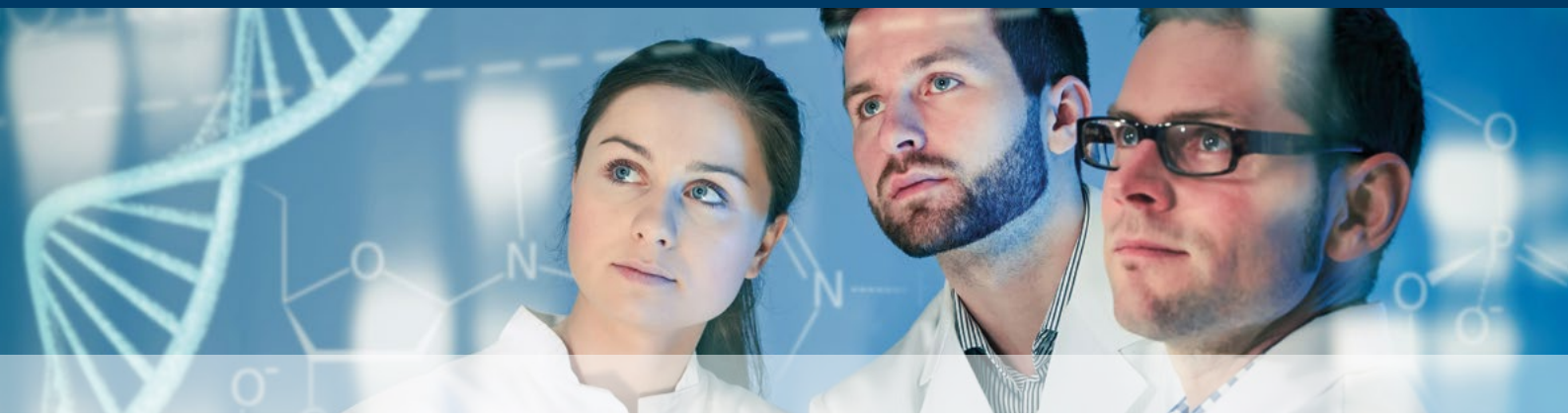
ISO 13485:2016 - Client Information Note

ISO 13485:2003 / EN ISO 13485:2012 superseded by ISO 13485:2016 / EN ISO 13485:2016
Medical Devices – Quality management systems – Requirements for regulatory purposes



Overview

ISO 13485:2016 / EN ISO 13485:2016 was published 1st March 2016.

IAF has advised that a 3 year transition period will apply to all existing ISO 13485:2003 and EN ISO 13485:2012 certifications.

This information note is intended to describe the key additions and changes introduced by the republication of ISO 13485, including the implications on certificates and upon medical device manufacturers using the EN ISO 13485 standard for presumption of conformity with the quality system requirements under the medical device directives.

EN ISO 13485:2012 maintains its status as a harmonised standard and the presumption of conformity and it is expected that this will stand until the end of the transition period.

No date has been given in respect of the harmonisation of the EN ISO 13485:2016 version at this time and interested parties wishing to monitor the situation should refer to:

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

Review

The republication of ISO 13485 / EN ISO 13485, whilst containing many detailed changes, has not been aligned with the Annex SL high level structure adopted by ISO 9001:2015 and other Quality Management Systems Standards. ISO 13485:2016 and EN ISO 13485:2016 retain the Guide 83 format of the previous version and that of ISO 9001:2008. The misalignment is down to the revision of ISO 13485 commencing before that of ISO 9001.

The scope of ISO 13485:2016 / EN ISO 13485:2016 remains unchanged which is for Medical Devices – Quality management systems – Requirements for regulatory purposes.

The standard retains the same 5 sections as in the previous version but includes a number of sub-clause changes and additions.

There are numerous subtle and detailed changes within the standard but one of the main areas of emphasis is risk management, which is shared with the other QMS standards.

