ISO 13485:2016 & ISO 9001:2015

Webinar 23rd March 2016

Presenters

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1 - ISO 13485:2003 & EN ISO 13485:2012

2 - ISO 9001:2015

3 - ISO 13485:2016

4 - Key Changes in High Level Structure, ISO 9001 & ISO 13485

5 - Timings

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ISO 13485:2003 & EN ISO 13485:2012

What is the difference?

ISO 13485:2003

- 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

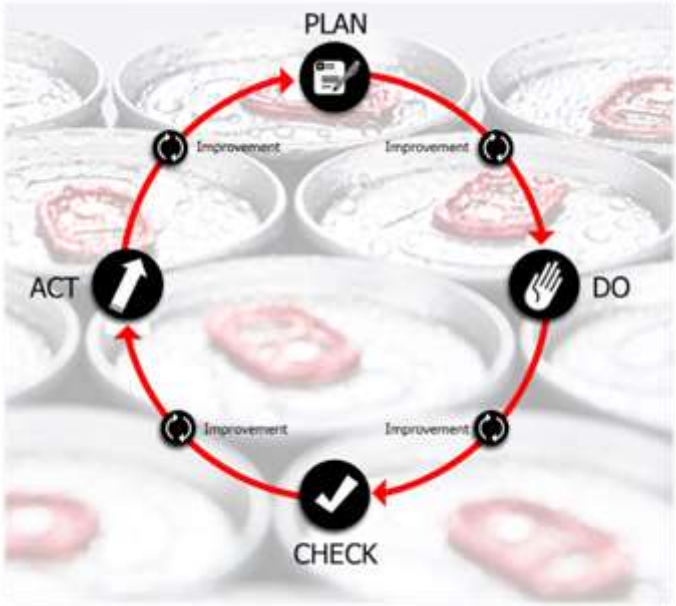
Relationship between Annex II of 93/42/EEC and clauses of ISO 13485

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 1st indent		Not covered
3.1 second sentence 2nd indent		Not covered
3.1 second sentence 3rd indent		Not covered
3.1 second sentence 4th 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 5th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 6th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 7th 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

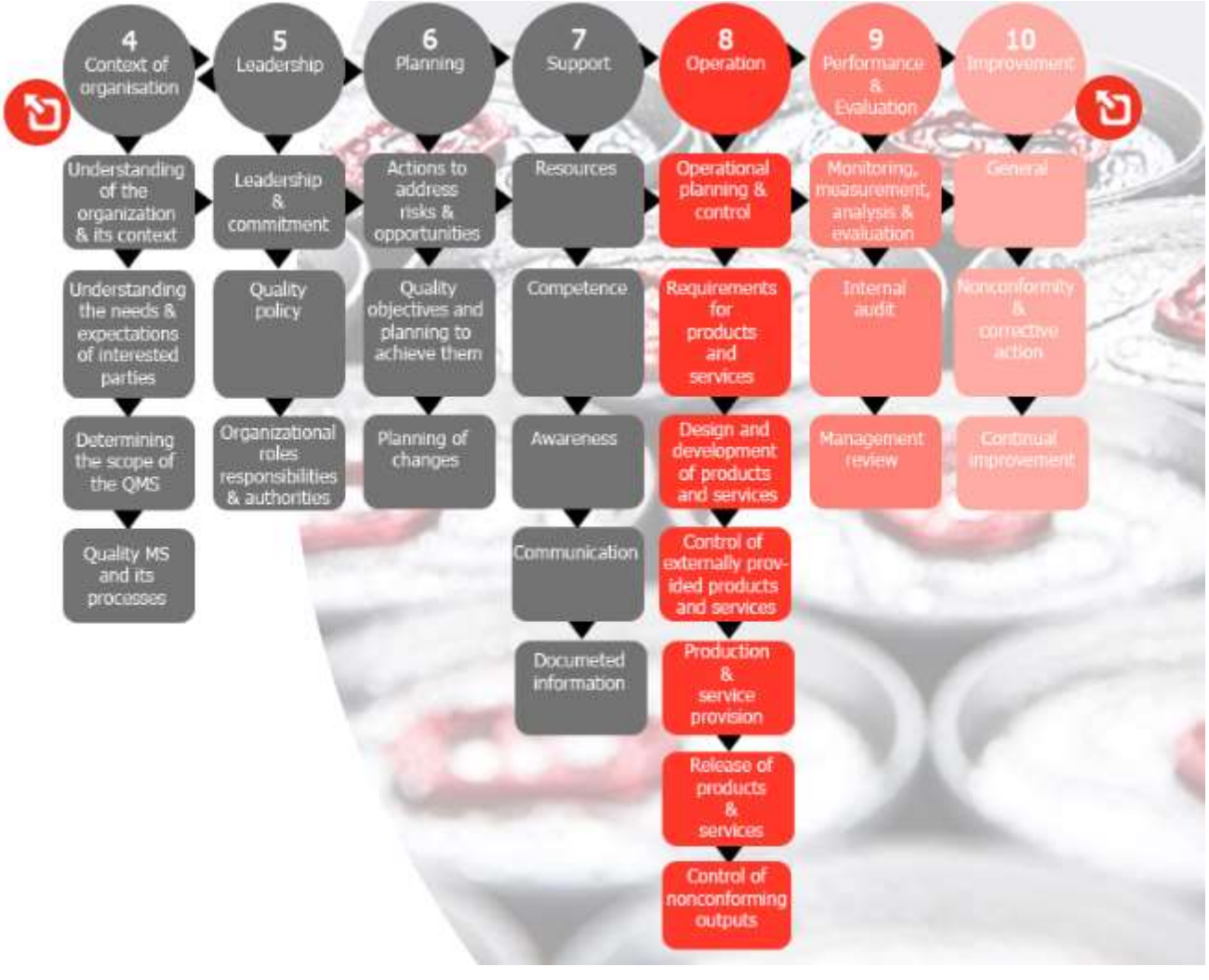
New ISO Management Systems High Level Structure

