Medical Device Regulation / In Vitro Diagnostic Regulation ISO 13485:2016 Alignment

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Presenters

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1 – MDR/IVDR update and timings

2 – ISO 13485:2016 overview and timings

3 – MDR/IVDR alignment with ISO 13485:2016

4 - Conclusions

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MDR/IVDR
Update and timings

MDR/IVDR Update and timings

June 2016 Consolidated text published

May 2016 EU reached political agreement

Final text is unlikely to change significantly from the consolidated text

Finalisation (publication in the Official Journal) estimated for late 2016/early 2017

3 year transition period for the MDR post finalisation

5 year transition period for the IVDR post finalisation

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IVDR Update

Medical devices: deal reached on new EU rules

Alignment of the **MDR** and IVDR

- '…There are specific features of *in vitro* diagnostic medical devices, in particular in terms of risk classification, conformity assessment procedures and clinical evidence, and of the *in vitro* diagnostic medical device sector which require the adoption of a specific legislation, distinct from the legislation on other medical devices,
- whereas the horizontal aspects common to both sectors should be aligned.'

ISO 13485:2016 Overview and timings

ISO 13485:2016

Medical Device Quality Management System (QMS)

Standard published 26th February, 2016

Introducing the new ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes.

The latest edition of ISO 13485, the internationally recognized quality management systems standard for the medical device industry, with over 27,000 certificates globally, has been published, March 2016.

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Regulatory Requirements

ISO 13485:2003	ISO 13485:2016
"Regulatory requirements" **Appears 9 times***	"Regulatory requirements" **Appears 37 times***

* Within Normative Requirements, i.e. Clauses: 4 - 8

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Definitions

Clause 3

ISO 13485:2003	ISO 13485:2016
Active implantable medical device Active medical device Advisory notice Customer complaint Implantable medical device Labelling Medical Device Sterile medical device	Advisory notice **Authorized representative** **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

Areas of Increased Emphasis

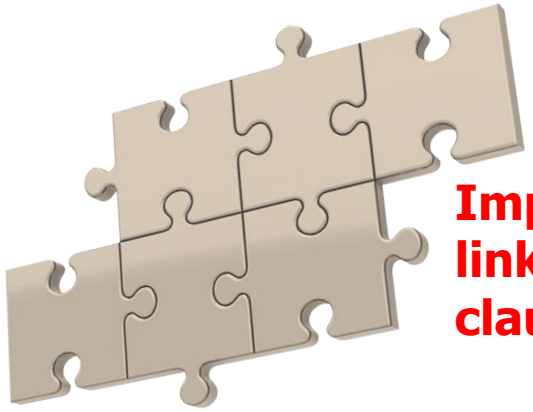
Regulatory Requirements

Risk Management

Validation, Verification & Design Transfer

Outsourced Processes & Supplier Control

Feedback



Improved linkage of clauses

ISO 13485:2016 Annexes

Annex A

- Comparison of content between ISO 13485:2003 and ISO 13485:2016

Annex B

- Correspondence between ISO 13485:2016 and ISO 9001:2015

European Annexes - ZA (AIMD), ZB (MDD) and ZC (IVD)

- Identifies relationship between the European Standard (EN ISO 13485:2016) and Conformity Assessment Requirements of the respective EU Medical Device Directives via each conformity assessment route for each directive
- Annexes will need to be rewritten to address MDR and IVDR

ISO 13485:2016 – Timings

26 February 2016
- ISO 13485:2016 published
- BS EN ISO 13485:2016 published
- 3 year transition period now started

2016
- European Harmonization
- Late 2016?

28 February 2018
- Cease issue of new ISO 13485:2003 Certificates and re-certifications to ISO 13485:2003

28 February 2019
- End of 3 year transition

MDR/IVDR
Alignment with ISO 13485:2016

IMPORTANT NOTES

- The following slides give a flavour of how ISO 13485:2016 aligns with the MDR/IVDR and is **NOT** an exhaustive review
- ISO 13485:2016 is an **international** standard which is intended to be applicable in jurisdictions **worldwide**
- Therefore it is not practicable for ISO 13485:2016 to cover all the European quality management system requirements
- ISO 13485:2016 can be used as the basis to meet requirements however manufacturers must ensure that their QMS also meets the applicable European regulatory requirements

MDR/IVDR QMS Requirements

- Article 8 includes requirements for the QMS
- The requirements for the quality management system are expanded further in Annex VIII
- This section of the presentation will focus on alignment with ISO 13485:2016 in the above sections
- As stated earlier manufacturers must ensure that their QMS meets all the applicable European regulatory requirements

MDR/IVDR Article 8

General obligations of the manufacturer

Article 8 Clause 5 – Quality Management System

- Manufacturers shall … proportionate to the risk class and the type of device, manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this regulation in the most effective manner
- The quality management system consists of all parts and components of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It is managing the structure, responsibilities, procedures, processes and management resources to implement the needed principles and actions to achieve compliance with the provisions of this regulation.

