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

Bill Enos
Global Head of Microbiology
BSI Healthcare

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

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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

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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,

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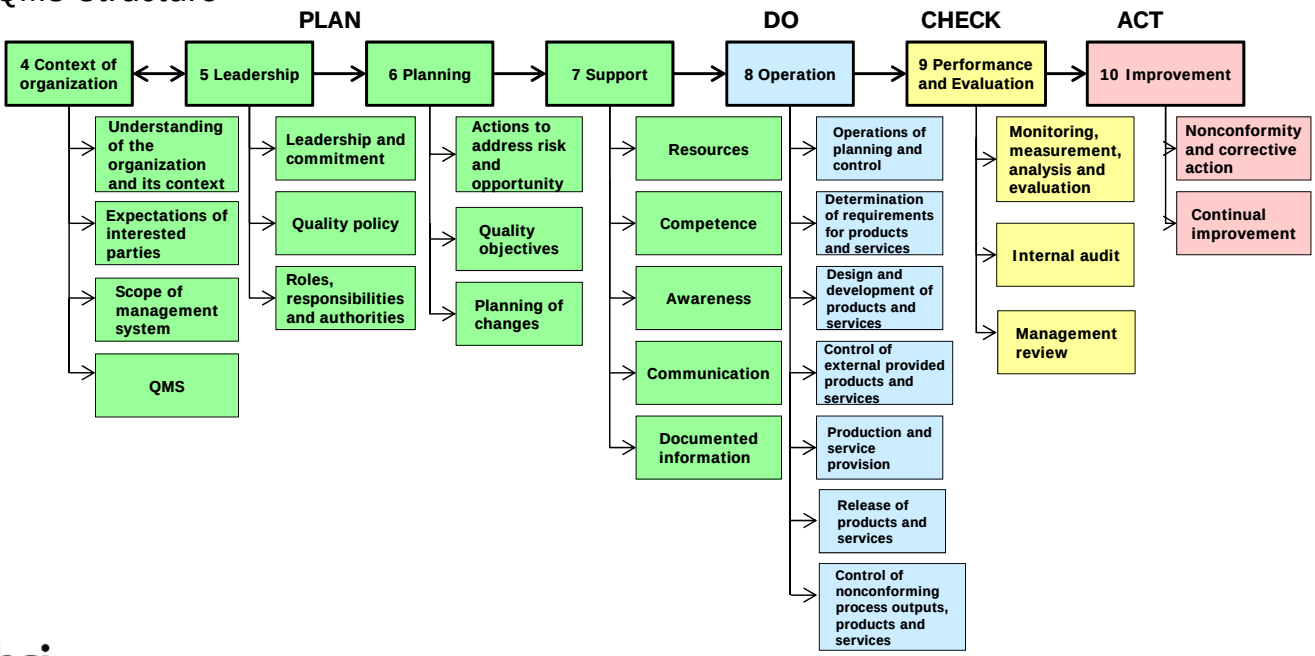
ISO 9001:2015

What's next?

10/5/2015

QMS Structure



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The Future?

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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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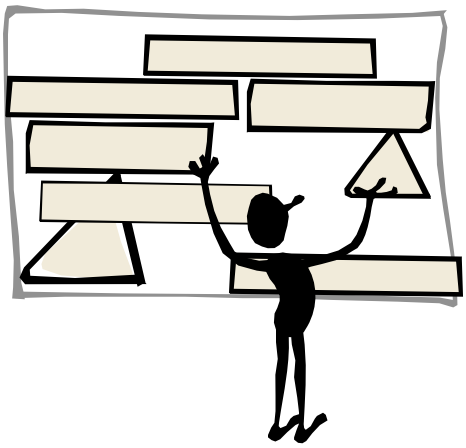
ISO 13485:2015 – What's New?



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

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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

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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

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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

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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.

