MEDICAL DEVICE SEMINAR

ISO 13485:2016 & MDR

May 2016

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

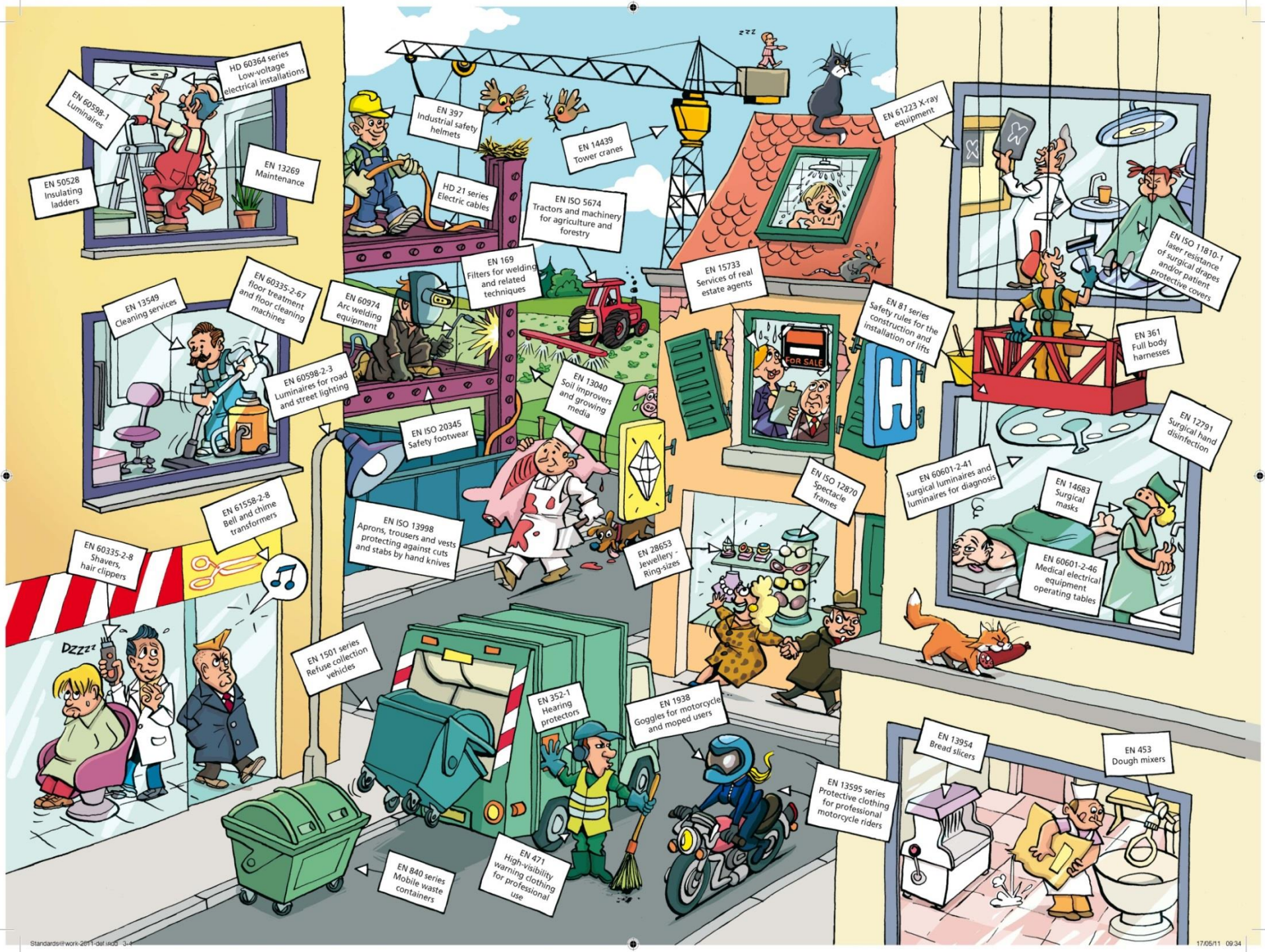
Why change ISO Standards?

