Breakfast seminar

MDR and its potential impact on Technical Files

QAdvis – Seminar, Sthlm/Uppsala/Lund, March 2017

QAdvis key competence areas

QMS in-the cloud

Turn key QMS
Digital signatures
Efficient and lean
Validated and compliant

System development

Project management
Product software validation
Regulated software validation
Requirement management
Risk management
Verification and validation
Process validation

QA&RA/Clinical Consulting

Interim management
Expert advise
Audits/Mock audits/Due diligence
Warning letters, compliance projects
PMA, 510k, CE-mark
Global regulatory support
Vigilance, recall, post market surveillance
Clinical evaluation and clinical studies

Training/courses

CE-marking
ISO 13485 & 21CFR820
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
SW life cycle
SW risk management
Risk management
And more…

Lean and Six Sigma

Training and Consulting
In cooperation with USA based partner.

European Authorized Representation

Providing European representation for non-EU MedTech companies

Active board member of EAAR: European Association of Authorised Representatives

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Presentation of the speaker Anneli Wiedenkeller

- Worked within the medical device industry since 1988 (manufacturing, QA, R&D, RA).
- Background mainly from electrotechnical devices.
- Working the recent years as a senior product assessor (active and non-active devises) at a Swedish MDD NB.

Agenda

- Transition of MDD, AIMDD and IVDD to MDR and IVDR
- Major changes in recent years
- Technical Files (MDR/IVDR annex II and III)

Transisiton of MDD Essential Requirements to General safety and performance requirements (GSPR)

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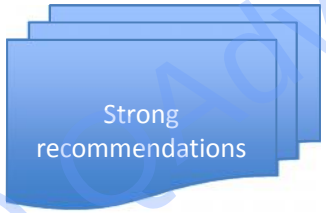
Change from AIMD,MDD and IVDMD to....

Directives

AIMDD (now: amendment 4)

MDD (now: amendment 5)

IVDMD (now: amendment 3)



- Guidance MEDDEV:s
- Consensus statements
- Informative documents
- Harmonized standards

Regulation

MDR

IVDR

Probable timelines

European Council vote on latest proposal 7 March 2017

European Parliament vote 20 March 2017

Expected to be formally published in late May or early June 2017

Transition period

- MDR will become applicable in three years after acceptance (2020)
- IVDR will become applicable in five years after acceptance (2022)

Translation to Swedish

Utg: 9 Augusti 2016
(15 juni 2016)

Utg: 31 Augusti 2016
(15 juni 2016)

Ed: August 9, 2016
(15 June 2016)

Ed: August 31, 2016
(" This is a "clean" version without any difference between "new text" and text from the Commission proposal.")

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Final draft (?)

”Position of the Council at first reading..”, dated 22 Feb 2017:

- BSI website

  https://www.bsigroup.com/en-GB/blog/BSI-Medical-Device-Blog---The-next-step-to-MDR-adoption/?utm_source=pardot&utm_campaign=SM-SUB-LG-CN-Blog1-ALL-1702A&utm_medium=email&utm_content=CTA

- TÜV Rheinland website
  http://www.tuv.com/en/corporate/business_customers/product_testing_3/medical_devices_engineering_1/medical_products.html

Globalization

- EU MDR/IVDR (Q2 2017?)
- MEDDEV 2.7.1 rev 4 (June 2016) (”CLINICAL EVALUATION...)
- QMS: ISO 13485:2016
- HA Analysis: EN ISO 14971:2012 annex Z and NBMED consensus paper

  http://www.team-nb.org/wp-content/uploads/2015/05/documents2014/NBRG_WG%20RM_Interim_NBmed_Consensus_Version_140812_1_1.pdf

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All ”old” news still not clear

- European database on medical devices (Eudamed)
- Unique Device Identification (UDI)
- Common specifications
- Reprocessing of single use devices
- Changed of risk classes (IVDD classes List A and B/IVDR classes A, B, C and D)
- Person responsible for regulatory compliance
- Responsibility of European Representative etc
- .....

Structure of MDR and IVDR

- Article 2 Definitions
- Article 10 General obligations of manufacturers
- Article 15 Person responsible for regulatory compliance

MDR Annexes (tot 17, 15 in IVDR)

I General safety and performance requirements

II Technical documentation

III Technical documentation on post-market surveillance

IV EU Declaration of conformity

V CE marking of conformity

VI Information to be submitted upon the registration of devices and economic operators in accordance with Articles 29(4) and 31; core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 28 and 29;and the UDI system

VII Requirements to be met by notified bodies

VIII Classification rules

IX Conformity assessment based on a quality management system and assessment of the technical documentation

MDR Annex (tot 17)

X Conformity assessment based on type examination

XI Conformity assessment based on product conformity verification

XII Certificates issued by a notified body

XIII Procedure for custom-made devices

XIV Clinical evaluation and post-market clinical follow-up

XV Clinical investigations

XVI List of groups of products without an intended medical purpose referred to in Article 1(2)

XVII Correlation table

Technical Documentation

- About 10 ”hits” in MDD an 4 in IVDD
- About 100 ”hits” in MDR and IVDR
- Own sections/annex

Example: Product/TF ”Big five” of MDD contra MDR

MDD	MDR
Intended Purpose/Use	Intended Purpose/Use
Risk classification, annex IX	Risk classification, annex VIII
Essential Requirements (E R), annex I	General Safety and Performance Requirements (GSPR), annex I
Clinical evaluation, annex X	Clinical evaluation XIV Clinical evaluation and post-market clinical follow-up XV Clinical investigations
EC DoC, annex VII	EC DoC, annex IV

Increased dependence

TF  QMS

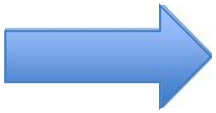
Importance of root cause analysis has increased in TF

GHTF/SG3/N18:2010

Quality management system –Medical Devices –
Guidance on corrective action and preventive action and related QMS processes, extract:

6.2 Identify Root Cause

Causes or contributing factors of detected nonconformity or potential nonconformity should promptly be identified so that corrective action can be taken to prevent recurrence, or preventive action taken to prevent occurrence…..



Update of a/several processes?
Need of a process?
Not following existing processes?

MDR/IVDR Annex regarding TF

I General safety and performance requirements

II Technical documentation

III Technical documentation on post-market surveillance

STED (“non-binding guidance”)

Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n011-2008-principles-safety-performance-medical-devices-080221.pdf

Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n063-2011-summary-technical-documentation-ivd-safety-conformity-110317.pdf

Requirement of structure in TF

..”thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner.”

MDR Annex II subsections

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

1.2. Reference to previous and similar generations of the device

MDR Annex II subsections

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

MDR Annex II subsections

3. DESIGN AND MANUFACTURING INFORMATION

MDR Annex II subsections

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

MDR Annex II subsections

5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

MDR Annex II subsections

6. PRODUCT VERIFICATION AND VALIDATION

6.1. Pre-clinical and clinical data

6.2. Additional information required in specific cases

MDR Annex II subsections

ANNEX III

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

Summary of areas in focus

- Risk Management
- Post Market Surveillance
- Clinical data

Summary

- Start to read!
- Gapanalysis!

Thank you for your attention!
Questions & Answers

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QAdvis can support you as needed

CE marking support:

- Technical File creation
- Pre-assessment of Technical Files
- EN ISO 13485:2016 (QMS)
- EN ISO 14971 (Risk management)
- EN 62304 (Software)
- EN 62366-1 (Usability)
- Support regarding clinical data e.g. clinical evaluation report

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