ISO 13485:2016

21st April 2016

- ISO 13485:2003 & EN ISO 13485:2012
- ISO 9001:2015
- Key Changes in ISO 13485:2016
- Timings and transition process

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

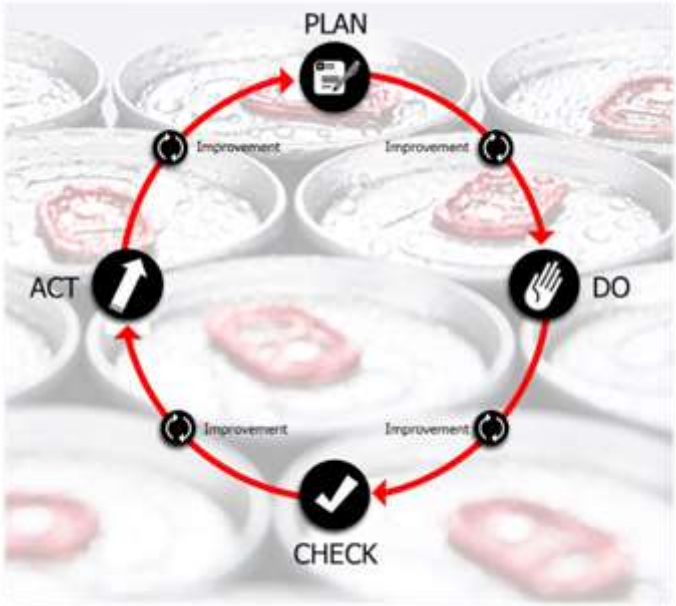
Relationship between Annex II of 93/42/EEC and clauses of ISO 13485

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

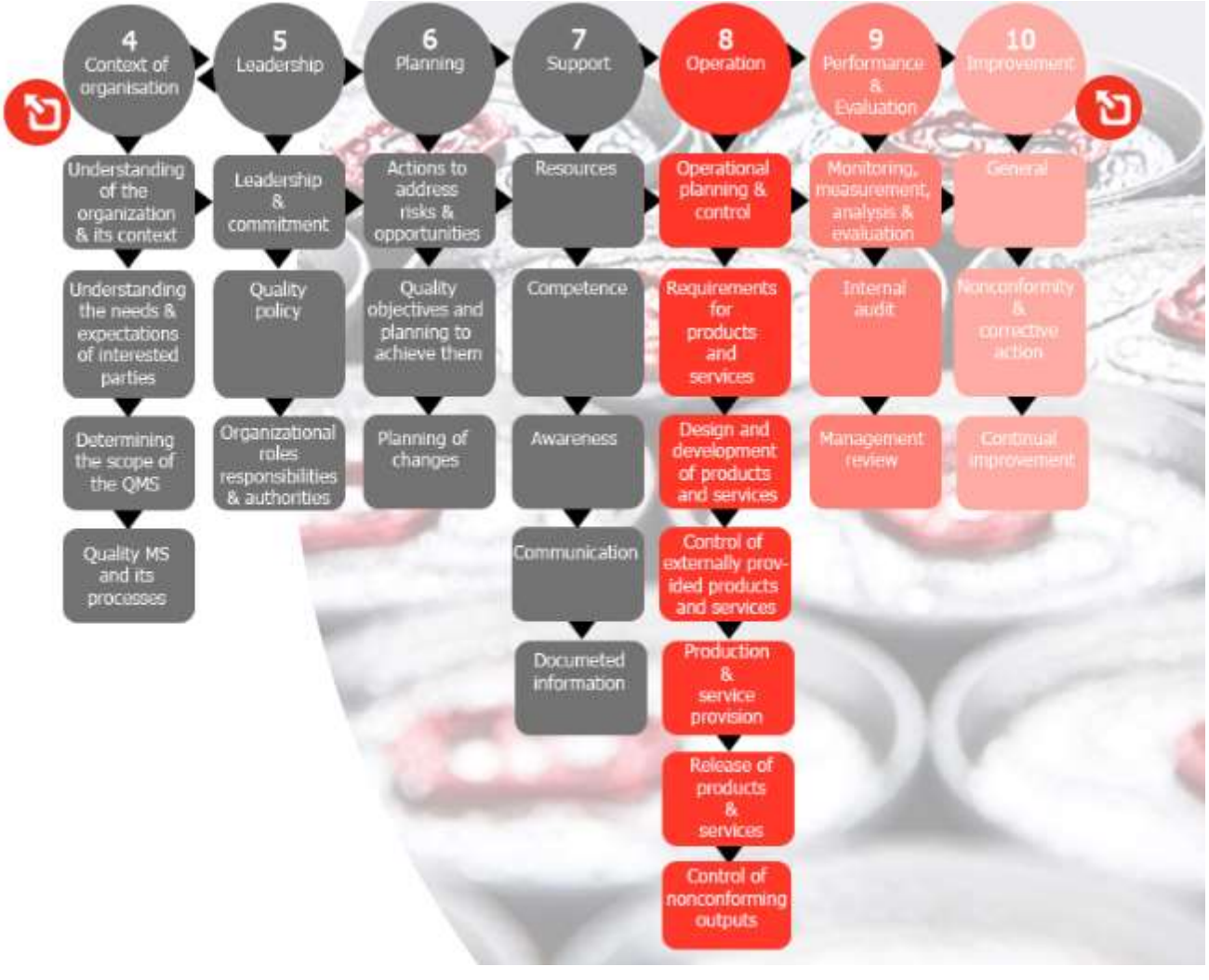
- New and revised ISO MS Standards now using ISO Annex SL: A standard for standard writers
- Provides a 10 clause high-level structure and common text
- Standardises terminology for fundamental Management System requirements
- Follows the Plan → Do → Check → Act (PDCA) principle



