have to validate off-the-shelf software that has already been validated?

Requirements relating to software are for the validation of the application of the computer software used for the particular process. You will need to demonstrate that the software is fit-for-purpose and validate it where necessary. The approach taken needs to be based on risk.

Note: ISO 80002-2 Medical device software, Part 2: Validation of software for regulated processes is currently under development.

Supply chain

Do we need ISO 13485:2016 if we do not manufacture a medical device?

ISO 13485:2016 can be applied to organizations involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, servicing or final decommissioning of a medical device, disposal of medical devices, and design and development or provision of associated activities (e.g. technical support). The Standard can also be used by suppliers or external parties that provide product, including QMS-related services to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of the Standard, or can be required by contract to conform.

Clause specific questions

Clause 4.1.6 – Requirement to validate computer software used in the QMS

Does clause 4.1.6 apply to all software used in the QMS?

Yes, the Standard requires this to be applied to software used in the QMS. However, the specific approach taken needs to be proportionate to the risk associated with the use of the software.

Clause 4.2.3 – Medical Device File

What type of file does "Medical Device File" refer to?

"Medical Device File" refers to both the device master record, and the technical documentation (technical file or design dossier). The requirements of this clause were previously documented in Clause 4.2.1 in ISO 13485:2003 and EN ISO 13485:2012.

Will technical documentation reviews for ISO 13485:2016 and the Medical Device Directives now be conducted at the same time?

No, QMS and technical audits for conformity assessment under the EU Directives will remain separate.

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Training

Does BSI have training on the new Standard?

Yes, BSI has a range of transition training, in addition to an updated suite of courses covering ISO 13485:

Transition training:

ISO 13485:2016 Transition

ISO 13485:2016 Auditor Refresher Training

ISO 13485:2016 Transition & Auditor Refresher Training

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