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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

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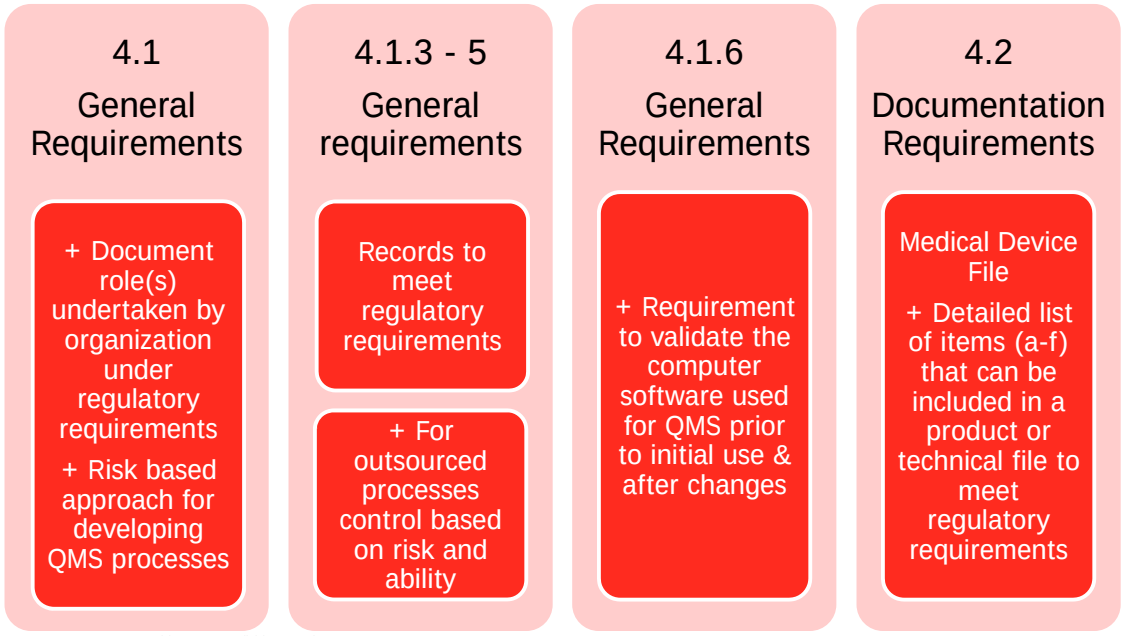
4 – Quality Management System



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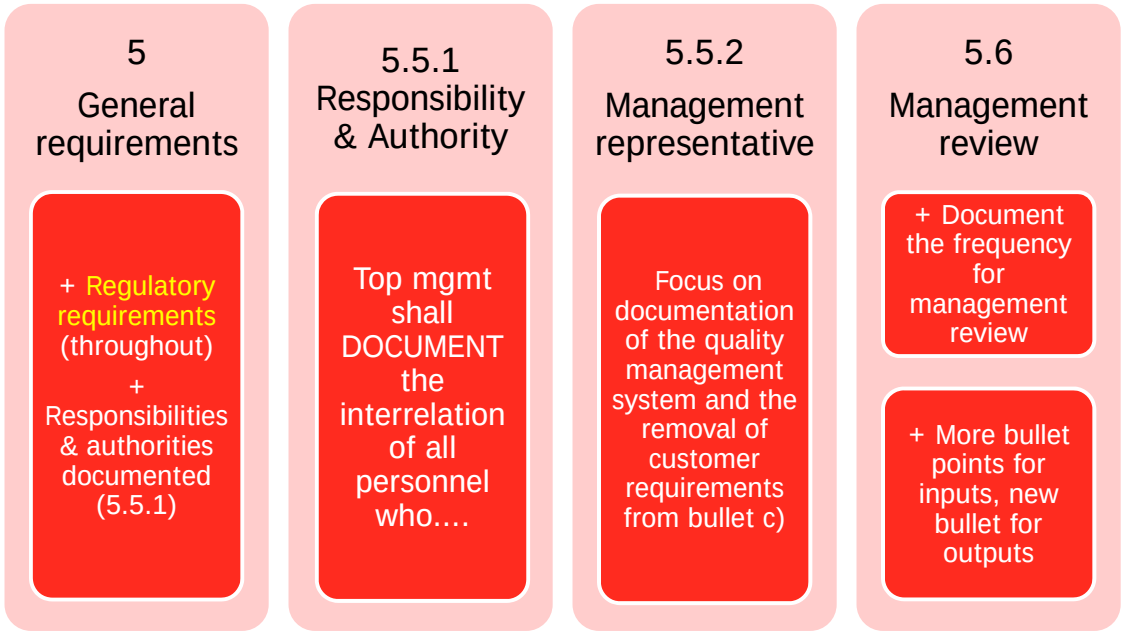
5 – Management Responsibility



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6 – Resource Management

6.2 Human resources	6.2 Human resources	6.3 Infrastructure
+ Shall document the processes for establishing competence, providing training, and ensuring awareness	+ Maintain competency + NOTE effectiveness methodology link to risk of work for which training provided	+ Prevent product mix up, ensure orderly handling; Maintenance of equipment applies to production, control of work env, monitor and measurement.

