MEDICAL DEVICE SEMINAR

ISO 13485:2016 & MDR

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Presenters

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Certification Overview
Welcome to NSAI - Aims of the morning

- A time of change for many Certification Management Standards
- Understanding changes & their impacts
- Management Standards – general
- ISO 13485:2016 Medical Devices - QMS

@NSAI_Standards
Why change ISO Standards?

- ISO Review and Revise to support Continual Improvement and Best Practice – the HLS

- ISO has supported the mantra of ‘Integration’ for many years – the HLS. See ISO guide

- NSAI audits, reports and audit teams delivered an integrated service – the HLS in practice

- Standards needed to catch up – 32 HLS MS by now
Management Systems Certification

Main Certification schemes – a time of great change *All HLS*

- ISO 9001:2008 to 2015, Quality
- ISO 14001:2004 to 2015, Environment
- Three year transition period – period of co-existence
- Common Language
- Common Structure - *HLS*
- Ease of integration
- Reduced: work, costs, less disruption, better understanding
- *Aligned with the business* - a Business Standard
Order out of Chaos
High level structure

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement
High level structure (1)
ISO 13485:2016 – odd one out

- ISO 13485:2016 revised but not in line with the HLS
- ISO TC 210 ducked the HLS for 3 and possibly 5 years
- ISO 9001:2015 and ISO 13485:2016 no longer in line
- Need to map the gaps – guidance to follow
Dedicated NSAI team

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Events:
- QI Conference November 2016
- ISO 45001:2016/17 ‘Understanding the Changes’
ISO 13485:2016
Are you ready for ISO 13485:2016?

New Technologies
New Regulations
New Era
What’s New in ISO 13485:2016?

- **ISO 13485:2016** did **NOT** follow ISO 9001:2015 into the Higher Level Structure format
  - ISO 9001:2015 now has 7* QS core “Processes”
  - ISO 13485:2016 retains 5* QS core “Processes”


*(excluding: Scope, Normative References, Terms & Definitions)*
What’s **New In 2016?**

**Introduction - General**

- The standard “*can be used by an organization involved in one or more stages of the life-cycle of a medical device*”

- And, by suppliers and other external parties providing product to such organizations
What’s New In 2016?

Section 1 – Scope

1.2 - Any requirement of Clause 6, 7, or 8 can be deemed "not applicable” to the organization (with documented justification)
“The processes required by this International Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization’s quality management system by monitoring, maintaining, and controlling the processes.”
What’s **New In 2016?**

**Section 4 - Quality Management System**

**4.1 – General (software):**

- New Technologies

- 4.1.6 – Requires *documented procedures for the validation of software* used in the Quality Management System

- 4.1.6 – Such software *shall be validated prior to initial use, and as appropriate, after changes*
Section 4 - Quality Management System

*4.2.3 - Medical Device File:

- For each medical device type or medical device family, the organization shall establish and maintain a file(s) either containing or referencing documents generated to demonstrate conformity with the requirement of this International Standard and compliance with applicable regulatory requirements.

- Regular references to the regulatory requirements

(*New sub-clause)
What’s New In 2016?

Section 6 - Resource Management

6.2 – Human Resources/ Competence
- The organization shall document the process(s) for establishing competence, providing needed training, and ensuring awareness of personnel

6.3 – Infrastructure:
- The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product
What’s New In 2016?

Section 7.3 - Design and Development

7.3.2 – Design and Development Planning

- The organization shall plan and control the design and development of product

- During design and development planning, the organization shall document:
  - the methods to ensure traceability of design and development outputs to design and development inputs; and
  - the resources needed including necessary competence of personnel
Section 7.3 - Design and Development

7.3.6 – Design and Development Verification

- The organization shall document verification plans
- If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced
- Verification shall be completed prior to release for use of the product to the customer
What’s **New In 2016?**

**Section 7.3 - Design and Development**

**7.3.7 – Design and Development Validation**

- *The organization shall document validation plans*

- *Design validation shall be conducted on representative product*

- Validation shall be completed prior to *release for use of the product to the customer*
Section 7.3: Design and Development

*7.3.8 – Design and Development Transfer

- The organization shall document procedures for transfer of design and development outputs to manufacturing.