Article 8 Clause 5 – Quality Management System

Clause 5 – The quality management system shall address at least the following aspects:

- a strategy for regulatory compliance, including compliance with conformity assessment procedures and management of modifications to the devices covered by the system;
- identification of applicable safety and performance requirements and exploration of options to address these;
- the responsibility of the management;
- resource management, including selection and control of suppliers and sub-contractors;
- risk management;

ISO 13485:2016 – Not covered

ISO 13485:2016 – Clause 7.3.3

ISO 13485:2016 – Clause 5

ISO 13485:2016 – Clause 6.1, 7.4.1

ISO 13485:2016 – Clause 4.1.2, 7.1

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Article 8 Clause 5 – Quality Management System

Clause 5 – The quality management system shall address at least the following aspects:

- clinical / performance evaluation, including PMCF / PMPF;
- product realisation, including planning, design, development, production and service provision;
- control of UDI-Code assignments, ensuring consistency of information provided;
- setting-up, implementation and maintenance of a systematic PMS system;
- handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

ISO 13485:2016 – Clause 7.3.7

ISO 13485:2016 – Clause 7

ISO 13485:2016 – Clause 7.5.8

ISO 13485:2016 – Clause 8.2.1, 8.5.1

ISO 13485:2016 – Clause 7.2.3, 8.2.3

Article 8 Clause 5 – Quality Management System

Clause 5 – The quality management system shall address at least the following aspects:

- processes for reporting of serious incidents and FSCA in the context of vigilance;
- management of corrective and preventive actions and verification of effectiveness;
- processes for monitoring and measurement of output, data analysis and product improvement.

ISO 13485:2016 – Clause 8.2.2, 8.2.3

ISO 13485:2016 – Clause 8.5.2, 8.5.3

ISO 13485:2016 – Clause 8

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MDR/IVDR Annex VIII Conformity Assessment

Annex VIII Chapter 1, Clause 1 – Quality Management System

- The manufacturer shall establish, document and implement a quality management system as described in Article 8(5) of this Regulation and maintain its effectiveness through the life cycle of the devices concerned…

Annex VIII Chapter 1 Clause 3.2 – Quality Management System

- Implementation of the quality management system shall ensure the compliance with the provisions of this Regulation. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records.

Annex VIII Clause 3.2 – Quality Management System

- Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:
- (a) the manufacturer's quality objectives;
- (b) the organisation of the business and in particular:
  - the organisational structures with clear assignment to procedures, the responsibilities of the managerial staff and their organisational authority,
  - the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and of device, including control of devices which fail to conform,
  - where the design, manufacture and/or final verification and testing of the devices, or elements of any of these, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,
  - where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;

ISO 13485:2016 – Clause 5.4.1

ISO 13485:2016 – Clause 5.5

ISO 13485:2016 – Cl. 7.3.5 8.2, 8.3

ISO 13485:2016 – Clause 4.1.5, 7.4

ISO 13485:2016 – Not covered

Annex VIII Clause 3.2 – Quality Management System

- (c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques, where these procedures and techniques shall specifically address:
  - the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures,
  - identification of applicable general safety and performance requirements and solutions to address these, under consideration of applicable CS and harmonized standards or equivalent solutions,
  - the risk management according to section 1a of Annex I,
  - the clinical / performance evaluation, according to Article 49 and Annex XIII, including PMCF / PMPF,
  - the solutions to address the applicable specific requirements regarding design and construction, including appropriate preclinical evaluation, addressing specifically Chapter II of Annex I,
  - the solutions to address the applicable specific requirements regarding the information to be supplied with the device, addressing specifically Chapter III of Annex I,
  - the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture,
  - management of design or quality management system changes;

ISO 13485:2016 – Not covered

ISO 13485:2016 – Clause 7.3.3

ISO 13485:2016 – Clause 7.1

ISO 13485:2016 – Clause 7.3.7

ISO 13485:2016 – Clause 7.3

ISO 13485:2016 – Clause 4.1/4.2

ISO 13485:2016 – Clause 7.5.8

ISO 13485:2016 – Cl. 4.1.4, 7.3.9

Annex VIII Clause 3.2 – Quality Management System

- (d) the verification and quality assurance techniques at the manufacturing stage and in particular:
  - the processes and procedures which will be used, particularly as regards sterilisation and the relevant documents,
- (e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.
- In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annex II.