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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.

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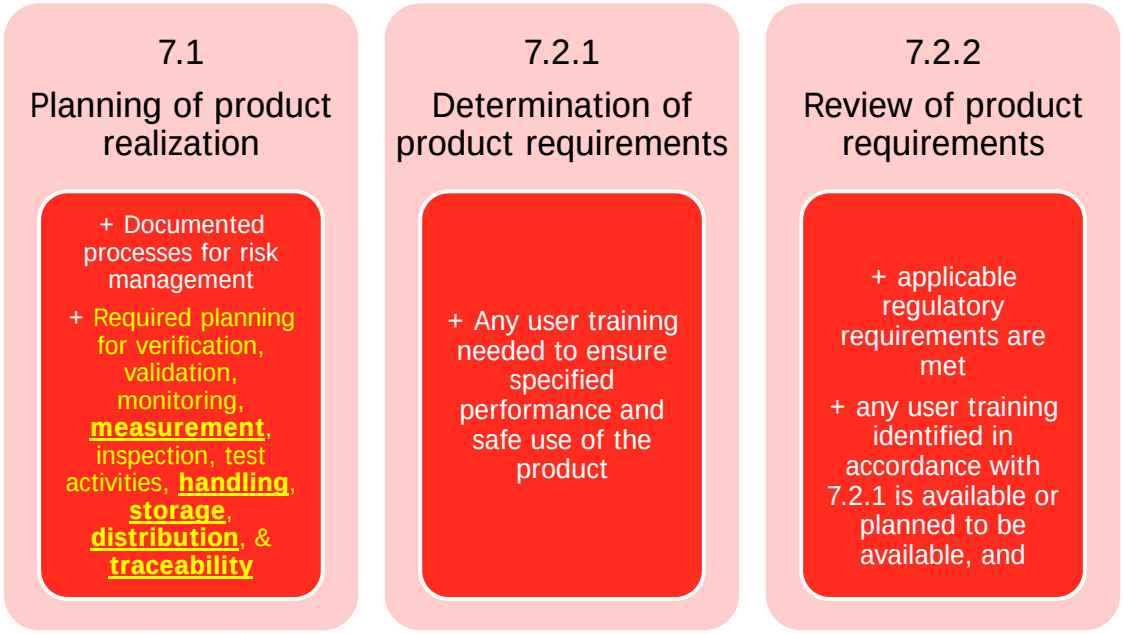
7 – Product Realization



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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!!!

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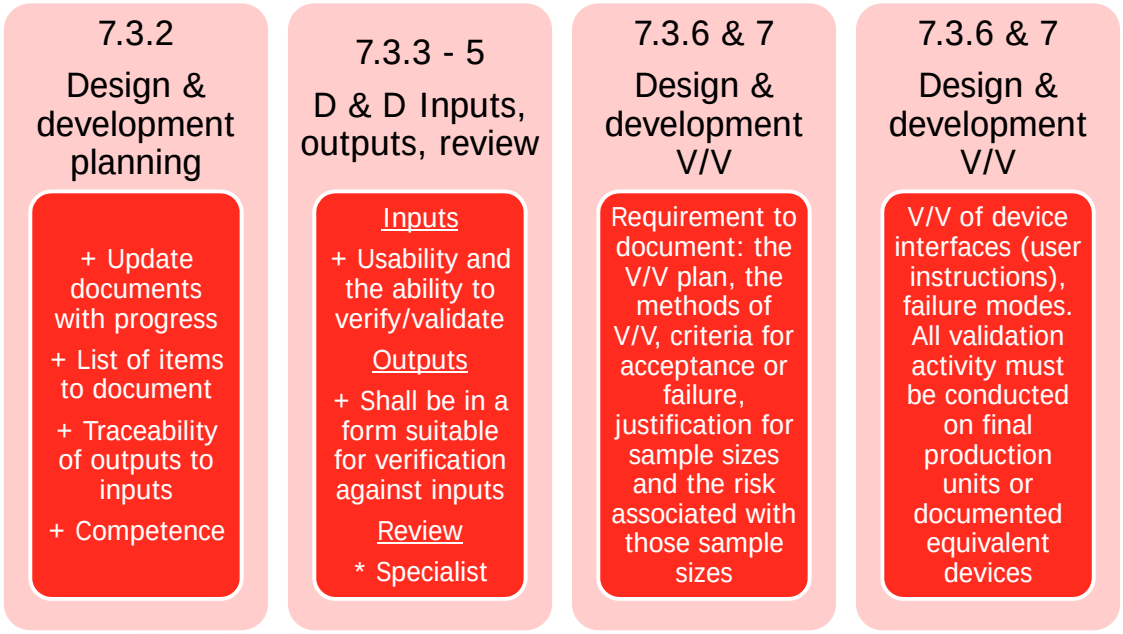
7 – Product Realization (continued)