- New and revised ISO MS Standards now using ISO Annex SL: A standard for standard writers
- Provides a 10 clause high-level structure and common text
- Standardises terminology for fundamental Management System requirements
- Follows the Plan → Do → Check → Act (PDCA) principle



New ISO 9001:2015

10 Clause Structure



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Now

ISO 13485:2016

Published 26 February 2016

Areas of Increased Emphasis

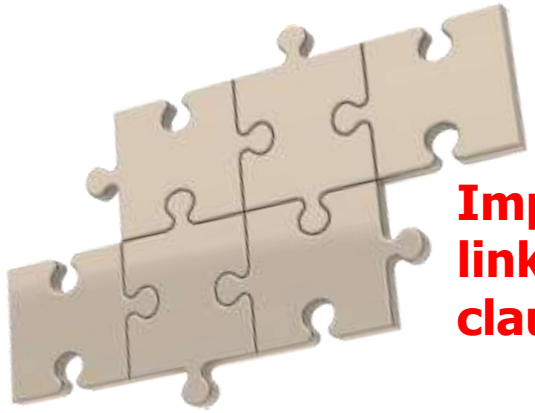
Regulatory Requirements

Risk Management

Validation, Verification & Design Transfer

Outsourced Processes & Supplier Control

Feedback



Improved linkage of clauses

ISO 13485:2016 Annexes

Annex B

- Comparison of content between ISO 13485:2016 and ISO 9001:2015
- Top level clause mapping

Annex B
(informative)

Correspondence between ISO 13485:2016 and ISO 9001:2015

Tables B.1 and B.2 show the correspondence between ISO 13485:2016 and ISO 9001:2015.

Table B.1 — Correspondence between ISO 13485:2016 and ISO 9001:2015

Clause in ISO 13485:2016	Clause in ISO 9001:2015
4 Quality management system	4 Context of the organization
4.1 General requirements	4.4 Quality management system and its processes
4.2 Documentation requirements	7.5 Documented information
4.2.1 General	7.5.1 General
4.2.2 Quality manual	4.3 Determining the scope of the quality management system 7.5.1 General 4.4 Quality management system and its processes
4.2.3 Medical device file	None

High level structure

Key points

High Level Structure

Major clause numbers and titles

Identical core text and numbering schemes

Organizations implementing an integrated system (e.g. QMS, EMS, ISMS etc.) should achieve optimum benefits.