bsi.

New ISO 9001:2015

10 Clause Structure



bsi.

The future

ISO 13485:2016

Published 26 February 2016

ISO 13485:2016 – What's New?

What's been added?	Many additions
What's come out?	Nothing!
What's the same?	Some expansion & clarification Increased clarity of interrelationship between clauses and requirements

Areas of Increased Emphasis

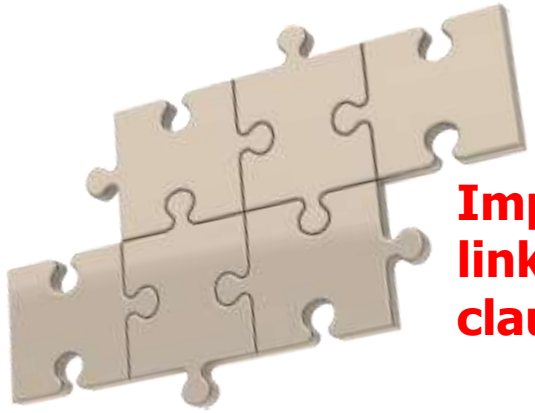
Regulatory Requirements

Risk Management

Validation, Verification & Design Transfer

Outsourced Processes & Supplier Control

Feedback



Improved linkage of clauses

Regulatory requirements

ISO 13485:2016

'Regulatory requirements' appears 37 times*

ISO 13485:2003

'Regulatory requirements' appears 9 times*

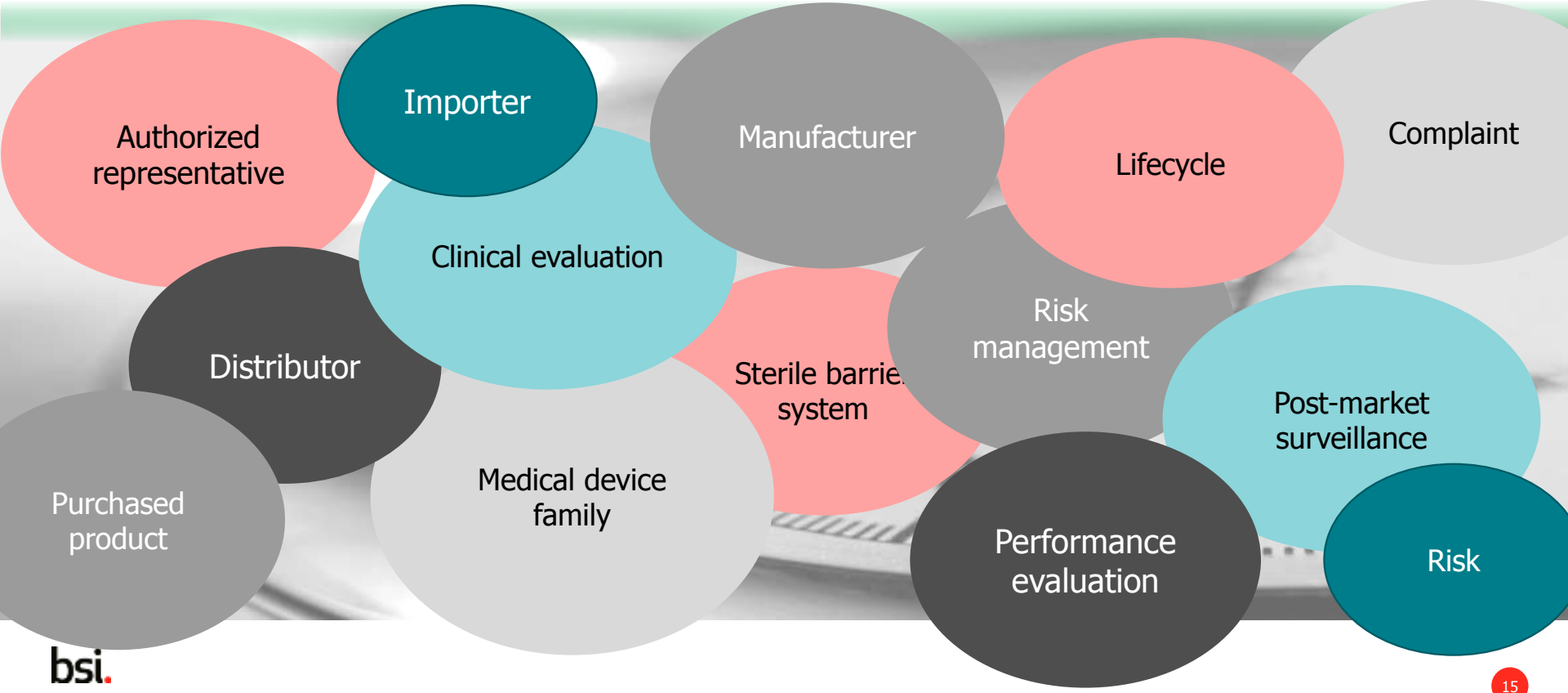
* Within Normative Requirements, i.e. clauses: 4 - 8

bsi.

Objectives and Scope

	ISO 13485:2003	ISO 13485:2016
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.

New definitions: Clause 3



Changes to clause numbering

Due to the inclusion of several new clauses, several subclauses have been renumbered

In order to work with MDSAP program of determining levels of non-conformance grading, the clauses and subclauses required formatting

See GHTF Document SG3 N19

bsi.

4 – Quality Management System

4.1 - 2 General Requirements

+ Document role(s) undertaken by organization under regulatory requirements

+ Risk based approach to control QMS processes

4.1.3 - 5 General requirements

Records to meet regulatory requirements. Change control

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 shall be included to meet regulatory requirements

Clause 5: Management responsibility

5 General requirements

- Increased emphasis on regulatory requirements

5.5.1 Responsibility and authority

- Top management shall document the interrelation of all personnel who…

Clause 5: Management responsibility

5.5.2 Management representative

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

5.6 Management review

- Procedures required, document planned intervals
- Plus more bullet points for inputs, new bullet point for outputs