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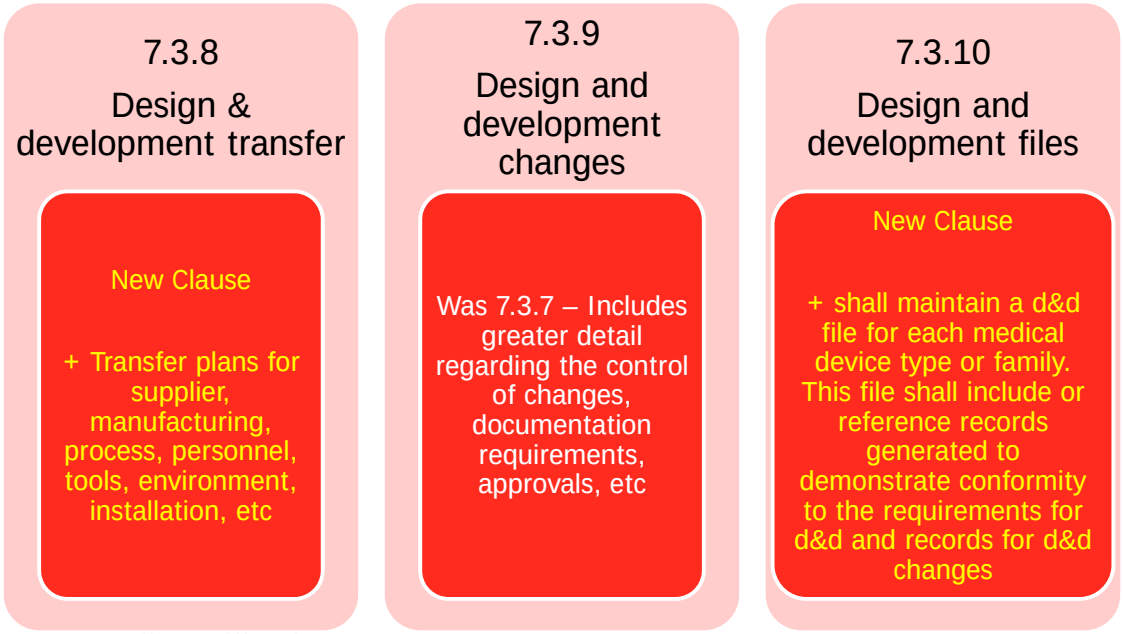
7 – Product Realization (continued)



