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EU MDR: Tips for Effectively Addressing the New Requirements

Mary Beth Henderson, Ph.D., MBA

September 26, 2018

Thank you for joining us

We will begin at 11:00 Central Time

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Your phone line has been muted.

Type in any questions you have in the Questions box

and we'll have Q&A at the end of the presentation

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Agenda

- History
- Actors
- Obvious Differences
- Still to come
- Time Sensitive Activities
- Key Changes
- Process
- Impact
- MDR Take-Aways
- Summary

History

How we got here:

2008: EU Commission launches consultation on MD framework

2012: EU Commission publishes proposal for new MD **Regulation**

2014 Q2: EU Parliament adopts position on MDR

2015 Q3: EU Council adopts position on proposed Regulation

2015 Q4: Trilogues between Commission, Parliament and Council begins

2016 Q2: Publication of Draft MDR and IVDR

2017 MAY: Publication of the MDR &IVDR in the Journal

Actors

Who's doing what?

EU Commission:

Administration, Development of legislation, Support Member States, Ensure cooperation

Member State Law Enforcement (Competent Authorities):

Ensure only safe, compliant products on the market, Designate Notified Bodies (NB)

Notified Bodies:

Conformity Assessment, QMS, Product, Manufacturer, Supplier, Subcontractor audits (some unannounced)

Manufacturer:

Retains ultimate responsibility for conformity

Obvious Differences

Length: 177 pages

101 Whereas (WHY)

Ten (X) Chapters (WHAT)

Sixteen (XVI) Annexes (HOW)

Emphasis on Risk-Benefit

Incorporation of many guidance documents into regulation (clinical/PMS)

Still to come (WIP)

- Regulatory status of groups of products
- Common Specifications
- Format of Summary of Safety and Performance
- UDI specific guidance
- EUDAMED databases

Time Sensitive Activities

MDR Certification from 26 May 2020

- Class I reusable
- Class III custom made implantable
- Reclassified Software
- Devices with no medical purpose
- Devices with changes to design or intended purpose

Time Sensitive Activities

Must be in place by 26 May 2020

- Post market surveillance
- Market surveillance
- Vigilance
- Registration of economic operators and devices

Key Changes

Notified Bodies

- Strengthened designation criteria
- Allows for joint audits
- Allows for unannounced audits

Key Changes

Clinical Evidence

- Less equivalence, more data for high risk devices
- Published Safety and Performance Data
- Post Market Clinical Follow-up

Key Changes

Pre-market

- Scrutiny (panel review) for high risk devices will lead to longer review cycles
- Common Specifications (CS)
- Responsible Person for Manufacturers and Authorized Reps

Key Changes

Post-Market Surveillance and Vigilance

- Central Database and co-ordination/sharing of data
- Trend reporting
- Enforcement activities

Key Changes

Transparency and Traceability

- Devices and Economic Operators Registered Centrally
- Unique Device Identification (UDI)
- Implant Cards

Key Changes

Governance and Oversight

- Central Committee: MDCG
- Expert Panels, Expert Laboratories

Process

1. Determine if you have a device (Ch I, An XVI)
2. Determine device class (Ch V, An VIII)
3. Select Conformity Assessment Procedure (Ch V)
4. ID Safety and Performance Requirements (Ch II, An I)
5. Assign UDI (Ch III, An VI)

Process

6. Assemble Technical Documentation (An I – IV)
7. Apply Conformity Assessment (An IX, X, XIA, XIB)
8. Complete DoC (Ch II, An IV)
9. Affix CE Mark (Ch II, An V)
10. PMA and Update Tech Documentation (Ch II, An III, An XIV)

Impact

Planning

- NB discussions
- Economic Operator ID and responsibility/ contract review
- Key timeline criteria
- Identify process versus product activities
- Prioritization of product mix

Impact

Planning (cont.)

- Documentation updates/creation
  - Labels
  - SOPs/WIs
  - Tech Files
  - PSUR
  - SSCP
- Resource identification
  - Project management

Impact

Economic Operators

- Manufacturer
- Authorized Representative
- Importer
- Distributor

Impact

Economic Operators (EO)

Record retention:

- ✓ ID any EO they have directly supplied
- ✓ ID any EO who has directly supplied them
- ✓ ID any health institution or healthcare professional to which they have directly supplied a device

For 10 or 15 years

Impact

Authorized Rep

- Must have Tech File “permanently available”
- Shares device liability with manufacturer
- Need access to a responsible regulatory person

Impact

Classification

- New dispute process
- MDR includes active implantables
- Addition of tissue engineered products
- Up-classification of devices in direct contact with the heart or central circulatory system
- Up-classification of orthopedic device and devices in contact with spinal column
- Addition of nanomaterials
- Updated definition of human origin material

Impact

Annex I: Safety & Performance Requirements

Analogous to Essential Requirements in MDD

- Chapter I. General requirements
- Chapter II. Requirement regarding design and manufacture
- Chapter III. Requirements regarding the information supplied with the device

Must include method of conformity demonstration (justification, V&V)

Must cross-reference documentation above specifically

Impact

Common Specifications

- Where no harmonized standards exist
- Where relevant harmonized standards are not sufficient
- Where there is a need to address public health concerns
- Can potentially apply to general safety and performance, tech documentation, CER, PMCFU, clinical investigation requirement

Impact

Clinical Data

- Significant new requirements for Class III and active implantable devices
- CER requirements

Impact

Post-market data trending

- Need for procedures, criteria, review

Impact

Technical Documentation

1. DEVICE DESCRIPTION, SPECIFICATION, VARIANTS & ACCESSORIES

   Device description and specification

   Reference to previous/similar generations of the device

2. INFORMATION SUPPLIED BY THE MANUFACTURER
3. DESIGN AND MANUFACTURING INFORMATION
4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS
5. RISK/BENFIT ANALYSIS AND RISK MANAGEMENT
6. PRODUCT VERIFICATION AND VALIDATION

   Pre-clinical and clinical data

   Additional information in specific cases

Impact

Declaration of Conformity

- Content will need to change/be updated to include all elements identified in Annex IV

Impact

Post Market Surveillance

Outputs:

- Design and Manufacturing changes
- Usability changes
- Trend analysis
- CERs
- CAPA
- Risk management
- Summary of Safety and Performance
- Periodic Safety Update Report (PSUR) – updated as per device classification

Impact

Documentation

- Measure, Assessment, Improvement SOPs will need to be linked to PMS/trending
- Labels require device name/"medical device symbol"
- Document Retention SOPs will need to be in alignment with new EU requirements
- Essential Requirements Checklist becomes obsolete (becomes General Safety and Performance Requirements)
- New SOPs will need to be written for PSUR and SSCP activities

MDR Take-Aways

- Greater emphasis on product life cycle (versus pre-approval activities)
- Increased NB training and certification requirements
- MDR incorporated MEDDEV guidelines (Authorized Rep, CER, vigilance, PMCF)
- New “Medical Devices”: cleaning/disinfection/ sterilization products, contraception devices, cosmetic devices, devices incorporating human tissues and cells

Take-Aways

- Definition of an accessory has expanded (“Assist”, rather than “Enable”)
- Label now requires Medical Device symbol
- UDI requirement
- Class III Summaries
- Expanded role of EUDAMED
- More information will be publically available
- Use of expert panels
- Role authorized rep and responsible persons

Summary

- Create a project plan
- Discuss/review your plan with your NB (frequently)
- Prioritize activities
  - Must haves
  - Need to haves
  - Nice to haves
- Educate organization as to new requirements/ timelines
- Ensure adequate staffing
- Work the plan

Questions?

Type any questions you have in the Questions box.

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