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IT'S HERE!!!!!! THE NEW ISO 13485:2015

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- 1 - Current - EN ISO 13485:2012
- 2 - ISO 9001:2015 Update
- 3 - ISO 13485:2015
- 4 - Key additions for ISO 13485:2015
- 5 - Potential Timings

EN ISO 13485:2012

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What is the difference?

ISO 13485:2003

- The current International Standard

EN ISO 13485:2003

- The previous version of the European Harmonised Standard
- Obsolete as of 30 August 2012

EN ISO 13485:2012

- Changes within Foreword & Annex Zs only
- **No change** to requirements (Normative Text)
- Annex Z's to provide greater clarity on applicability & alignment with AIMDD, MDD & IVDD

Example

EN ISO 13485:2012 Annex ZB

Relationship between
Annex II of 93/42/EEC and
clauses of ISO 13485

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first sentence		Not covered
3.1 second sentence 1 st indent		Not covered
3.1 second sentence 2 nd indent		Not covered
3.1 second sentence 3 rd indent		Not covered
3.1 second sentence 4 th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex II unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second sentence 5 th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 6 th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 7 th indent		Not covered
3.2 first paragraph first sentence		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 93/42/EEC. The legal requirements must be examined,

ISO 9001:2015

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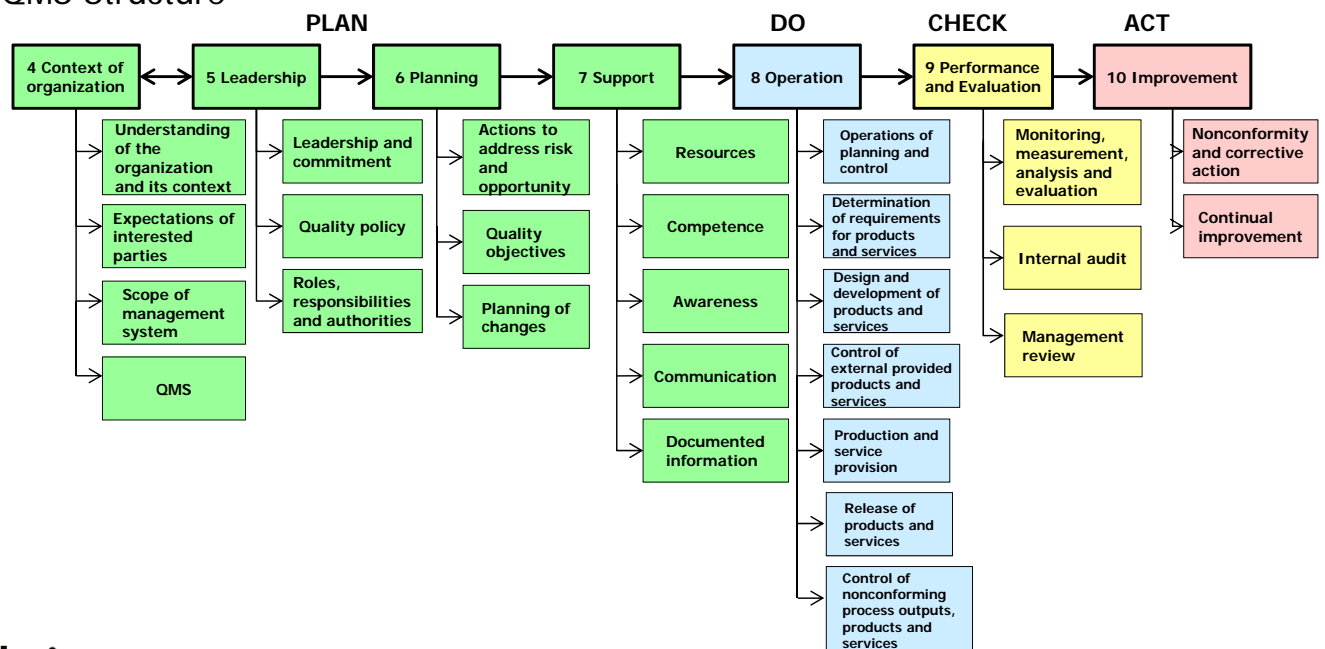
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What's next?

ISO 9001 Timeline



QMS Structure



The Future?