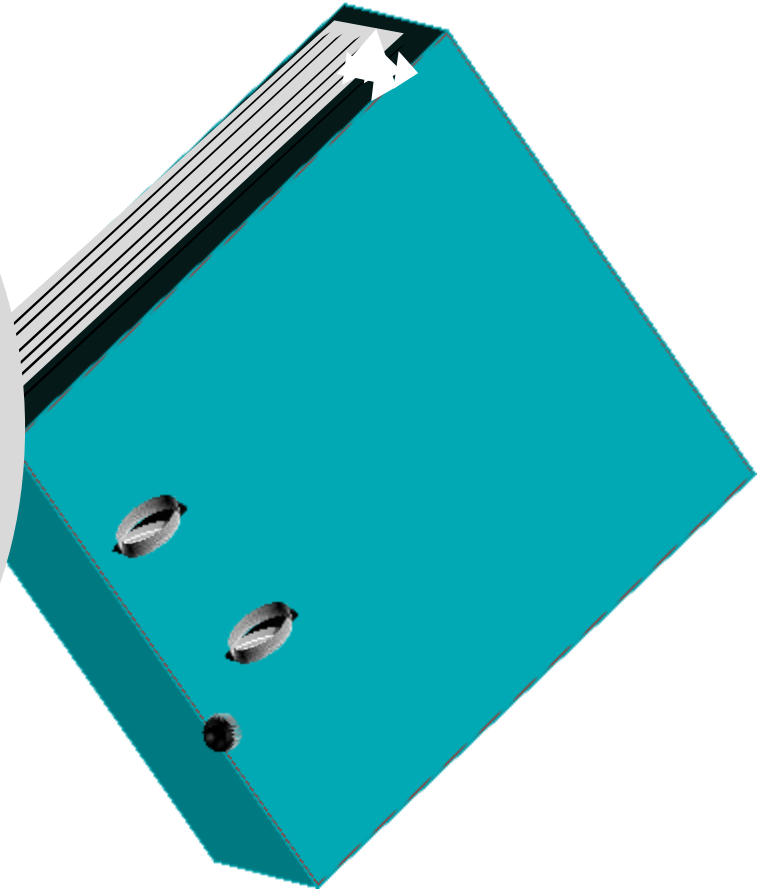
Clause 6: Resource management

6.2 Human resources

- Document processes for competence, training and awareness
- Focus on maintaining competency
- Effectiveness methodology link to risk of work for which training provided