- Results and conclusions of the transfer shall be recorded (see 4.2.5)

(*New sub-clause)
The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.
What’s New In 2016?

Section 7.3 - Design and Development

7.3.9 – Control of Design and Development Changes (cont’d)

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.
Section 7.3: Design and Development

*7.3.10 – Design and Development Files

- The organization shall maintain a design and development file for each medical device type or medical device family

(*New sub-clause)
What’s New In 2016?

Section 7.4 - Purchasing

7.4.1 – Purchasing Process

- The organization shall establish criteria for the evaluation and selection of suppliers
- The organization shall plan the monitoring and re-evaluation of suppliers
- Non fulfillment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements
Section 7.4 – Purchasing

7.4.2 – Purchasing Information

- Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.
Section 7.4 – Purchasing

7.4.3 – Verification of Purchased Product

- The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

- When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.
7.5.4 – Servicing Activities

- The organization shall analyze records of servicing activities carried out by the organization or its supplier:
  a. to determine if the information is to be handled as a complaint
  b. as appropriate, for input to the improvement process
What’s **New In 2016?**

**Section 7.5 - Production & Service Provision**

**7.5.6 – Validation of Processes**

- The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications.
7.5.8 – Identification

- The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization

- If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device
What’s New In 2016?

Section 7.5 - Production & Service Provision

7.5.11 – Preservation of Product

- The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution
What’s New In 2016?

Section 8 - Measurement, Analysis & Improvement

8.2.1 – Feedback

- The organization shall document procedures for the feedback process. *This feedback process shall include provisions to gather data from production as well as post-production activities*

- The information gathered in the feedback process shall serve as potential input *into risk management*
8.2.2 – Complaint Handling

- The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements

(*New sub-clause)
What’s New In 2016?

Section 8 - Measurement, Analysis & Improvement

*8.2.3 – Reporting to Regulatory Authorities

- If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities

(*New sub-clause)
What’s **New In 2016?**

Section 8 - Measurement, Analysis & Improvement

8.3 – Control of Nonconforming Product

*Now contains 4 separate sub-clauses:*

1) 8.3.1 – **General**
2) 8.3.2 – **Actions in response to nonconforming product detected before delivery**
3) 8.3.3 - **Actions in response to nonconforming product detected after delivery**
4) 8.3.4 – **Rework** (NOTE: same requirements as 2003 version)
What’s New In 2016?

Section 8 - Measurement, Analysis & Improvement

8.5.2 – Corrective Action

- The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay

- The organization shall document a procedure to define requirements for:
  - Verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device
Summary

A. Regulatory Requirements
B. Competence
C. Design controls
D. Purchasing controls
E. Software validation

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Structure</strong></td>
<td>Follow the HLS with 7 processes</td>
<td>Retains 5 processes</td>
</tr>
<tr>
<td><strong>Scope</strong></td>
<td>Meet customer requirements</td>
<td>Meet customer requirements &amp; regulatory requirements</td>
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<tr>
<td><strong>Focus</strong></td>
<td>Continual Improvement to enhance customer satisfaction</td>
<td>Continuing suitability, adequacy and effectiveness of QMS &amp; safety and performance of the Medical Device</td>
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<tr>
<td><strong>Personnel</strong></td>
<td></td>
<td>Retains need for Management Rep</td>
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- See Annex B to see the mapping of 9001 to 13485 (and visa versa)
  - Use this as a basis for your company gap analysis.