- 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*

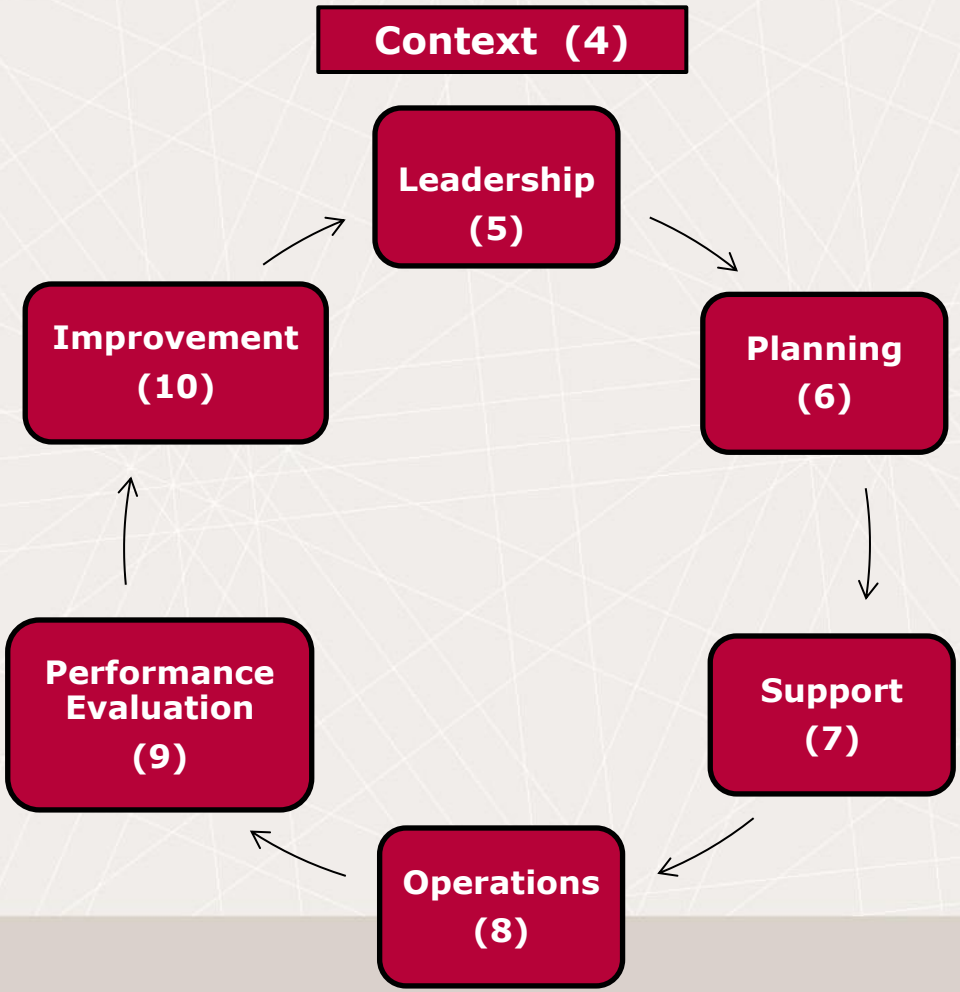
- ISO 9001:2008 to 2015, Quality
- ISO 14001:2004 to 2015, Environment
- OHSAS 18001:2007 to ISO 45001:2016/17 Occupational Health & Safety
- Three year transition period – period of co-existence
- Common Language
- Common Structure - *HLS*
- Ease of integration
- Reduced: work, costs, less disruption, better understanding
- *Aligned with the business - a Business Standard*



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

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Dedicated NSAI team

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Events:

- *'A Clients perspective' ISO 9001:2016 & ISO 14001:2015 – Autumn 2016*
- *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"

- **Annex B of ISO 13485:2016** provides a handy cross-reference between ISO 9001:2015 and ISO 13485:2016 normative requirements.

***(excluding: *Scope, Normative References*, Terms & *Definitions*)**

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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)*

What's New In 2016?

Section 1.2 – *Scope*

- ✓ **Of Particular Note in 1:**

*"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***

What's New In 2016?

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)

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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***

What's New In 2016?

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***

What's New In 2016?

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)

What's New In 2016?

Section 7.3 - *Design and Development*

7.3.9 – Control of Design and Development Changes

- 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***

What's New In 2016?

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***

What's New In 2016?

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***

What's New In 2016?

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***

What's New In 2016?

Section 7.5 - *Production & Service Provision*

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***

What's New In 2016?

Section 7.5 - *Production & Service Provision*

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***

What's New In 2016?

Section 8 -*Measurement, Analysis & Improvement*

***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***

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Summary

A. *Regulatory Requirements*

B. *Competence*

C. *Design controls*

D. *Purchasing controls*

E. *Software validation*

Comparison between ISO 13485:2016 & ISO 9001:2015

	ISO 9001:2015	ISO 13485:2016
Structure	Follow the HLS with 7 processes	Retains 5 processes
Scope	Meet customer requirements	Meet customer requirements & regulatory requirements
Focus	Continual Improvement to enhance customer satisfaction	Continuing suitability, adequacy and effectiveness of QMS & safety and performance of the Medical Device
Personnel		Retains need for Management Rep

- See Annex B to see the mapping of 9001 to 13485 (and visa versa)
  - Use this as a basis for your company **gap analysis**.

Comparison between ISO 13485:2016 & ISO 9001:2015

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

- ISO 13485:2016, replaces ISO 13485:2003 and incorporates the Technical Corrigendum ISO13485:2003/Cor. 1:2009

Co-existence period

- ISO 13485:2003 & ISO 13485:2016 will co-exist for a 3 year period
- Effective March 1st 2018, ISO 13485:2003 certificates will **no longer** be issued by NSAI

Co-existence period

- Effective March 1st 2019 all ISO 13485:2003 **certificates** will become invalid
- Effective **until** March 1st 2018 any new, modified or revised ISO 13485:2003 issued by NSAI will have an expiry date not to exceed 1st March 2019

Manufacturer's responsibility

- Carry out a gap analysis between ISO 13485:2003 &ISO 13485:2016
- 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