6.3 Infrastructure

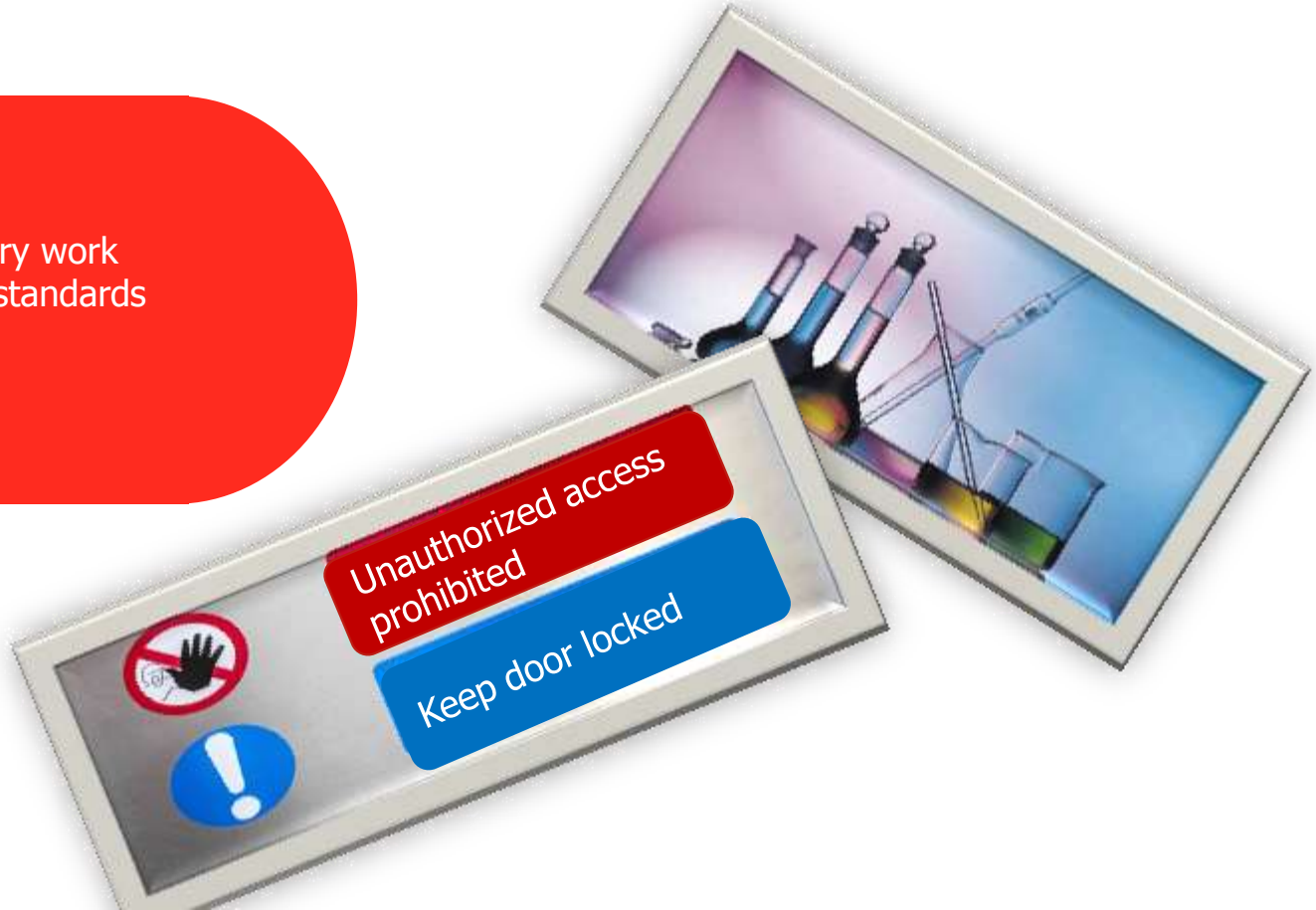
- Prevent product mix up
- Ensure orderly handling
- Maintenance of equipment applies to production, control of work environment, monitor and measurement
- Document intervals