ISO 13485:2016 – Clause 7.5. 8.2.6

ISO 13485:2016 – Clause 7.5

ISO 13485:2016 – Clause 7.4.3, 7.6, 8.2.6

ISO 13485:2016 – Not covered

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Some examples of what is not covered in ISO 13485:2016

1

- ISO 13485:2016 does not explicitly refer to the European regulations

2

- ISO 13485:2016 does not cover detailed European regulatory requirements for inclusion in the QMS e.g. labels, IFU, UDI, clinical evaluation, technical documentation, vigilance, PMS, PMCF.

3

- ISO 13485:2016 does not require continual improvement of the QMS

Conclusions

- ISO 13485:2016 shows good alignment with the MDR/IVDR
- ISO 13485:2016 can be used as the basis to meet MDR/IVDR requirements
- It is important that manufacturers ensure that the QMS also meets the applicable European regulatory requirements (see ISO 13485:2016 clause 4.1)
- Implementation of QMS requirements of the EU Regulation and ISO 13485:2016 will require modifications to QMS processes
- The changes to the QMS need to be driven through applicable QMS processes

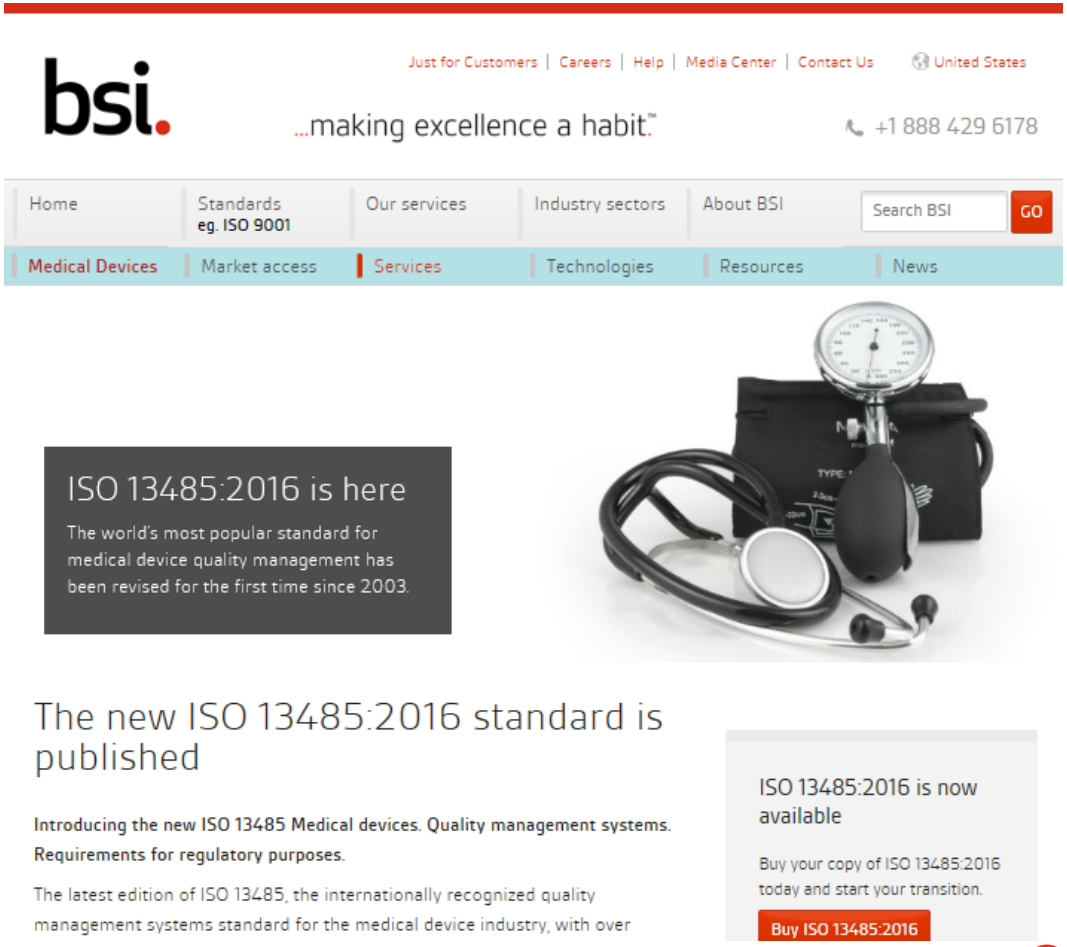
What can you do now?

1. Study the standard and regulation(s)
2. Prepare initial transition plans, with timescales
3. Factor any additional resources & costs into budgets
4. Review staff awareness / knowledge and determine training required
5. Compile project / implementation plans
6. Discuss top–level plans and timescales with BSI Client Manager
7. Look out for additional help, information and resources

BSI Resources

- e-Updates
- Webinars & Recordings
- White Papers
- Frequently Asked Questions - Coming Soon

bsigroup.com/ISO13485revision



Questions

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