ISO 13485:201x

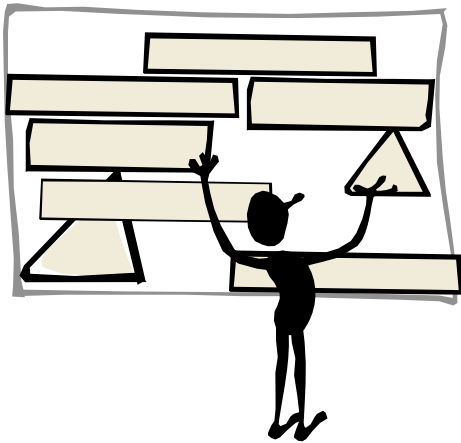
3rd Edition – Presentation material based on the text as prepared for the Final Draft International Standard (FDIS) by ISOTC 210 Working Group 1



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ISO 13485:2015 – What's New?



- Many additions
- Some new requirements
- Some expansion & clarification
- Increased clarity of interrelationship between clauses and requirements

DISCLAIMER!!!!!!!

THE FOLLOWING INFORMATION IS PREPARED AS A FINAL DRAFT.

THE ITEMS OUTLINED HERE ARE CURRENT PROPOSED CHANGES.

THE FINAL MEETING VOTE IS EITHER "YES" OR "NO", NO FURTHER COMMENTS OR CHANGES AT THIS TIME

Overall Numbering of Clauses

- Due to the inclusion of several new clauses, several sub-clauses have been re-numbered. Although the content may not have changed, the sub-clause reference may have changed. This presentation covers changes to content, not every sub-clause re-number.
- In order to work with the MDSAP program of determining levels of non-conformance grading*, the clauses and sub-clauses required formatting

* See GHTF Document SG3 N19

1. New and Key Changes - Regulatory Requirements

ISO 13485:2003	ISO 13485:2015
Regulatory appears 16 times	72 times in new draft
1 Scope and application 4.2.1 Documentation 4.2.3 Document control 4.2.4 Record control 5.1 Management commitment 5.3 Quality policy 5.5.1 Responsibility & authority 5.6 Management review 6.1 Provision of resource 6.2 Human resource 7.2 Customer related processes 7.3.2 Design input 7.3.6 Design validation 8.1 Statistical technique 8.2.1 Customer feedback 8.5.1 Advisory notice and reporting	3.1 Advisory notices 3.10 Manufacturer 4.1 General requirements 4.2.3 Medical device file 5.2 Customer focus 5.4.1 Quality objective 7.2.3 Communication with regulatory authorities 7.3.3 Design inputs 7.3.7 Design and development validation 7.3.9 Design change 7.4.1 Purchasing process 7.5.8, 7.5.9 Identification and traceability 8.2.2 Complaint handling 8.2.3 Reporting to regulatory authorities 8.2.4 Internal audit 8.3 Nonconforming products, product re-work 8.5.2, 8.5.3 Corrective and preventive action

Objectives and scope

	ISO 13485:2003	ISO 13485:2015
Objectives	Facilitate harmonization	Facilitate global alignment
Scope & Role	Organizations provide Medical devices and related services	Organizations can be involved in one or more stages of the life-cycle including the design and development, production, storage and distribution, installation, or servicing of a medical device and the 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.

Definitions

	ISO 13485:2003	ISO 13485:2015
3.7 Definition (8 → 19)	Active implantable medical device Active medical device Advisory notice Customer complaint Implantable medical device Labelling Medical Device Sterile medical device	Advisory notice Clinical evaluation Complaint Distributor Implantable medical device Importer Labelling Life cycle Manufacturer Medical device Medical device family Performance evaluation Post market surveillance Purchased product Risk Risk management Sterile barrier system Sterile medical device

4 – Quality Management System

4.1 General Requirements

- + Document role(s) undertaken by organization under regulatory requirements
- + Risk based approach for developing QMS processes

4.1.3 - 5 General requirements

Records to meet regulatory requirements

- + For outsourced processes control based on risk and ability

4.1.6 General Requirements

- + Requirement to validate the computer software used for QMS prior to initial use & after changes

4.2 Documentation Requirements

- Medical Device File
- + Detailed list of items (a-f) that can be included in a product or technical file to meet regulatory requirements

5 – Management Responsibility

5 General requirements

+ **Regulatory requirements**
(throughout)
+ Responsibilities
& authorities
documented
(5.5.1)

5.5.1 Responsibility & Authority

Top mgmt
shall
DOCUMENT
the
interrelation
of all
personnel
who....

5.5.2 Management representative

Focus on
documentation
of the quality
management
system and the
removal of
customer
requirements
from bullet c)

5.6 Management review

+ Document
the frequency
for
management
review

+ More bullet
points for
inputs, new
bullet for
outputs

6 – Resource Management

6.2 Human resources

+ Shall document the processes for establishing competence, providing training, and ensuring awareness

6.2 Human resources

+ Maintain competency
+ NOTE effectiveness methodology link to risk of work for which training provided

6.3 Infrastructure

+ Prevent product mix up, ensure orderly handling; Maintenance of equipment applies to production, control of work env, monitor and measurement.