6.4 – Work environment and contamination control

6.4.1 Work environment
- Document requirements
- Competence for temporary work
- Reference to cleanroom standards

6.4.2 Contamination control
- Document requirements
- Sterile medical devices



7 – Product realization

7.1 Planning of product realization

Risk management; Resources;
Complete lifecycle of medical device

7.2.1 Determination of requirements related to product

Regulatory requirements; User training

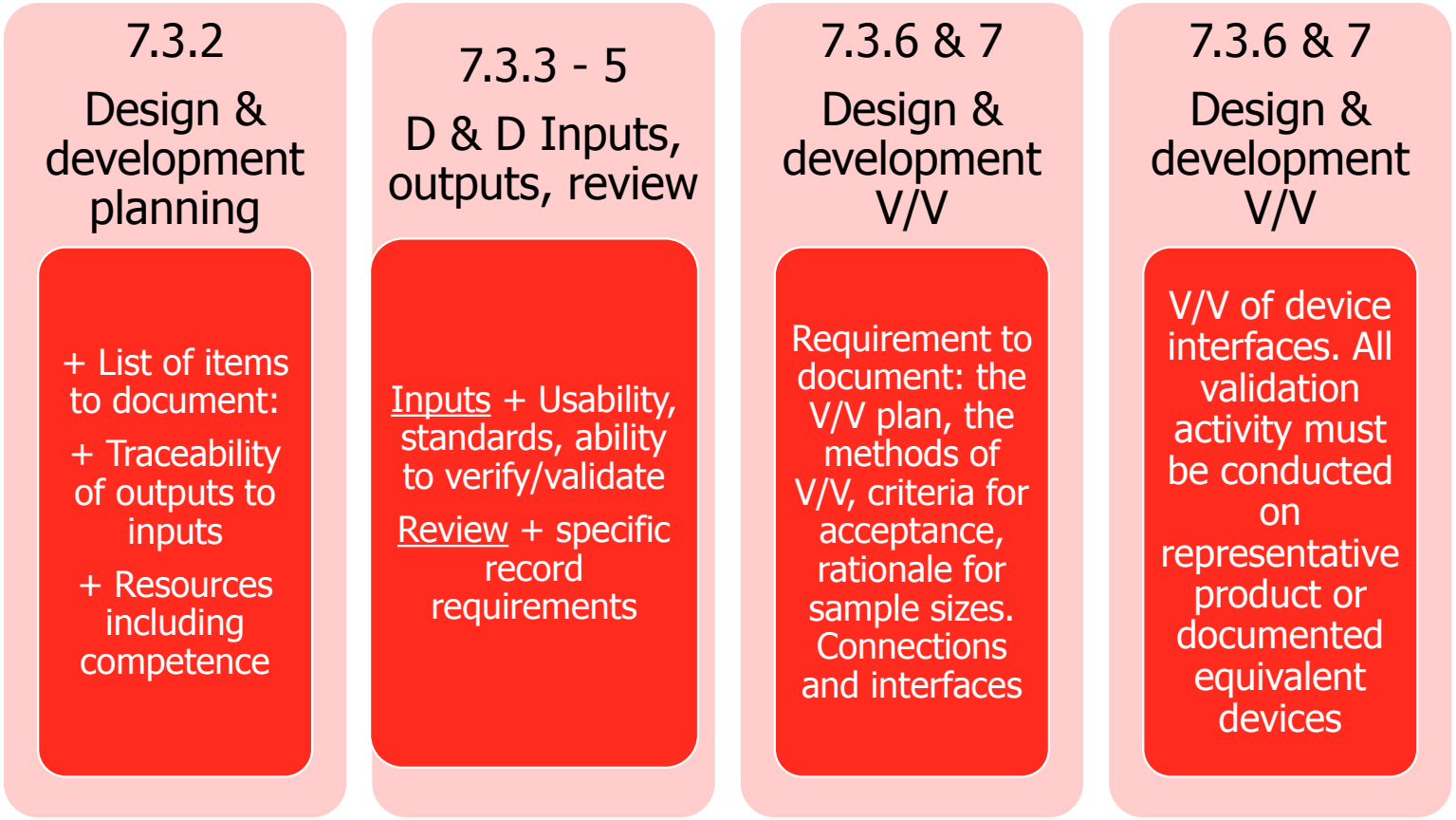
7.2.2 Review of requirements related to product

