• ISO 9001:2015
• Key Changes in ISO 13485:2016
• Timings and transition process
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

<table>
<thead>
<tr>
<th>Paragraph of Directive 93/42/EEC, Annex II</th>
<th>Clause(s) of EN ISO 13485</th>
<th>Comments/Qualifying remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 first sentence</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 1st indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 2nd indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 3rd indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 4th indent</td>
<td>4.1, 4.2</td>
<td>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.</td>
</tr>
<tr>
<td>3.1 second sentence 5th indent</td>
<td>4.1, 5.1, 5.4, 5.5, 5.6</td>
<td>Covered</td>
</tr>
<tr>
<td>3.1 second sentence 6th indent</td>
<td>4.1, 5.1, 5.4, 5.5, 5.6</td>
<td>Covered</td>
</tr>
<tr>
<td>3.1 second sentence 7th indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.2 first paragraph first sentence</td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>
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
The future
ISO 13485:2016

Published 26 February 2016
**ISO 13485:2016 – What’s New?**

<table>
<thead>
<tr>
<th>What’s been added?</th>
<th>Many additions</th>
</tr>
</thead>
<tbody>
<tr>
<td>What’s come out?</td>
<td>Nothing!</td>
</tr>
<tr>
<td>What’s the same?</td>
<td>Some expansion &amp; clarification</td>
</tr>
<tr>
<td></td>
<td>Increased clarity of interrelationship between clauses and requirements</td>
</tr>
</tbody>
</table>
Areas of Increased Emphasis

- Improved linkage of clauses
- Risk Management
- Regulatory Requirements
- Validation, Verification & Design Transfer
- Outsourced Processes & Supplier Control
- Feedback
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
## Objectives and Scope

<table>
<thead>
<tr>
<th></th>
<th><strong>ISO 13485:2003</strong></th>
<th><strong>ISO 13485:2016</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objectives</strong></td>
<td>Facilitate harmonization</td>
<td>Facilitate global alignment</td>
</tr>
<tr>
<td><strong>Scope &amp; Role</strong></td>
<td>Organizations provide Medical devices and related services</td>
<td>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.</td>
</tr>
</tbody>
</table>
New definitions: Clause 3

- Authorized representative
- Importer
- Clinical evaluation
- Manufacturer
- Lifecycle
- Risk management
- Post-market surveillance
- Purchased product
- Medical device family
- Sterile barrier system
- Performance evaluation
- Risk
- Distributor
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
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

Unauthorized access prohibited
Keep door locked
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
### 7.3.2 Design & development planning

+ List of items to document:
  + Traceability of outputs to inputs
  + Resources including competence

### 7.3.3 - 5 D & D Inputs, outputs, review

Inputs + Usability, standards, ability to verify/validate

Review + specific record requirements

### 7.3.6 & 7 Design & development V/V

Requirement to document: the V/V plan, the methods of V/V, criteria for acceptance, rationale for sample sizes. Connections and interfaces

### 7.3.6 & 7 Design & development V/V

V/V of device interfaces. All validation activity must be conducted on representative product or documented equivalent devices
## 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
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
7.5.1 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.

7.5.2 Cleanliness and contamination control
Similar to 2003 requirements, adds contamination control.

7.5.3 Installation activities
Similar to 2003 requirements.

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 – 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

- Risk Management
- Regulatory Requirements
- Validation, Verification & Design Transfer
- Outsourced Processes & Supplier Control
- Feedback

Improved linkage of clauses
ISO 13485:2016 Annexes

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Annex B</td>
<td>Correspondence between ISO 13485:2016 and ISO 9001:2015 – top level clause mapping</td>
</tr>
<tr>
<td>European Annexes - ZA (AIMD), ZB (MDD) and ZC (IVD)</td>
<td>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</td>
</tr>
</tbody>
</table>
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
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

28 February 2018

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ISO 9001:2015 Certification Transition Timeline

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.
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
<table>
<thead>
<tr>
<th>Name:</th>
<th>Linda Moon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
<td>QMS Certification Specialist</td>
</tr>
<tr>
<td></td>
<td>Medical Devices</td>
</tr>
<tr>
<td>Address:</td>
<td>BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, United Kingdom</td>
</tr>
<tr>
<td>Links:</td>
<td>bsigroup.com/ISO13485revision</td>
</tr>
<tr>
<td>LinkedIn:</td>
<td>Please Join our New Global Medical Device LinkedIn Group</td>
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