6.4 – Work environment and contamination control

6.4.1

Work environment

Additional reference - + NOTE
For information see for
example ISO 14644 and ISO
14698 series.

6.4.2

Contamination control

+ planned arrangements shall be documented for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product

For sterile medical devices, the organization shall document requirements for control of contamination with micro-organisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

7 – Product Realization

7.1

Planning of product realization

- + Documented processes for risk management
- + Required planning for verification, validation, monitoring, measurement, inspection, test activities, handling, storage, distribution, & traceability

7.2.1

Determination of product requirements

- + Any user training needed to ensure specified performance and safe use of the product

7.2.2

Review of product requirements

- + applicable regulatory requirements are met
- + any user training identified in accordance with 7.2.1 is available or planned to be available, and

7 – Product Realization

7.2.3 Communication

New Note Added

+ As appropriate, the organization shall communicate with regulatory authorities in accordance with planned arrangements.

Sounds a lot like the MDD – Post Market Surveillance and Vigilance!!!

7 – Product Realization (continued)

7.3.2 Design & development planning

- + Update documents with progress
- + List of items to document
- + Traceability of outputs to inputs
- + Competence

7.3.3 - 5 D & D Inputs, outputs, review

Inputs

- + Usability and the ability to verify/validate

Outputs

- + Shall be in a form suitable for verification against inputs

Review

- * Specialist

7.3.6 & 7 Design & development V/V

Requirement to document: the V/V plan, the methods of V/V, criteria for acceptance or failure, justification for sample sizes and the risk associated with those sample sizes

7.3.6 & 7 Design & development V/V

V/V of device interfaces (user instructions), failure modes. All validation activity must be conducted on final production units or documented equivalent devices

7 – Product Realization (continued)

7.3.8 Design & development transfer

New Clause

+ Transfer plans for
supplier,
manufacturing,
process, personnel,
tools, environment,
installation, etc

7.3.9 Design and development changes

Was 7.3.7 – Includes
greater detail
regarding the control
of changes,
documentation
requirements,
approvals, etc

7.3.10 Design and development files

New Clause

+ shall maintain a d&d
file for each medical
device type or family.
This file shall include or
reference records
generated to
demonstrate conformity
to the requirements for
d&d and records for d&d
changes

7 – Product Realization (continued)

7.4.1 Purchasing

Clarify requirements for: a documented procedure or the process of supplier approval, monitoring compliance; documented rationale/justifications for suppliers, criteria used to evaluate suppliers, and re-evaluation is requirements

7.4.2 Purchasing information

+ Purchasing information to include, where possible, suppliers agree to notify changes

7.4.3 Verification of purchased product

+ Extent of verification commensurate with risks and result of evaluation and re-evaluation

7 – Product Realization (continued)

7.5.1

Control of production & service provision

Production and service provisions must be monitored and controlled as well as planned and carried out to ensure products meet established specifications

7.5.2

Cleanliness & contamination control

The organization must document the cleanliness requirements for devices, whether non-sterile or to be sterilized

7.5.3

Installation activities

Unchanged

7.5.4

Servicing activities

Servicing activity records must be analyzed to determine if the issue is a complaint or must be utilized as an improvement input

7 – Product Realization (continued)

7.5.5 Particular requirements for sterile medical devices

- + Maintain records of sterilization process parameters for every batch
- + Sterilization records shall be traceable to each production batch

7.5.6 Validation of processes for production and service provision

- + Validate processes for production & service provision where output cannot be or **is not** verified
- + Document statistical techniques and rationale for sample sizes, approval of changes, and validation of software after any changes

7.5.7 Validation of sterilization and sterile barriers

- + Documented procedures required for validation of sterilization and sterile barriers
- + Validation required prior to implementation
- + Document results and CONCLUSION

7.5.8 Identification

- + UDI where required by national or regional regulations
- + Requirement for procedures for separation of returned products from conforming product

7 – Product Realization (continued)

7.5.9

Traceability

Unchanged from the current version, including requirements for AIMD

7.5.10

Customer property

Consistent with 7.5.4 of current document.
Although not stated, customer property also is understood to include confidential patient health information

7.5.11

Preservation of product

+ NOTE Sterile barrier systems of sterile medical devices are a constituent part of a medical device.