Contract review; Regulatory requirements; User training

7.2.3 Communication

Customer; Document; Regulatory authorities

7 – Product Realization (continued)



7 – Product Realization (continued)

7.3.8
Design & development transfer

New sub-clause

Procedures required

7.3.9
Design and development changes

Was 7.3.7 – more detail added, link to risk management and product realization added, added detail regarding determining significance of change

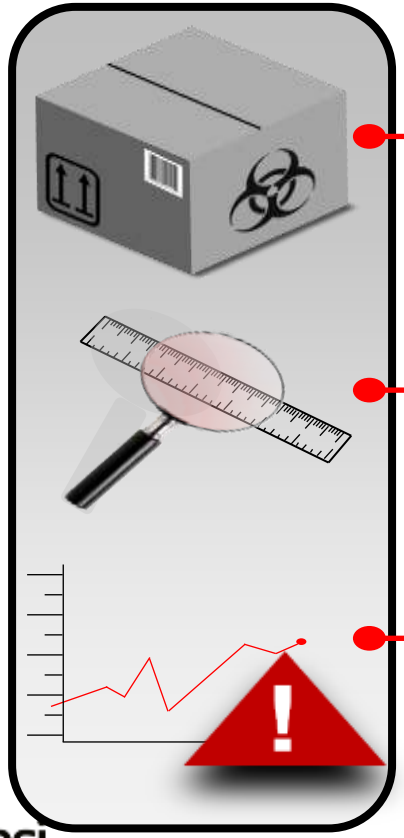
7.3.10
Design and development files

New sub-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

bsi.

7 – Product realization (continued)



7.4.1 Purchasing

Criteria for evaluation and selection of suppliers; Performance and risk; Plan monitoring and re-evaluation process; Additional record requirements

7.4.2 Purchasing information

Purchasing specifications; Written agreements with suppliers; Notification of changes

7.4.3 Verification of purchased product

Verification based on risk/supplier evaluation; Change control

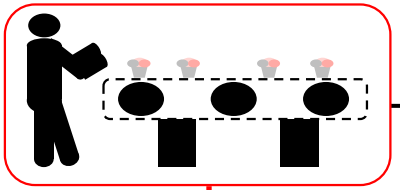
7 – Product Realization (continued)

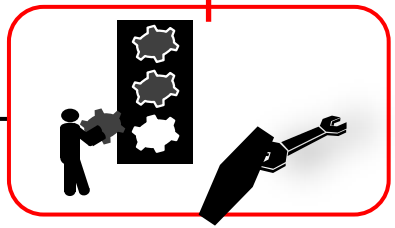
7.5.2 Cleanliness and contamination control

Similar to 2003 requirements, adds contamination control

7.5.4 Servicing activities

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





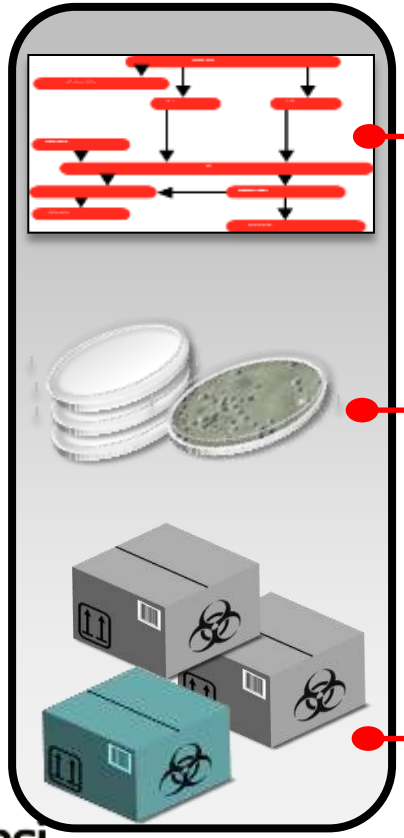
7.5.1 Control of production and service provision

Production and service provisions must be monitored and controlled as well as planned and carried out to ensure product conforms to specifications

7.5.3 Installation activities

Similar to 2003 requirements

7 – Product Realization (continued)



7.5.6 Validation of processes for production and service provision

Validate where output cannot be; Procedures required; Statistical techniques; Rationale for sample sizes; Approval of changes; Validation of software; Risk based