The high level structure and common text is public information and can be found at www.iso.org/directives

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Identical core text and numbering schemes

1) Scope

2) Normative references

3) Terms and definitions

4) Context of the organization

- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the XXX MS
- 4.4 XXX management system

Identical core text and numbering schemes

5) Leadership

- 5.1 Leadership and commitment
- 5.2 Policy
- 5.3 Organizational roles, responsibilities and authorities

6) Planning

- 6.1 Actions to address risks and opportunities
- 6.2 XXX objectives and planning to achieve them

Identical core text and numbering schemes

7) Support

- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information
  - 7.5.1 General
  - 7.5.2 Creating and updating
  - 7.5.3 Control of documented information

8) Operation

- 8.1 Operational planning and control

Identical core text and numbering schemes

9) Performance evaluation

- 9.1 Monitoring, measurement, analysis and evaluation
- 9.2 Internal audit
  - 9.2.1 *[Internal Audits]*
  - 9.2.2 *[Programmes(s)]*
- 9.3 Management review

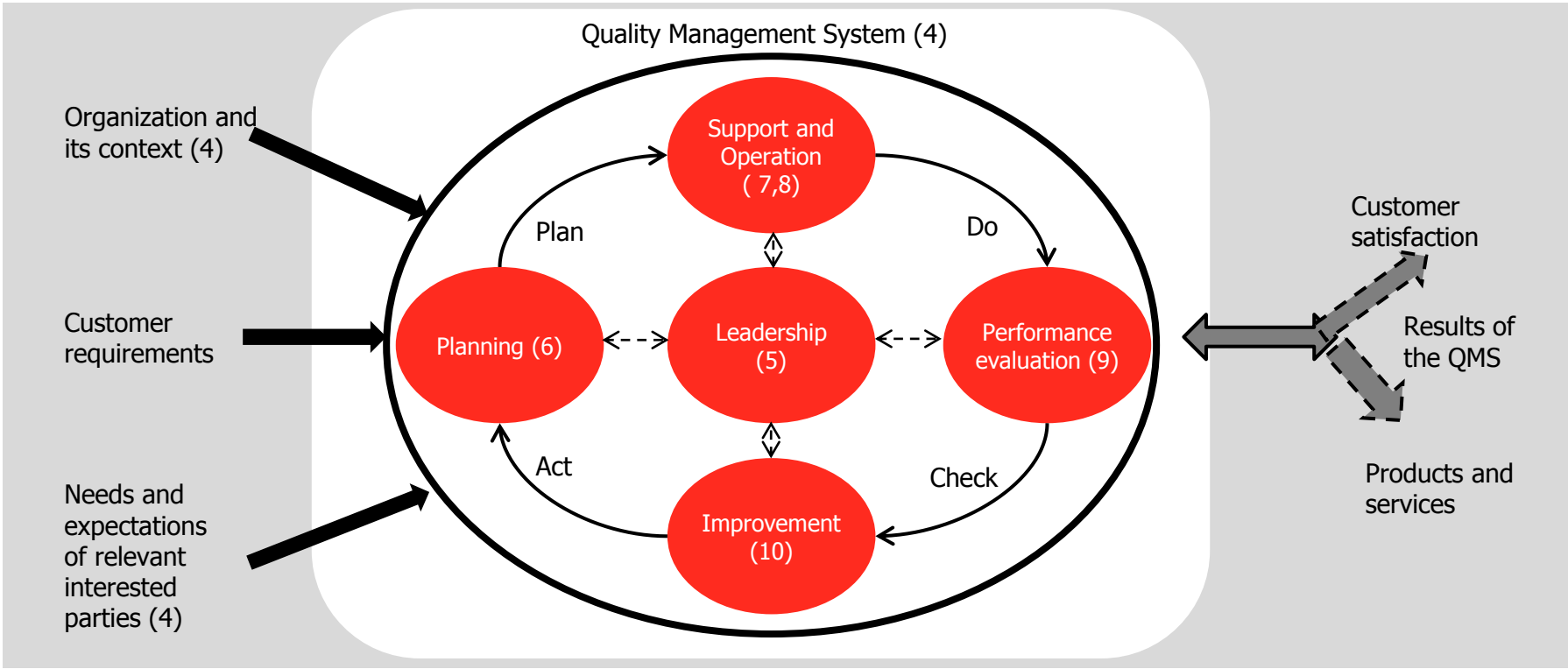
10) Improvement

- 10.1 Nonconformity and corrective action
- 10.2 Continual improvement

ISO 9001:2015

Key changes

Representation of the structure of ISO 9001:2015 in the PDCA cycle



ISO 9001:2015 – Key changes from 2008

Specific changes

- Greater integration with strategic direction and business processes
- Risk based thinking
- Context of the organization must be understood
- Outsourcing and purchasing is combined
- A quality manual is no longer a requirement