Clauses not directly mapped in ISO 9001 are:

- Cleanliness of product
- Installation
- Servicing
- Particular requirements for sterile medical devices
- Particular requirements for validation of processes for sterilisation & sterile barrier systems
- *New to ISO 13485:2016 – Medical Device File
ISO 13485:2016
Transition Policy
Current Situation

- ISO 13485:2003
- EN ISO 13485:2012
Regulatory requirements

- ISO 13485:2003
  - CMDCAS
  - Australia
  - Japan
  - MDSAP

- EN ISO 13485:2012
  - EU
Co-existence period

Co-existence period

- ISO 13485:2003 & ISO 13485:2016 will co-exist for a 3 year period

- Effective March 1\(^\text{st}\) 2018, ISO 13485:2003 certificates will no longer be issued by NSAI
Co-existence period

- Effective March 1\textsuperscript{st} 2019 all ISO 13485:2003 certificates will become invalid

- Effective \textbf{until} March 1\textsuperscript{st} 2018 any new, modified or revised ISO 13485:2003 issued by NSAI will have an expiry date not to exceed 1\textsuperscript{st} March 2019
Manufacturer’s responsibility

- Update QMS to the requirements of ISO 13485:2016
- Request registration to ISO 13485:2016 from your registrar
Registrar’s responsibility

- Develop a checklist to help the manufacturers meet compliance to ISO 13485:2016
- Carry out upgrade audits either at the next surveillance or re-assessment audit
- **Two years** following publication, new registrations will be issued **only** to ISO 13485:2016
- Three years following implementation of ISO 13485:2016, ISO 13485:2003 will be withdrawn
EN ISO 13485:2016

- Refer to the Official Journal (OJ) for updates
- In the meantime EN ISO 13485:2012 remains valid
Changes to the Regulatory framework

ARE YOU READY ?
Current situation

- Both regulations are in the final stages of the legislative procedure and are estimated to finish sometime in 2016, allowing them to come into effect by the end of 2016 or early 2017.

- Some time will be needed to polish the agreed text and have it translated into the official EU Languages.
Why Change from Directives to Regulations?

- High profile vigilance cases with hips
- Pelvic floor meshes exposé by British Newspapers
- Discovery of fraud in PIP breast implants using low quality “industrial grade” silicone oil
Why Change from Directives to Regulations?

Outcome

More focus on Notified Bodies through the;

- Commission recommendation 2013-473
  - Annex I product assessment
  - Annex II on QMS assessment
  - Annex III Unannounced audits

- Implementing regulation 920/2013 on the designation and monitoring of Notified Bodies
New Monitoring mechanism of Notified Bodies

- All Notified Bodies are to be re-designated per the requirements of 920/2013
- The audit team comprise representatives of
  - Food and Veterinary Office (FVO)
  - NB’s Competent Authority
  - 2 other CA’s
- The designation is valid for 5 years unless the NB wants to extend their scope
- All results available on the NANDO website:
  
  ec.europa.eu/growth/tools-databases/nando
What the FVO found

Summary of audit findings

- Insufficient evidence that staff employed for conformity assessment activities were appropriately qualified and experienced for the task
- Thoroughness of NB’s review of manufacturer’s clinical evaluations
- The sampling and depth of review of technical files for Class IIA & Class IIB Devices
- The overall documentation and traceability of the certification process was not always deemed appropriate
Output from FVO

- Some Notified Bodies have been de-designated
- Some Notified Bodies have elected to stop certification activities due to constraints of the new system
- Some Notified bodies have scope reductions / limitations to their operation
  - Exclusion of medical devices in class III
  - Subset of devices within a NANDO designation
  - Medical devices including the Machinery Directive to include active medical devices only
What lies ahead?
Chapter 1 Definitions

Significant changes ahead

- Products currently not classified as medical devices under the MDD will be included in the MDR
  - Accessories will now include devices that specifically or directly assist another device in its intended purpose
  - Custom made excludes mass produced by industrial means
  - Inclusion of products containing non-viable human cell or tissue derivatives
  - Importantly non medical devices with a risk profile similar to medical devices e.g. aesthetic implants, cosmetic laser products and contact lenses (Annex XV)
Common Specifications (CS)

**Where**

- No Harmonised Standard exists
- Current standards are not sufficient
- Pertain to safety, performance and risk with a prominent focus on clinical data
- Applicable in
  - Annex 1, safety and performance
  - Annex II technical documentation
  - Annex XIII, Clinical evaluation and PMCF
  - Annex XIV Clinical evaluation
  - Annex XV Design requirements
Next steps

What do I need to do?