+ Distribution is specified

8 – Measurement, Analysis and Improvement

8.2

Monitoring and measurement

+ Feedback procedures, input to risk management, statistical analysis for proper entry into CAPA

8.2.2 and 8.2.3

Complaint handling & Reporting to regulatory authorities

New Clauses

Requires procedures for timely complaint handling, investigation, regulatory notification and more
Procedures for reporting to regulatory authorities regarding complaints is are required

8 – Measurement, Analysis and Improvement

8.2.6

Monitoring and measurement of product

+ Test equipment and persons authorizing release of product shall be identified

8.3

Control of nonconforming product

+ NC product shall be considered for corrective action following investigation (or documented justification for lack of investigation)

+ 8.3.1 - 4 New clauses for nonconforming product before delivery, after delivery and rework

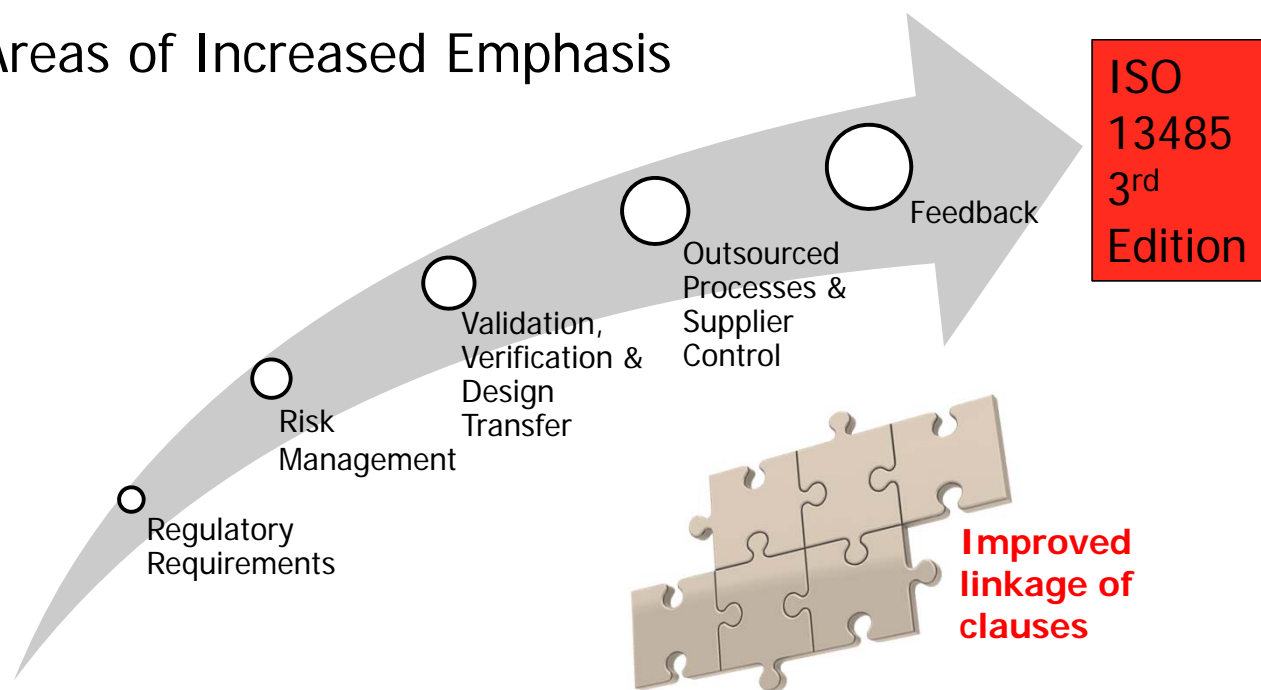
8 – Measurement, Analysis and Improvement

8.5.2 & 8.5.3

Corrective & Preventive action

- 1) verifying that the corrective or preventive action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of product; and
- 2) Impact to QMS and regulatory requirements arising from CAPA
- 3) Update to risk analysis????

Areas of Increased Emphasis



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Potential Timings

Timing

- At the time this presentation was drafted, the FDIS (final draft international standard) has not been published.
- If publication occurs in short order, then the official standard ISO 13485 may be available late 2015 but more likely early in 2016.
- Upon publication, there will be a 3 year transition period.
- It is also anticipated the EN version will be published in a similar timeframe, and harmonization at a later date.

Bigger Global Picture

- ISO 9001 and ISO 13485 Revisions
- Medical Device Directive Updates, AIMD Directive Updates
- IVD Directive Updates
- Japanese Requirement Updates (November 2014)
- MDSAP (US, Canada, Brazil, Australia, Japan with the EU watching carefully)

Questions?

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Thank you

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