4 Context of the organization

4.1 Understanding the organization and its context
4.2 Understanding the needs and expectations of interested parties
4.3 Determining the scope of the XXX management system
4.4 XXX management system

5 Leadership

Leadership and commitment

Policy

Organizational roles, responsibilities and authorities

6 Planning

6.1 Actions to address risks and opportunities

6 Planning

6.2 Objectives and plans to achieve them

7 Support

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7 Support

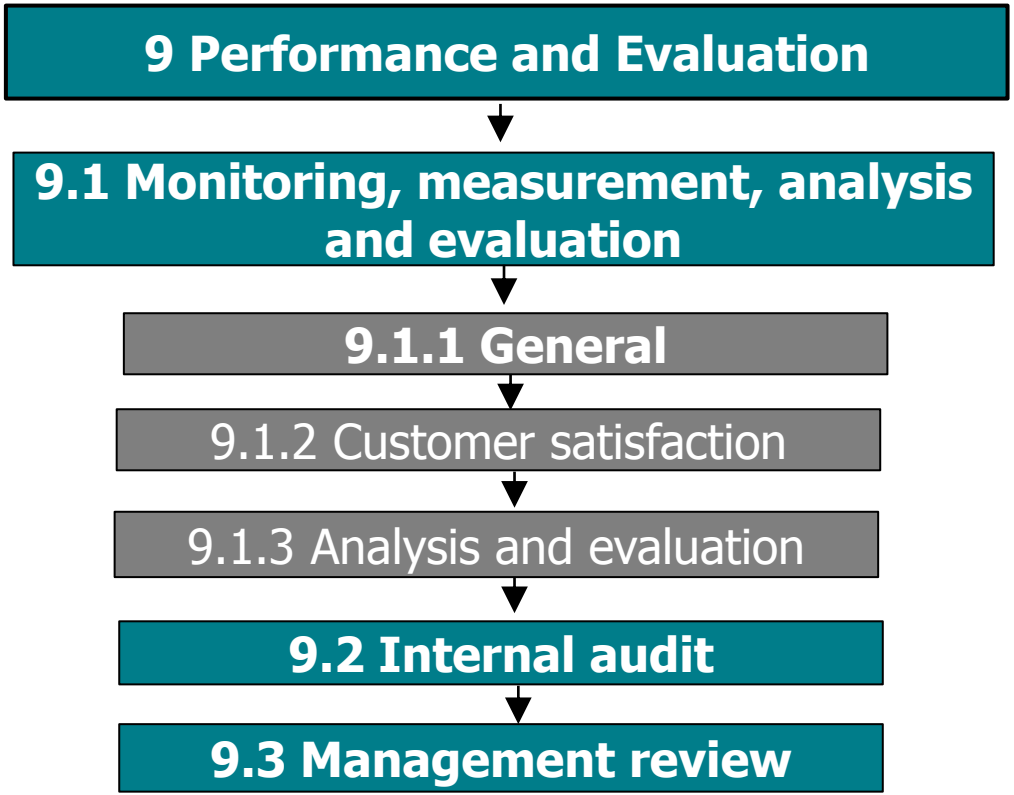
7.5 Documented information

8 Operation

Clause 8, Operation is the replacement for clause 7 from ISO 9001:2008. There are many similarities in the 2015 version, but there are also some important changes.

Most of the clause titles have changed, but the fundamental requirements of many clauses have not changed

9 Performance evaluation



10 Improvement

10.1 Nonconformity and corrective action

10.2 Continual improvement

Summary - Key changes ISO 9001:2015

- Determining the organizational context (HLS)
- Greater emphasis on processes
- Greater alignment with strategic direction (HLS)
- Integration of the QMS into organization's business processes (HLS)
- Determining risks/opportunities within the context (HLS)
- Change management
- Knowledge management
- Communication expanded (HLS)
- Explicit performance evaluation requirements (HLS)
- Improvement expanded (HLS)

Summary of Key Differences and Similarities

ISO 9001:2015

Improvement

Customer satisfaction

No exclusions – applicability managed through scope

No quality manual required

No management representative specified – leadership

Strategic planning

Documented information

Preventive action not specifically referenced – risk based thinking used

ISO 13485:2016

Maintain effectiveness

Meet regulatory requirements

Can exclude from clause 7.3.