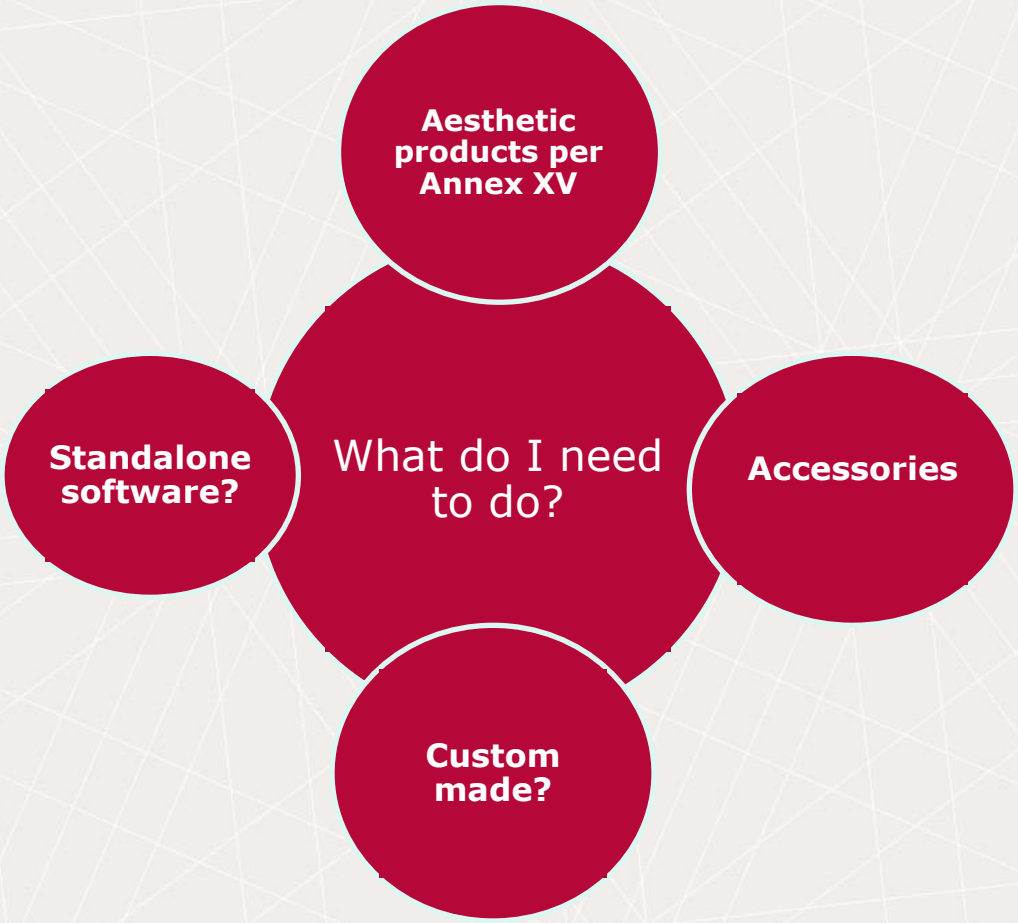
- Products currently not classified as medical devices under the MDD will be included in the MDR
  - Accessories will now include devices that specifically or directly assist another device in its intended purpose
  - Custom made excludes mass produced by industrial means
  - Inclusion of products containing 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)

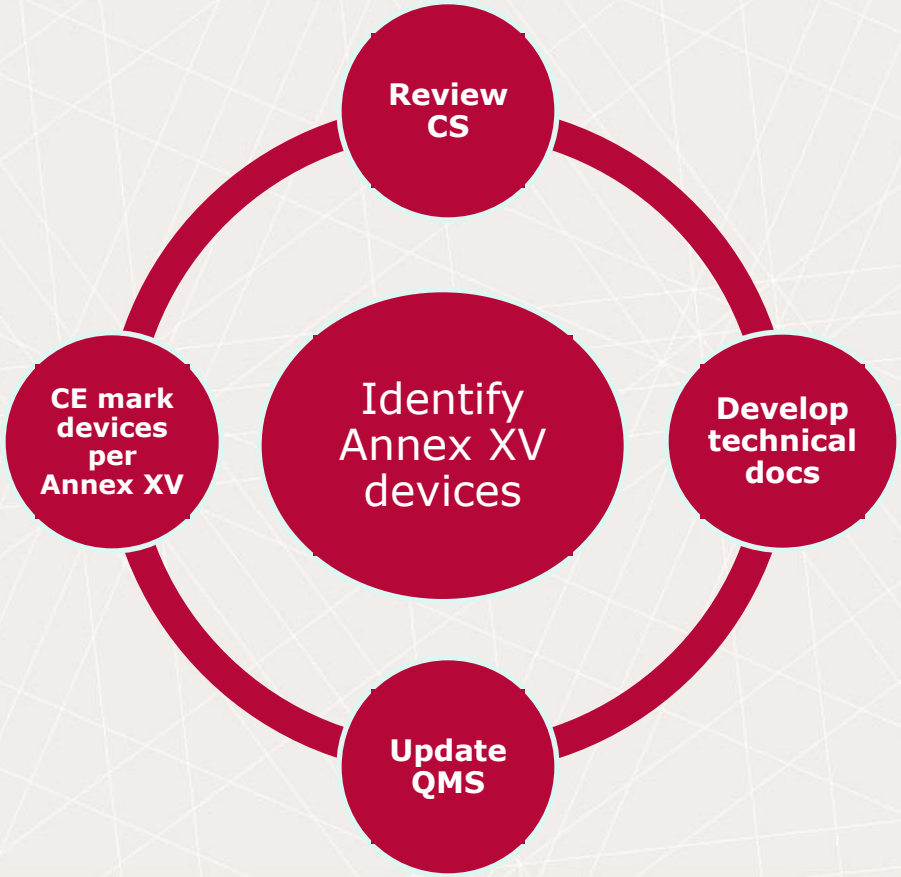
Where

- 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


Aesthetic products per Annex XV
Standalone software?
What do I need to do?
Accessories
Custom made?

