Fact Sheet

TÜV NORD CERT – The forthcoming new version of DIN EN ISO 13485

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General

For many years the internationally-recognised standard DIN EN ISO 13485 has provided the basis for efficient quality management for a wide variety of organisations. The current version dates from 2012. DIN EN ISO 13485 is based on the English-language ISO 13485 from the year 2003, which is valid throughout the world. In contrast to the ISO standard, the German-language DIN EN ISO 13485 has a national and European foreword in addition to the translated text; the content of the text itself is identical to that of the ISO standard. The European Annexes are also included, which form a connection between the standard and the underlying requirements of the EU directives in the area of medical devices.

Since 2011, the ISO/TC 210 Technical Committee has been working on a new version of the base standard ISO 13485. Following several revisions of the drafts, the last adjustments to the Final Draft (FSDIS) have been underway since the end of October. These adjustments generally take two months, which means that publication of the new ISO 13485 is expected for the start of 2016. DIN EN ISO 13485 will then probably be available in March/Aprifl 2016. First the European elements will be drawn up (Foreword and Annexes) and then the German standards organisation, DIN, will create the German version.

The new version aims to improve formulation of the normative clauses so as to more clearly demonstrate agreement of the standard with regulatory requirements. To this end, many areas of the current text will be expanded, however without the addition of major requirements as such.

Timeline for the new DIN EN ISO 13485:2016

Expected changes at a glance

- NO “High Level Structure”
  – different structure than ISO 9001:2015
- Based on ISO 9001:2008
- Clause 7.3.7, requirements for development validation extended
- Division of normative part of standard into 8 sections is unchanged
- Expanded definition of terms
- Risk management extended
  – risk-based approach throughout the organisation
- Annex A expanded: differences and common areas in relation to ISO 13485:2003
- Annex B removed: comparison of ISO 13485 with ISO 9001

Effects of the changes on certification

Certification according to the new version of DIN EN ISO 13485 will only be possible after its publication, which will probably mean as of April 2016. The transition period is expected to be three years. The time needed for the audit in which the changeover takes place will be increased by an amount yet to be specified. Changeover can be undertaken in line with client certifiability and is often carried out at the time of the recertification.

If you have any questions regarding combined certification (ISO 9001 and DIN EN ISO 13485), please speak to us directly.

We would like to put our expertise at your disposal and answer any questions you may have. Simply send us an email at office@tuv.mk or call us on +389 2 3221 603.

Our experts will be happy to discuss the procedure with you. Why not contact us.

Further information can be found at:
www.tuev-nord.de/medicaldevices

Purchase ISO standards over the Beuth Verlag: **www.beuth.de/en**

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