Non-applicability needs to be documented and justified.

Quality manual required

Management representative required

Documented procedures and records

Preventive action as a separate clause

Similarities

Process approach

Risk based thinking
Quality Policy

Quality objectives

Resources
Statutory and regulatory requirements

Measurement traceability

Competence and awareness

How do we manage both standards in a QMS?

- The higher requirement takes precedence
- No need to re-structure your Quality Management System around the clause numbers
- ISO 13485:2016 is meant to be compatible with the High Level Structure

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Timings

ISO 9001:2015 Certification Transition Timeline

September 2015
ISO Publication

September 2015 start of 3 years transition period to September 2018

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ISO 13485:2016 – Timings

25 February 2016

ISO 13485:2016 published

BS EN ISO 13485:2016 published

3 year transition period now started

March – June 2016

European Harmonization ??

28 February 2018

Cease issue of ISO 13485:2003 Certificates

NOTE: Draft guidance - No new ISO 13485:2003 certificates issued in final year of transition

28 February 2019

End of 3 year transition

ISO 13485:2016 Transition Process

Early or Late Transition?

- Additional assessment time will be needed
- Early transition by reassessment + limited additional assessment time

Gradual Transition Over Assessment Cycle

- Transition over at least 2 visits
- Limited additional assessment time is required
- Probably 0.5 - 2 days additional assessment per site: Dependant on employee numbers, products, processes, activities, scope and complexity

Note: The above is subject to confirmation of acceptance by relevant Accreditation Bodies

ISO 9001:2015 Transition Process

Timings

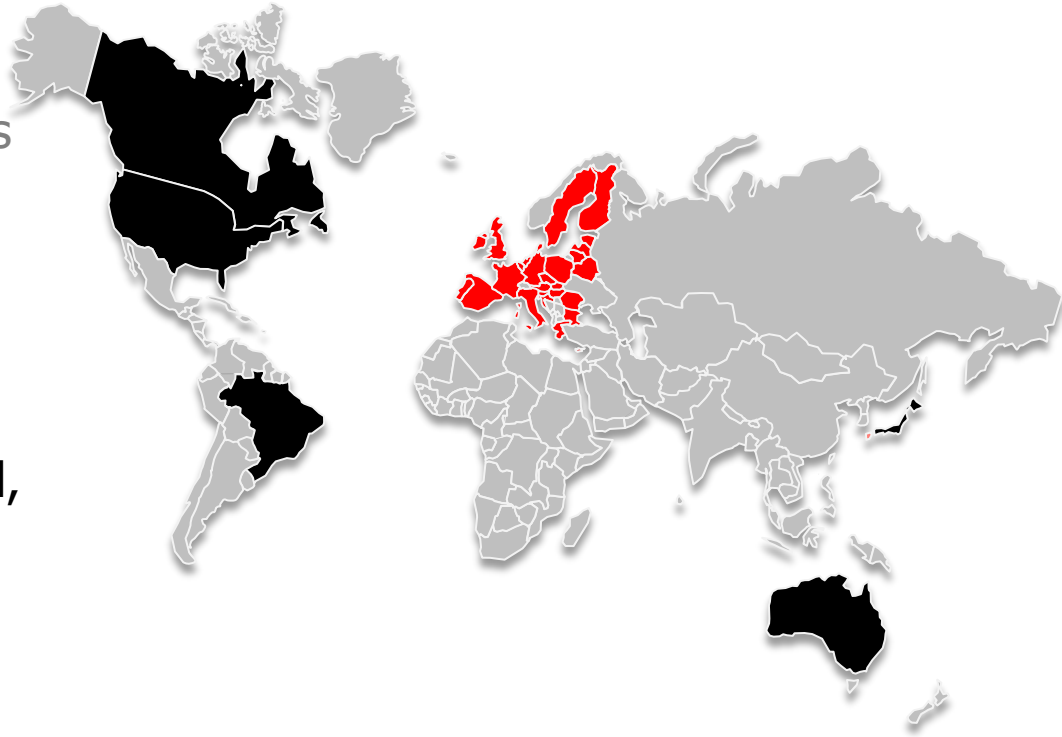
- ISO 9001:2015 was published 15 September 2015
- Transition period ends 14 September 2018

Transition

- IAF ID 9:2015 applies
- Where transition audits are carried out in conjunction with scheduled surveillance or recertification additional time is likely to be required to ensure that all activities are covered for the existing and new standards

Global Picture

- ISO 13485 & ISO 9001 Revisions
- Europe - New MDR / IVDR
- MDSAP Pilot - US, Canada, Brazil, Australia + Japan with Europe watching carefully
- Japanese Requirement (JPMD Act)



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What can you do now?