7.5.7 Validation of sterilization and sterile barriers

Added sterile barriers; Validation required prior to implementation and changes; Document results, conclusions, actions

7.5.8 Identification

Status identification; UDI where required by national or regional regulations; Separation of returned products from conforming product

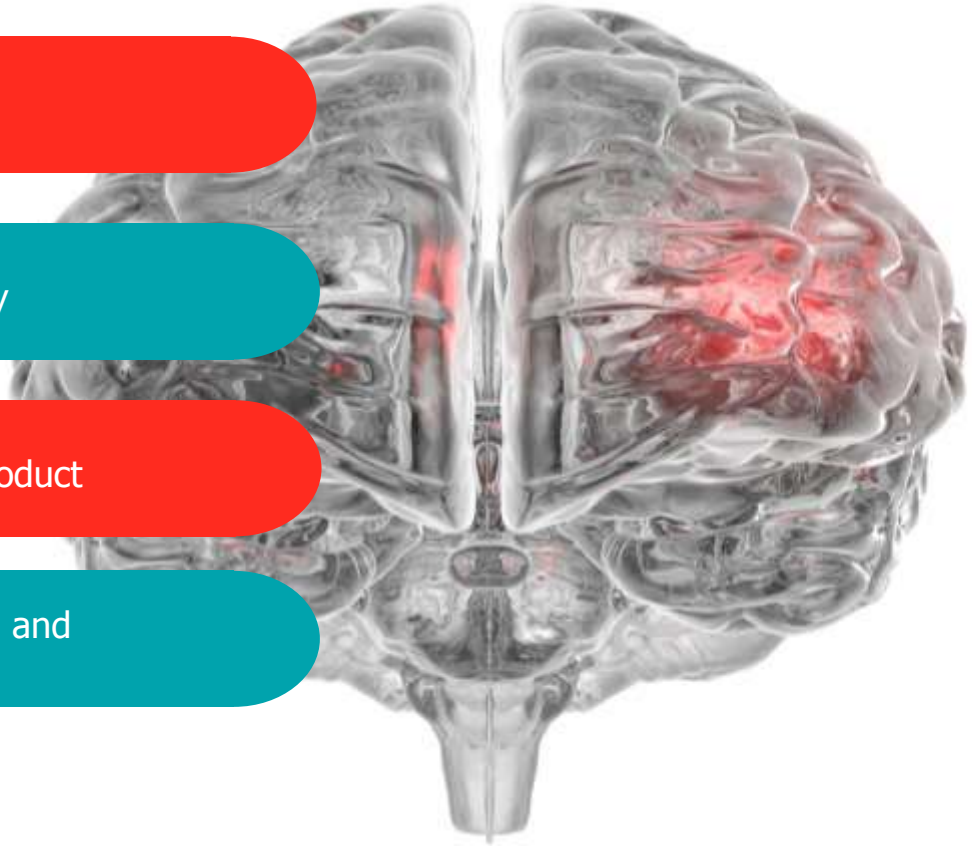
7 – Product realization (continued)

7.5.9 Traceability

7.5.10 Customer property

7.5.11 Preservation of product

7.6 Control of monitoring and measuring equipment



8 – Measurement, analysis and improvement

8.2.6 Monitoring and measurement of product
- Plus test equipment shall be identified as appropriate

8.3 Control of nonconforming product
- Plus details in respect of controls, concessions and records. Clause restructured

8.5.2 and 8.5.3 Corrective and preventive action
- Verifying that CAPA does not have an adverse effect, actions to be taken without undue delay

Areas of Increased Emphasis

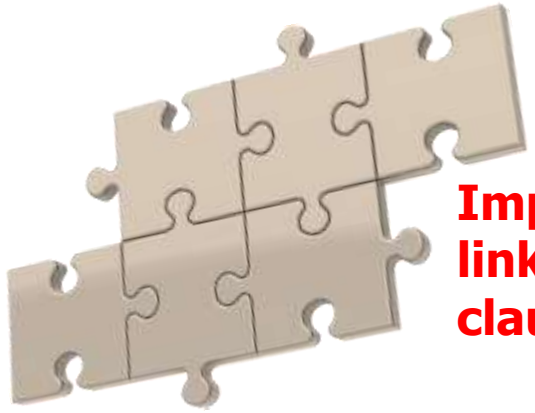
Regulatory Requirements

Risk Management

Validation, Verification & Design Transfer

Outsourced Processes & Supplier Control

Feedback



Improved linkage of clauses

bsi.