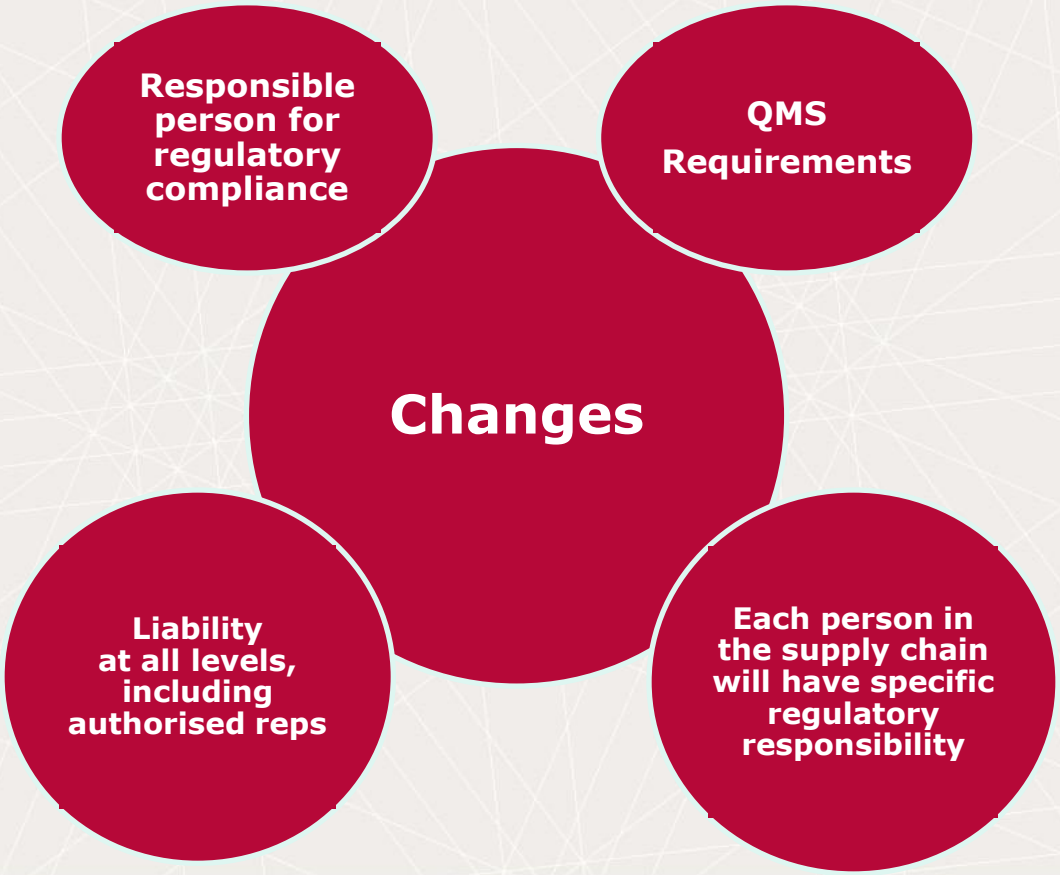
Annex XV, Products without an intended medical purpose