- Aesthetic products per Annex XV
- Accessories
- Custom made?
- Standalone software?
Annex XV, Products without an intended medical purpose
Chapter II

- Making available of devices
- Obligations of economic operators
- Reprocessing
- CE Marking
- Free movement
Changes

- Responsible person for regulatory compliance
- QMS Requirements
- Liability at all levels, including authorised reps
- Each person in the supply chain will have specific regulatory responsibility
Under Discussion

Product liability insurance for both manufacturers and Authorised Reps

Under discussion

Reprocessing of single use devices (art 15)
Next steps

- Reprocessing
- Items to review
- Recall criteria?
- New QMS requirements?
- OBL
- Access to Technical files
Next steps

- Product liability within the chain
- AR contracts
- Reporting obligations of importers and distributors
- Person responsible for regulatory compliance
- Items to review
Next steps

- Implant cards, (information to be provided to the patient with an implanted device)
- Parts manufacturers vs adverse events
- Update DOC, MDR model available
- Items to review
Chapter III

Eudamed

- Traceability
- Registration
- Publication of device performance
- UDI
Changes

Summary of safety and clinical performance

- Class 3 & implants

Summary to include

- Intended purpose
- Device indications & contra-indications
- Reference to standards and CS
- Summary of clinical evaluations
- Profile and training of users
Next steps

- Prepare for implementation of EU UDI
- Single UDI for manufacturers, AR & importers
- Traceability /UDI
- Apply to the device and higher levels of packaging for all devices
- Manufacturer, authorised rep, economic operator
Chapter V

Classification

- Up classification
  - Nanotechnology
  - Spinal disk replacements
  - Life saving AMD
  - Substance based devices
Changes

Conformity assessment

- New Essential safety and performance requirements
- Mandatory tech file structure and content
- Clinical evaluation for all devices (not new)
- Scrutiny procedure for the most complex high risk medical devices where no CS have been developed
Next steps

- Gap analysis of all approved devices on the market
- Review and implement new classification requirements
- Adapt new conformity assessment where required
Chapter VI

New concepts relating to

- Article 42 relates to following Annex VIII (full QA) for all implantables, (with the exception of sutures)
- Clinical evaluation and Clinical investigation processes are better defined
- Clinical investigations will be required for implantable and Class 3 devices with few exemptions

**Mandatory PMCF & PSUR**
(periodic safety update reports)
Chapter VI

High Risk devices and permanent implants

- Summary of clinical evaluation will be publically available
- Provided in layman’s terms
- Use of clinical data form equivalent devices must be robust, clinically evidenced and scientifically justified
Next steps

- Gap analysis on current data
- Clinical evaluations & investigations
- Mandatory PMCF
- New requirements for claiming equivalence
- Update clinical evaluations in line with new requirements
Next steps

Clinical evaluation and PMCF

Generate clinical evidence

Implement new requirements
Next steps

- Perform gap analysis
- Clinical investigations (derogation)
- Implement for new and existing devices
Chapter VII

**PMS**
- To become a continuous evaluation and improvement loop
- Linking to continuous reviews of risk management &
- Annual update of public summary of safety and performance
- Clinical evaluation

**Vigilance**
- New reporting requirements
- Implement trend reporting
Next steps

PMS/Vigilance

- Implement new plan for ongoing PMCF & PMS requirements
- Gather PMS data as early as possible
- Implement new Vigilance reporting criteria
- Implement trend reporting
Chapter VIII

Centralised Governance
Development of Common Specifications

- Developed by expert groups
- Focus heavily on clinical data sets and minimum patient outcomes for specific device categories
Chapter IX

Penalties regime

- Implementation of market funded market surveillance
- Companies need to prepare for this fund
Chapter X

Final provisions

- Transition period not yet fixed
- What happens in the interim?
  - It is possible to comply with the new rules during the transition period
  - Need to find a Notified Body that is designated under the regulation
Final Provisions

Investment required

- People and time

Grandfathering is not an option

- All device must transition
- Appropriate supporting evidence will be required
  - Additional clinical evidence, updated technical files
  - Declarations of Conformity must be updated
Where to from here?
Questions & Answers