EU MDR and IVDR:

Review of Significant Changes and Timeline for Manufacturers

THE CRO GROUP

Agenda

A brief overview on the MDR

A Notified Body Perspective

A Manufacturer/Consultant Perspective

Timelines

Some Unanswered Issues

A Brief Overview on the MDR

- History
- Stats
- Objectives
- Main Changes
- Certificately Yours

A Brief Overview on the MDR - History

- 2008: EU Commission begins consultation on ‘framework’ for Directive revision
- Oct. 2015: Member States agree on ‘general approach’ to revision
- Mar. 2017: Member State representatives agree to adopt regulations to replace AIMD, MDD, and IVDD
- 05 May 2017: Publication of MDR (to replace AIMD and MDD) and IVDR (to replace IVDD) but dated 5 Apr 2017
- 26 May 2017: First date of ‘application’ of MDR/IVDR, transition period 3 years for MDR, 5 years for IVDR (before going mandatory)

A Brief History on the MDR - Stats

- Medical Devices Directive
  - CD 93/42/EEC, amended by CD2007/47EC
  - 20 Articles
  - 60 Pages
  - 12 Annexes
  - Doesn’t Cover AIMD
  - Doesn’t Cover non-medical devices (do not diagnose or treat a disease, ex. hair removal, regrowth)
- Medical Device Regulation
  - Regulation 2017/745
  - 123 Articles
  - 175 Pages
  - 17 Annexes
  - Covers AIMD (Active Implantable Medical Devices)
  - Covers certain non-medical devices (aesthetic beauty photooptical)

A Brief Overview on the MDR – Objectives

- Increased / more consistent Notified Body Controls and Operations
- Increased / more consistent Vigilance Reporting
- Bolster Post Market Surveillance (Unannounced Inspections, PMCF, etc.)
- Improved Information Sharing via Eudamed (Comp Authorities, Notified Bodies)

A Brief Overview on the MDR – Main Changes

- One regulation covers AIMD and Medical Devices
- Covers ‘non-medical’ devices (ex. cosmetic contact lens)
- Formalizes ‘Recommendation/Guidance Creep’ of past 4 years
- Reclassifies devices with provocative safety
- New definitions bring new players (Economic Operator), devices (those with Nanomaterials), etc. into scope
- Will lead to a Notified Body consolidation
- Keeping up with the FDA-ers (ex. UDI, regulates non-medical, etc., more regulation of re-usables)
- UA’s from randomly every 3 to every 5 years

A Brief Overview on the MDR – Certificately Yours

- MDD or AIMD Certificates issued before MDR (26 May 2017) have *up to* 5 year expiry (the date on the Cert except AIMD /MDD Annex IV which expire 27 May 2022 at latest)
- MDD or AIMD Certificates issued during transition (26 May 2017 – 26 May 2020) have *up to* a 5 year expiry, but NLT 27 May 2024
- Notified Bodies may not issue MDD certificates after 26 May 2020
- If MDR Certification not achieved during transition, and MDD Cert expires, Manufacturer must not place devices on market after 26 May 2025.

A Notified Body Perspective

- Applying for Redesignation
- Resources
- Assessment Transparency
- NANDOGEDDON
- Getting a Grip on Rule 11
- Technical File / Design Dossier Re-Review
- Meet the Panels
- And then there's….

Thanks for viewing the preview

- For the complete presentation, please contact us at:
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