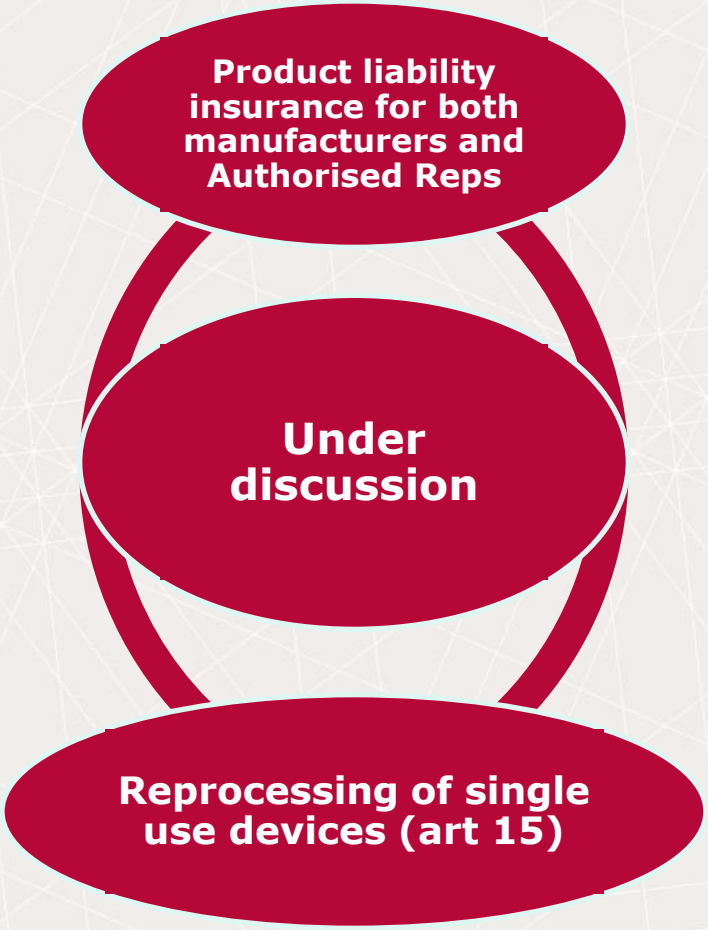
Chapter II

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

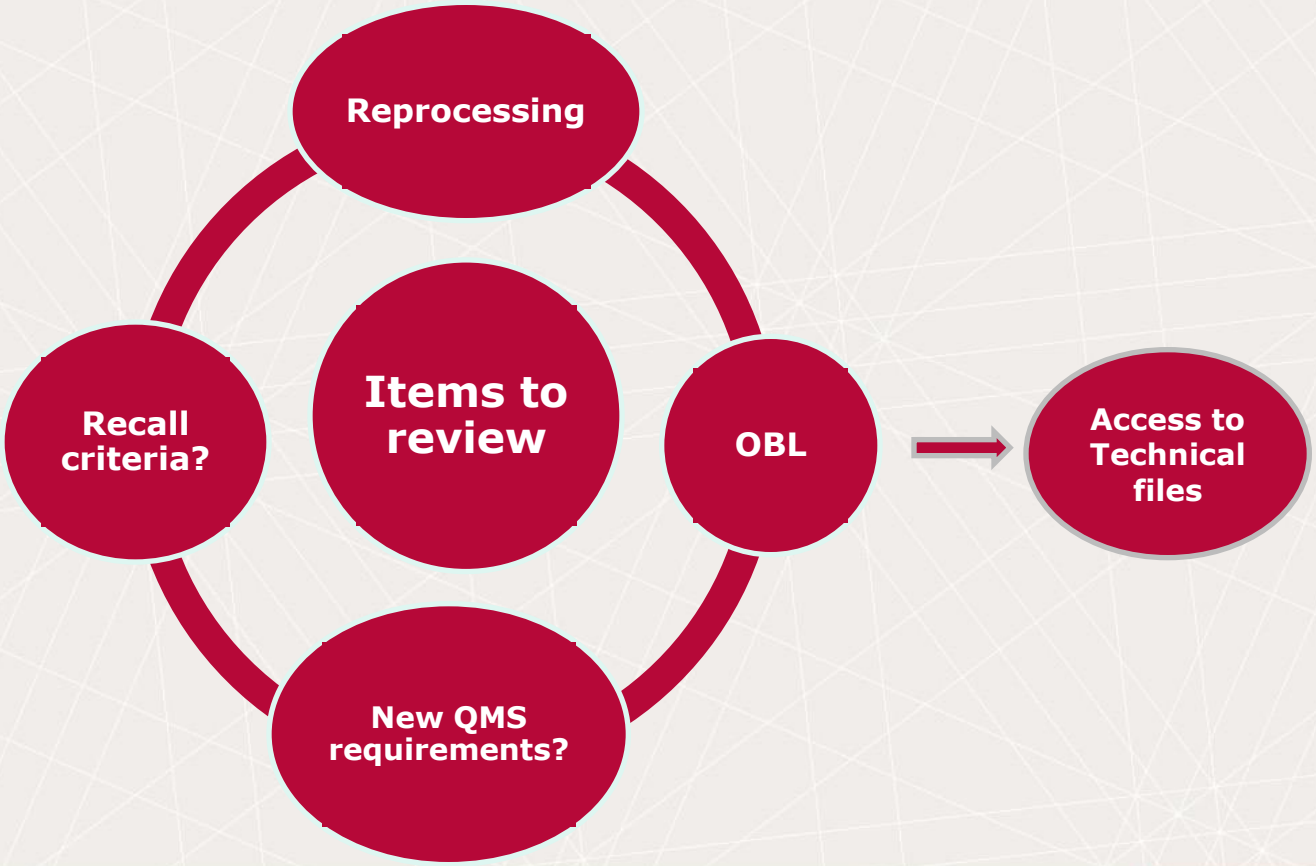
Changes


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

Under Discussion



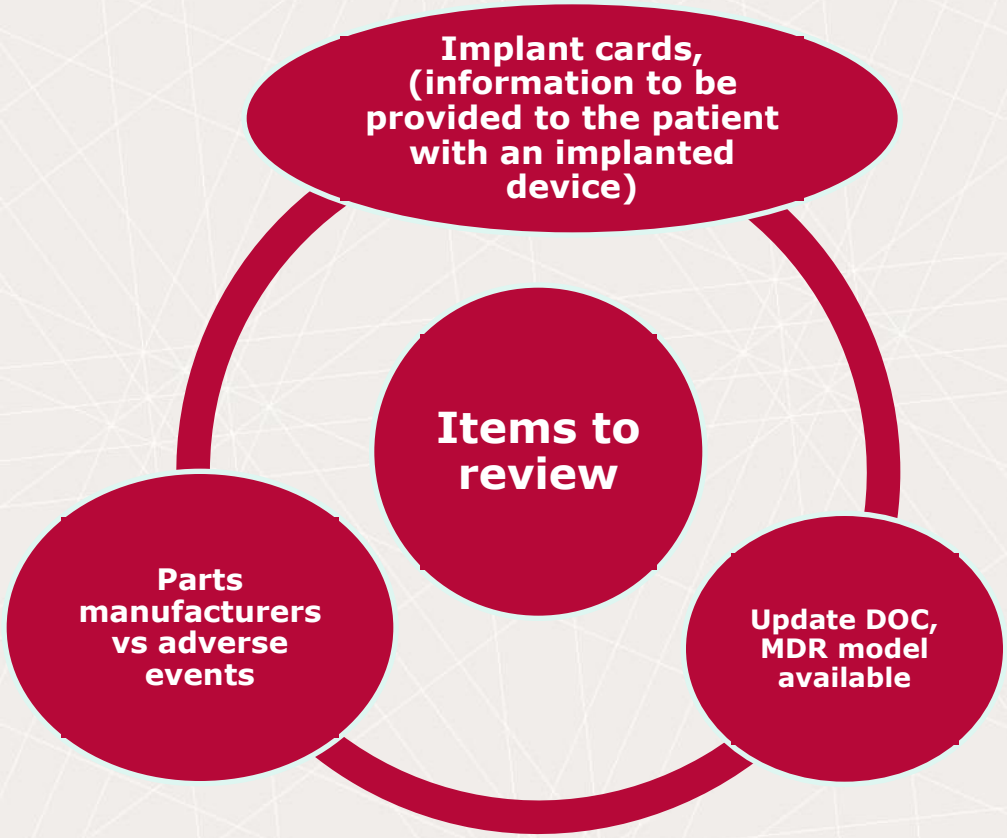
Next steps


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

Next steps


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

Next steps


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