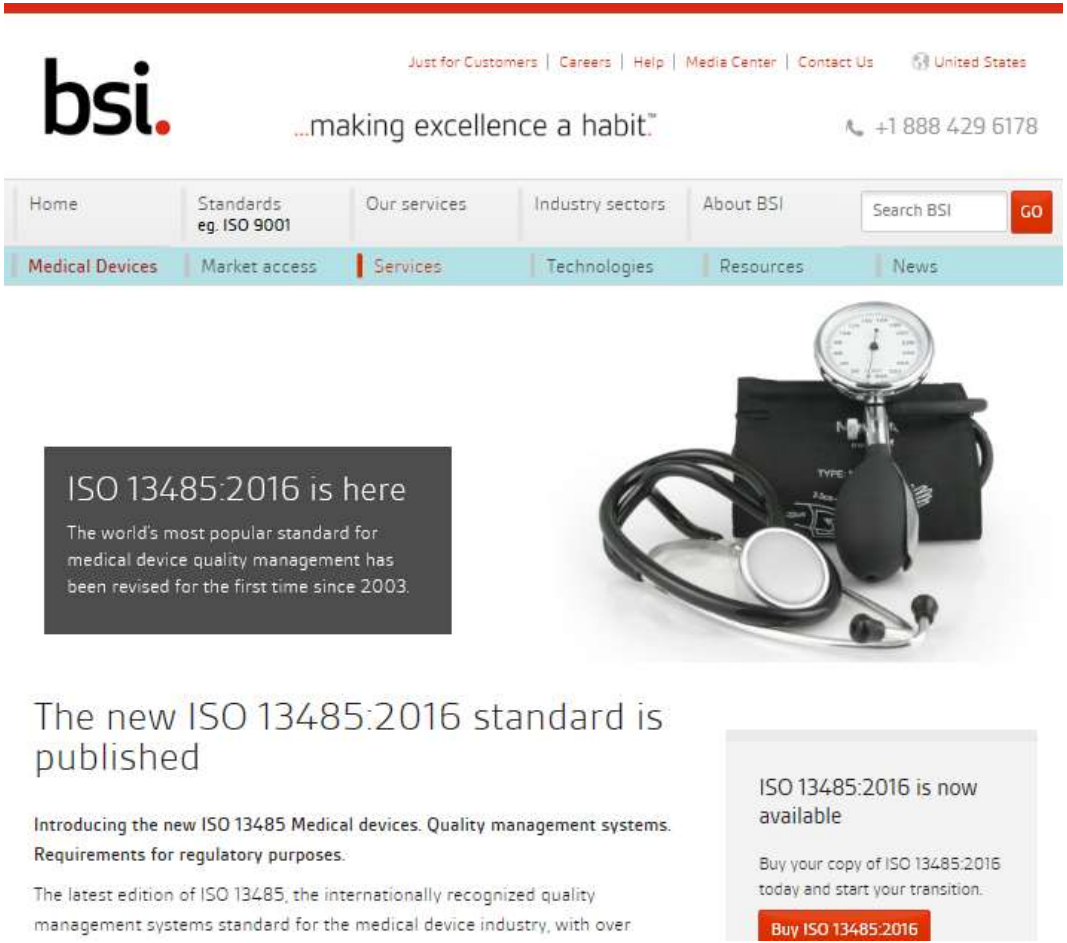
1. Study the standards
2. Consider gap analysis of current QMS Vs. new requirements
3. Prepare initial transition plan, with timescales
4. Factor any additional resources & costs into budgets
5. Review staff awareness / knowledge and determine training required
6. Compile project / implementation plan
7. Discuss top–level plan and timescales with BSI Client Manager
8. Look out for additional help, information and resources

BSI Resources

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

bsigroup.com/ISO13485 revision

bsigroup.com/en-GB/iso-9001-quality-management/



Questions

Thank you

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