ISO 13485:2016 Annexes

Annex A	Comparison of content between ISO 13485:2003 and ISO 13485:2016 – comments on changes
Annex B	Correspondence between ISO 13485:2016 and ISO 9001:2015 – top level clause mapping
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

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

bsi.

Timings

ISO 13485:2016 – Timings

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

May – Dec 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 9001:2015 Certification Transition Timeline

September 2015
ISO Publication

September 2015 start of 3 years transition period to 14th 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

bsi.

Is additional assessment time required?

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

What can you do now?

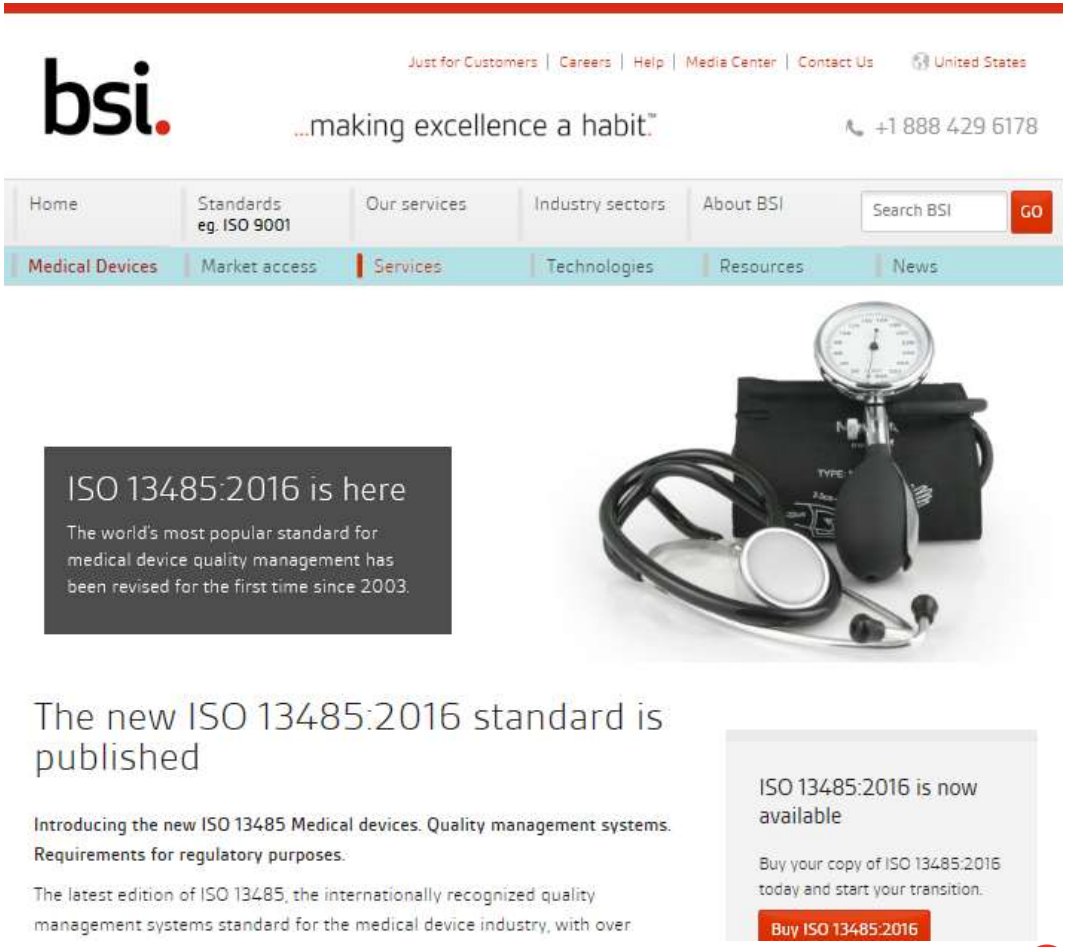
1. Study the standard (s)
2. Consider gap analysis of current QMS Vs. new requirements
3. Prepare initial transition plan, with timescales
4. Factor any additional resources & costs into budgets
5. Review staff awareness / knowledge and determine training required
6. Compile project / implementation 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

Name:	Linda Moon
Title:	QMS Certification Specialist
	Medical Devices
Address:	BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, United Kingdom
Links:	bsigroup.com/ISO13485revision
LinkedIn:	Please Join our New Global Medical Device LinkedIn Group
	http://www.linkedin.com/groups/BSI-Global-Medical-Devices

bsi.

...making excellence a habit.™