Chapter III

Eudamed

- Traceability
- Registration
- Publication of device performance
- UDI

Changes

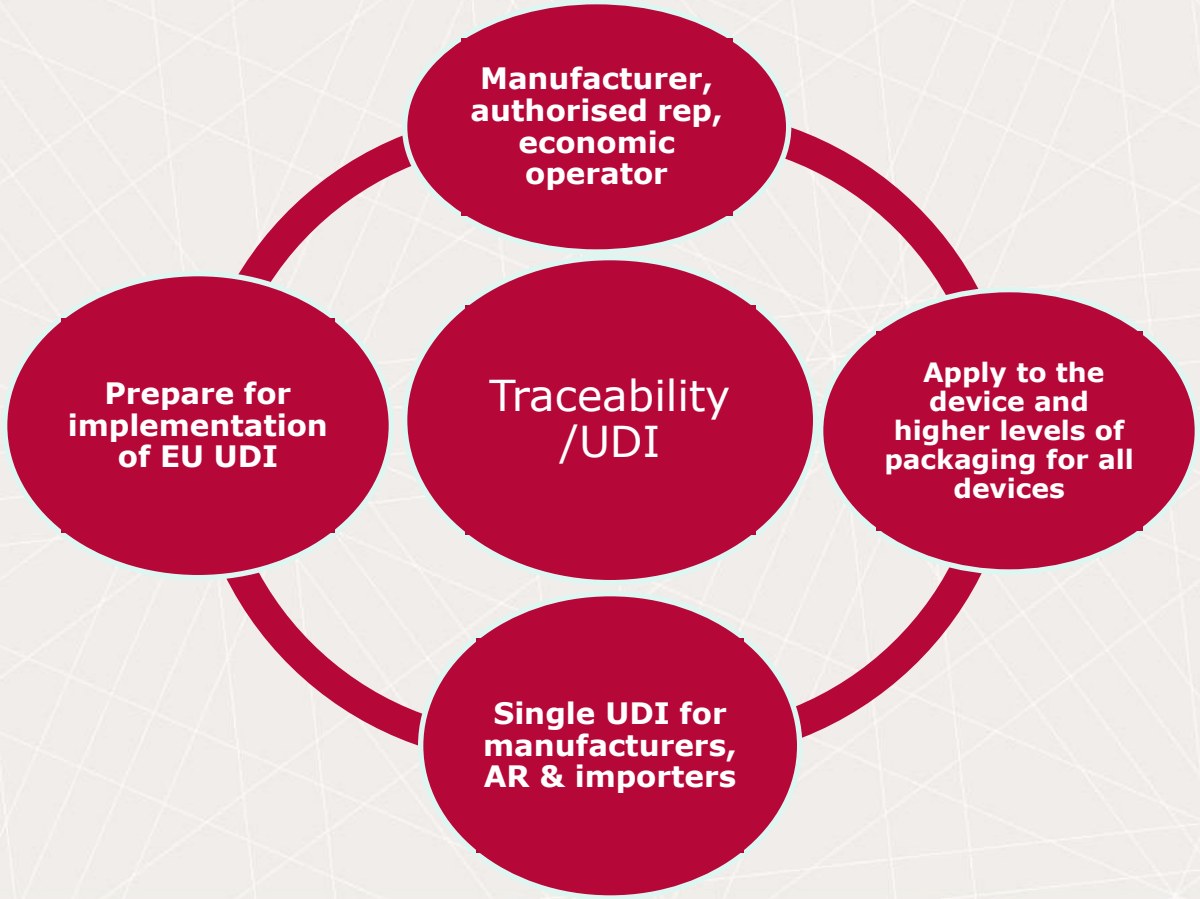
Summary of safety and clinical performance

- 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


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

Chapter V

Classification

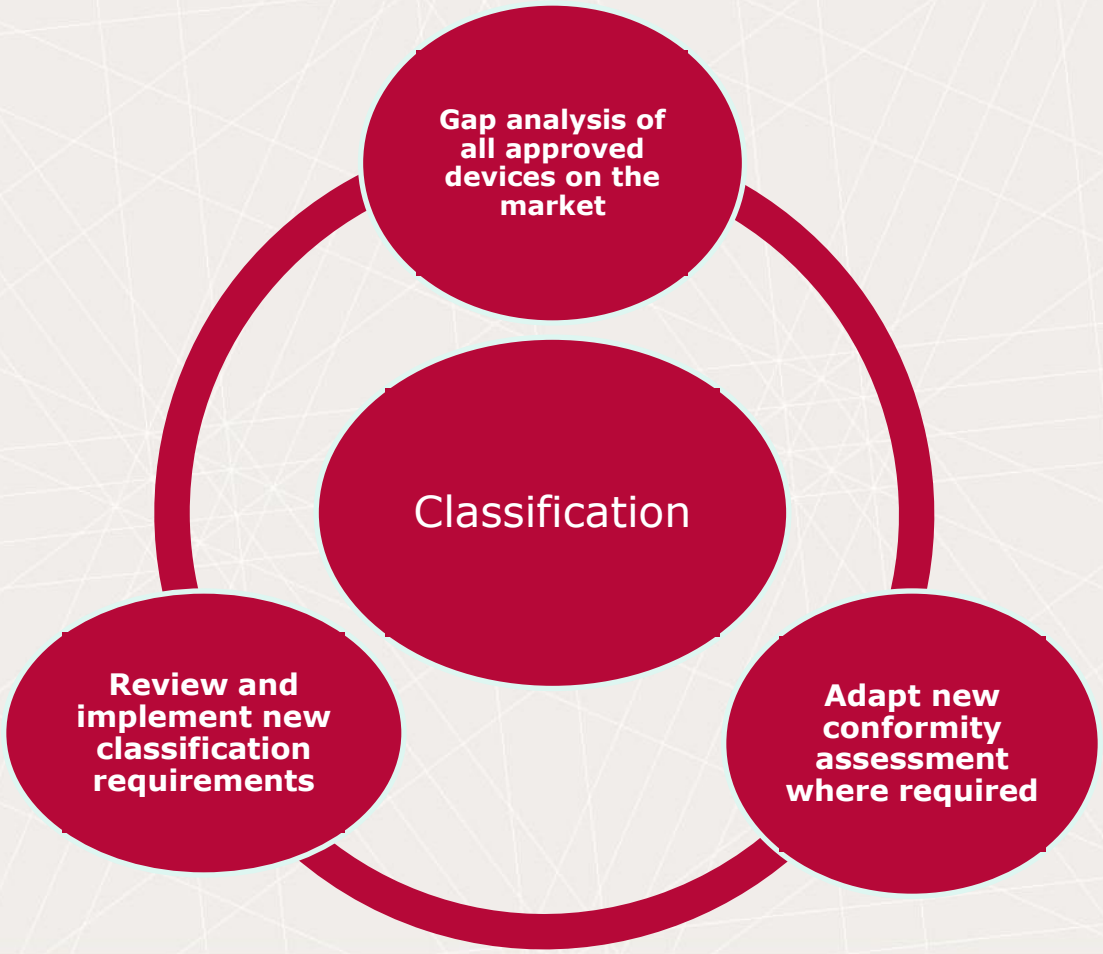
- Up classification
  - Nanotechnology
  - Spinal disk replacements
  - Life saving AMD
  - Substance based devices