Although the process approach is maintained within the standard, it reflects the continued emphasis upon compliance with regulatory requirements and the prescriptive nature with the now increased number of documented procedures and documented processes that are defined.

The other main areas of emphasise in the new standard include:

- the introduction of a risk-based approach to the QMS
- greater emphasis on regulatory requirements and the responsibilities and commitment of top management
- increased controls over suppliers and outsourced activities
- risk management throughout the product life cycle

Conclusion

Clients currently certified to ISO 13485:2003 or EN ISO 13485:2012

Holders of UKAS accredited certificates issued against either of the above versions of the standard will have until 31st March 2019 to transition to the revised standard otherwise the certificates will cease to be valid. Therefore,

- all transitional audits must be completed in order to allow the process to be completed by this date
- transitional audits can be conducted either as a single assessment or under a phased approach
- the single audit is the preferred option of LRQA particularly due to the closely integrated process changes.

Lloyd's Register LRQA

Improving performance, reducing risk

What will happen if my existing certificate is due to expire before 1st March 2019?

- All new certifications must be to ISO 13485:2016 after 1st March 2018
- this applies to re-certifications
- if your certificate is due to expire on or after 1st March 2018, then the transitional assessment will need to be completed in order to allow the certification process to be completed before this date.

What will be the situation should I wish to apply for certification to ISO 13485 / EN ISO 13485 now?

- LRQA suggests that it is best for new clients to consider ISO 13485:2016 now as this will alleviate the need for a transitional assessment shortly after initial certification
- the decision lies with the applicant who would need to be aware of the deadline date for certification of 1st March 2018 and the consequences of not meeting it
- no new applications accepted to 2003/12 versions after 1st September 2017
- an assessment against the 2016 version would be arranged without reference to the previous version. The assessment team would prepare an audit plan against the new standard in the normal manner
- a new applicant would have to consider the possibility of a gap assessment and this could be discussed at the time of the enquiry.

How will the ISO 13485:2016 / EN ISO 13485:2016 Transitional assessment be arranged?

- All LRQA certificate holders against the above standards should be preparing for the transition by examining existing processes and procedures
- transitional arrangements and planning for the audit should start as early as possible. Your assessor will discuss with you the options and timings for assessment
- all transitional audits will need to be additional to existing surveillance, focus or recertification durations and will be a minimum of 1 extra day. This may need to be increased subject to complexity and scope of assessment e.g. multiple sites
- if the organisation holds ISO 9001 certification, transitional arrangements for this standard must be independent and additional to the days required for ISO 13485 and in accordance with scheme requirements
- in situations where a client holds ISO 9001 certification and has completed transition to the 2015 version at the time of the ISO 13485:2016 assessment, the Certified Body has to ensure that any 'integrated' audits comply with the additional man-day requirements specified within MD11.

If you wish to gain new ISO 13485:2016 certification or transition to the latest version what should you do now?

- If you are ready for transitional assessment or keen to gain certification to ISO 13485:2016 / EN ISO 13485:2016 you should talk to LRQA without delay.
- LRQA is ready to discuss your requirements and to plan and conduct your assessment
- LRQA has ISO 13485 / EN ISO 13485:2016 trained auditors ready to conduct your assessments
- LRQA has been recommended for accreditation to ISO 13485:2016 / EN ISO 13485:2016 and is ready to discuss your assessment requirements.

Summary

- All new and renewed certificates issued on or after **1st March 2018**, will need to be in accordance with the 2016 version of the standard
- all existing ISO 13485 / EN ISO 13485 certificates will need to be satisfactorily transitioned to the 2016 version of the standard by **31st March 2019** or will become invalid after that date.

LRQA helps to unlock the power of your management systems to improve organisational performance and reduce risk.

To find out more about how LRQA can help you to with your requirements, visit **lrqa.co.uk/13485**, email **enquiries@lrqa.co.uk** or call **0800 783 2179**

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