Getting Ready for ISO 13485:2016

Review of Significant Changes and Recommendations for Manufacturers

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Agenda

Overview on ISO 13485:2016

Key Changes by Clause

Differences vs. QSR

Planning the Upgrade

Overview on EN ISO 13485:2016

- History
- Stats
- Scope
- Who Is It For?

Overview of ISO 13485 - History

- Last global (ISO) standard edition: 2003 (2nd ed)
- Last European (EN ISO) standard edition: 2012 (for CE Marking)
- Most recent standard: EN ISO 13485:2016 (also ok for CE Marking)
- Transition to the 2016 standard required by 2019-03-01

Overview of ISO 13485 - Stats

ISO 13485:2003/2012 (same text)

- 70 Pages
- 23 Requirement Clauses
- “Regulatory Requirements” 7 times
- Terms defined: 8
- Risk Management: Product Realisation

ISO 13485:2016

- 83 Pages
- 23 Requirement Clauses, 40+ new requirements in subclauses
- “Regulatory Requirements” 37 times
- Terms defined: 19
- Risk Management: ALL QMS Processes

-Asia / Pacific manufacturers have had more ISO 13485 certifications (6637) than USA (5175).

-China more than 1/3 of all Asia / Pacific ISO 13485 Certs

-Top countries with new certs: USA 5175, GERMANY 2890, CHINA 2559

Overview of ISO 13485 - Scope

ISO 13485:2003/2012 Scope: This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation and servicing of medical devices, and the design, development, and provision of related services.

It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements.

Overview of ISO 13485 Scope

- ISO 13485:2016 Scope: This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Overview of ISO 13485:2016- Who is it for?

ISO 13485:2003/2012 Certificate Holders

- Device manufacturers
- Distributors
- Installers/Service providers

ISO 13485:2016 Certificate Holders:

- 2003/2012 Cert holders +
- Critical component manufacturers
- Re-manufacturers
- Re-furbishers

Key Changes by Clause

- 4 Quality Management Systems
- 5 Management Responsibility
- 6 Resource Management
- 7 Product Realisation
- 8 Measurement, Analysis, Improvement

4 QMS – Key Changes

- ALL processes within the QMS need to be established using a risk-based approach (in 2003/2012, only Product Realisation processes)
- Outsourced processes need to be established using a risk-based approach.
- ANY software used as part of the QMS must be validated and documented (in 2003/2012, only software used in production and quality controls)
- A Medical Device File is required to be maintained for each manufactured device including a description of the device along with all relevant specifications and records (in 2003/2012, only if required by regulation)

❑Thanks for viewing the preview. For more info, email us at info@crogroup.com