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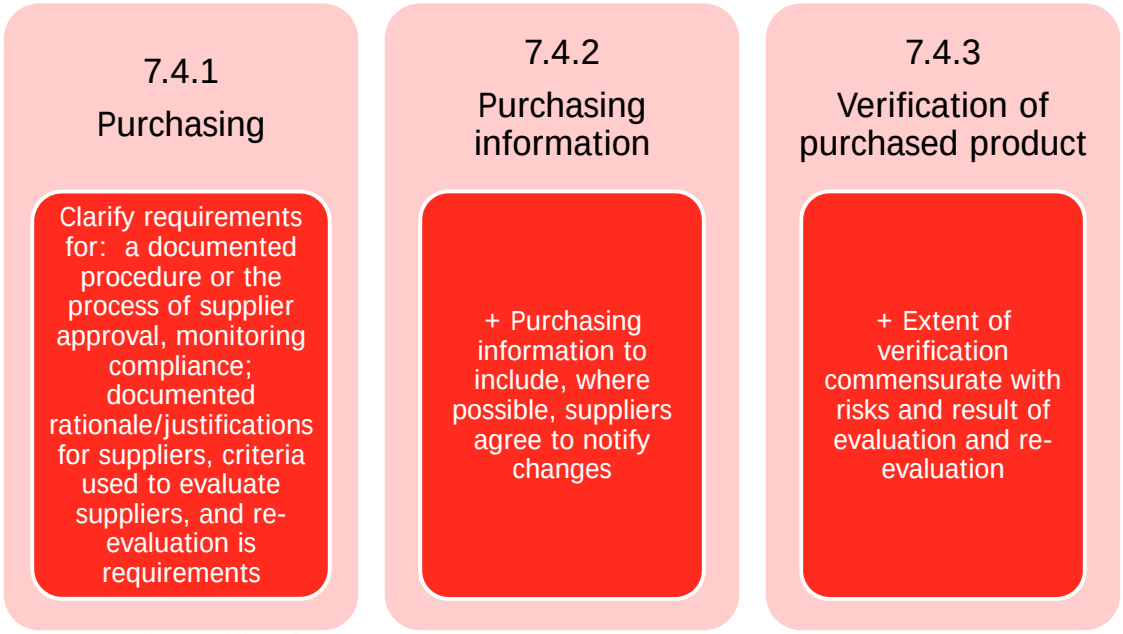
7 – Product Realization (continued)



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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 of the issue is a complaint or must be utilized as an improvement input

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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

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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

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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

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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????

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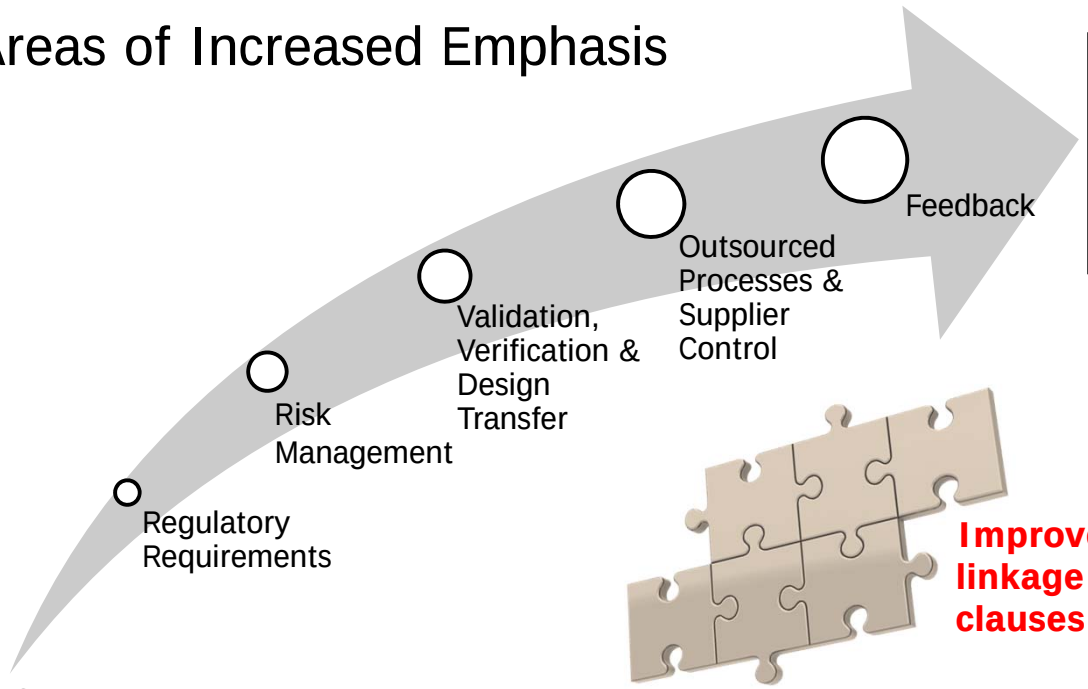
Areas of Increased Emphasis



ISO 13485 3rd Edition

Improved linkage of clauses

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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.

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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)

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Questions?

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Thank you

Name:	Stefan Burde
Title:	IVD Product Expert, BSI Healthcare
Address:	BSI America, 12950 Worldgate Drive, Suite 800, Herndon VA 20170
Telephone:	571-439-9363
Email:	stefan.burde@bsigroup.com
Links:	www.bsigroup.com

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