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
Classification
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

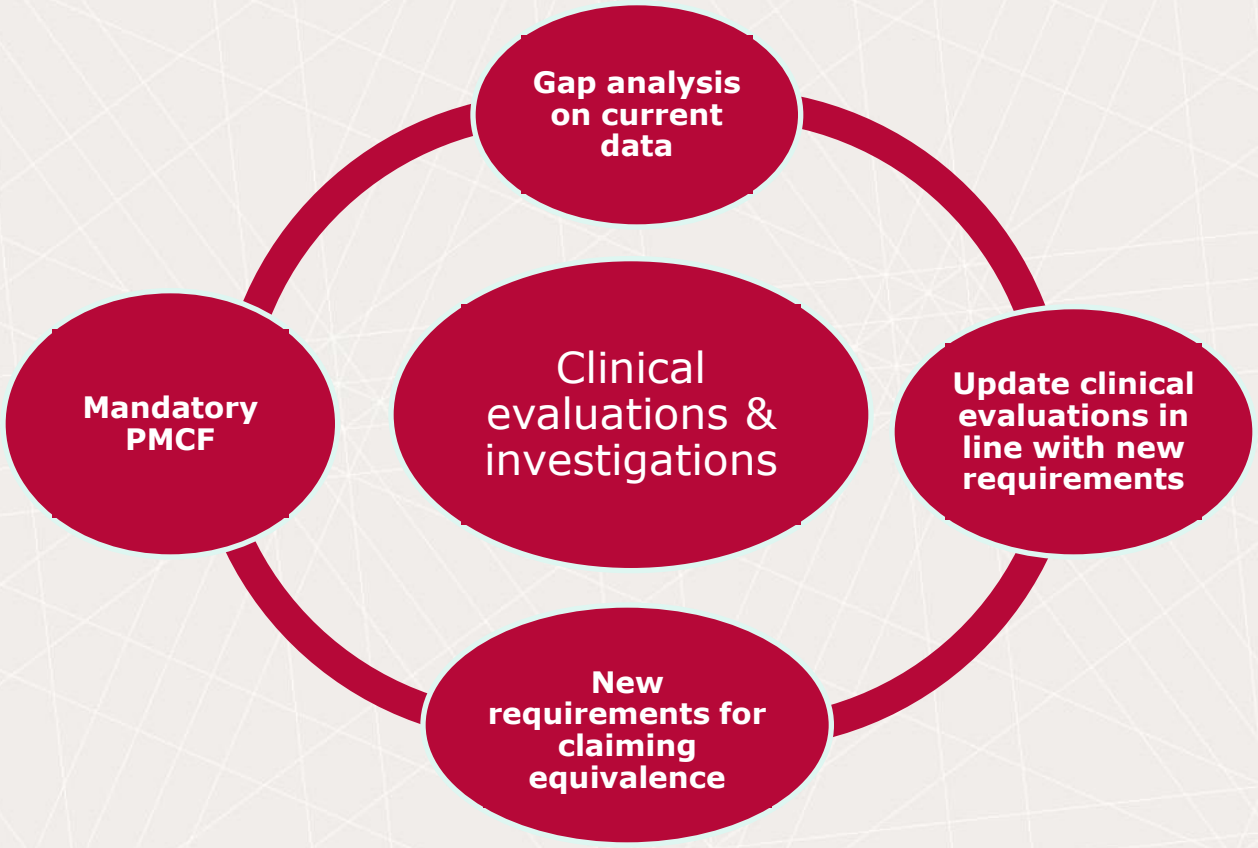
(periodic safety update reports)

Chapter VI

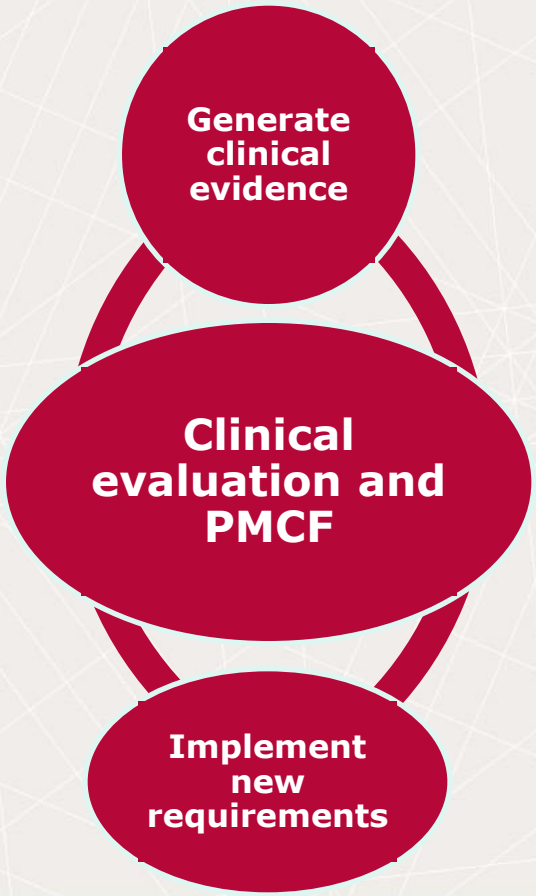
High Risk devices and permanent implants

- 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
Update clinical evaluations in line with new requirements
New requirements for claiming equivalence
Mandatory PMCF
Clinical evaluations & investigations

Next steps


Generate clinical evidence
Clinical evaluation and PMCF
Implement new requirements

Next steps


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

Chapter VII

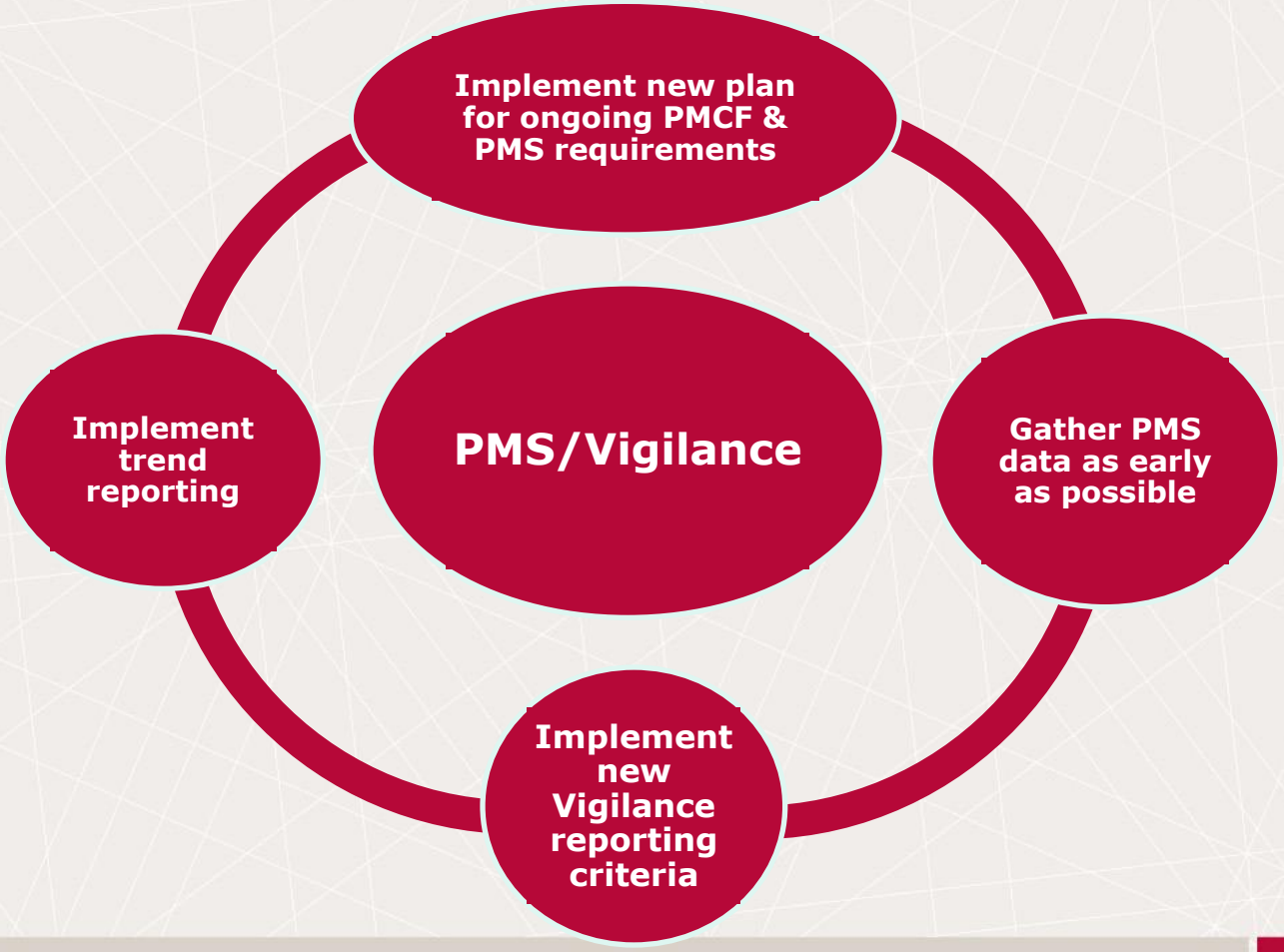
PMS

- 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


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

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