Your Regulatory Partner

Navigate the Risk Management Maze – 5 tips for successful MDR transition

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sis STANDARD DEVELOPER 2019

SEK SVENSK ELSTANDARD

EA AR European Association of Authorised Representatives

SWEDISH Medtech

QAdvis – Key competence areas

QMS In-the-cloud

Turn Key QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

European Authorised Representation

Providing European representation for non-EU MedTech companies

Active member of EAAR (European Association of Authorized Reps)

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management
And more…

Agile, Lean and Six Sigma

Training and consulting in cooperation with US partner

QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Files
Global Regulatory Support
Vigilance, Recalls, PMS
Clinical Evaluation and Clinical Studies

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Presentation of the speaker Cristina Barkman

- 20+ years experience from development and manufacture of medical devices
- Extensive experience from risk management
- Co-author of standard ISO 14971:2019

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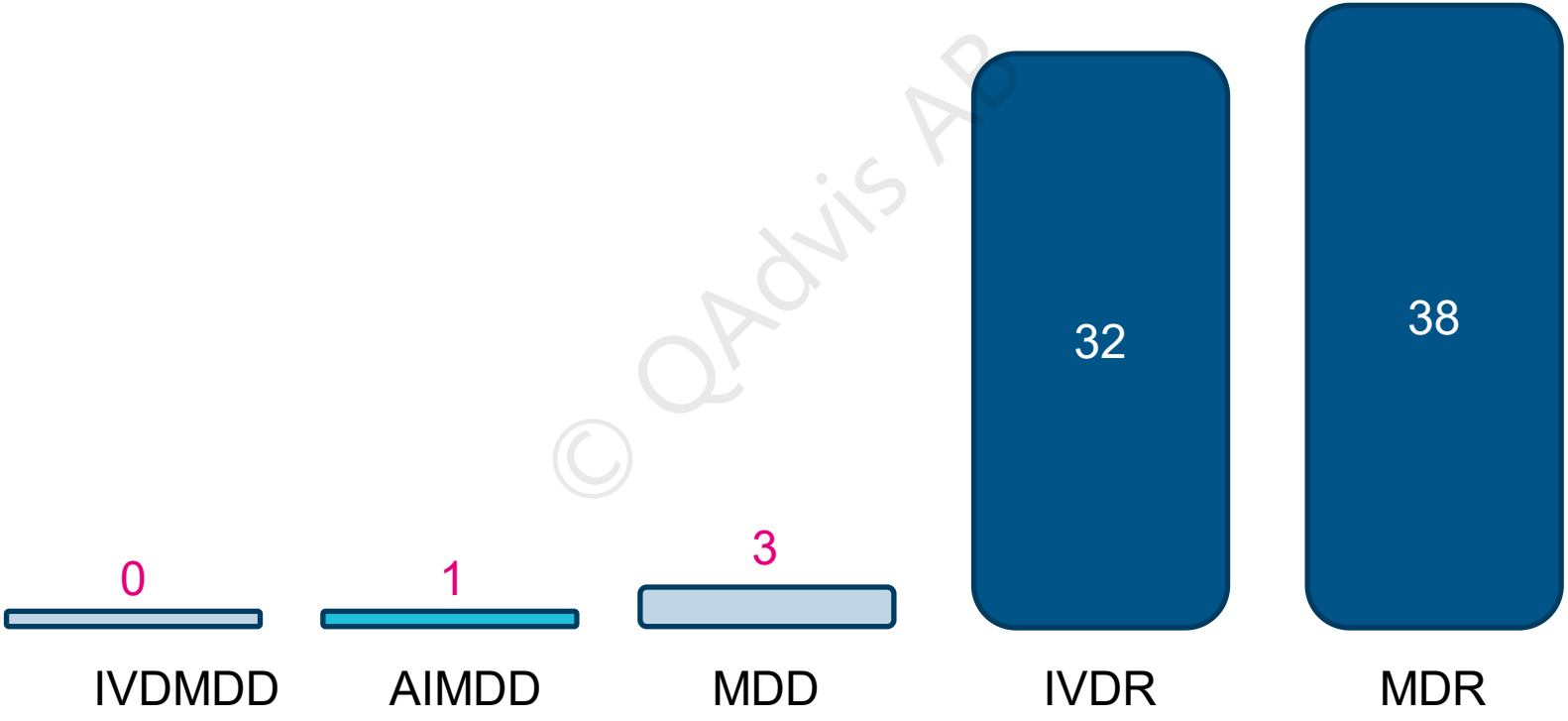
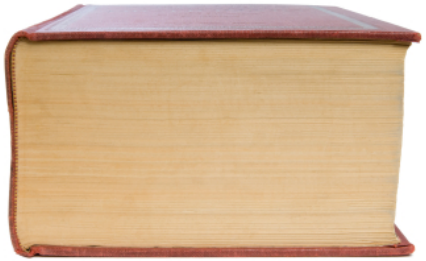
“Risk Management” in European Legislation



Introduction - Legislative Act

MDR, IVDR



…. “in order to minimize risks or prevent incidents related to devices, manufacturers should establish a **system for risk management**”…

Ref: MDR I Legislative act (32), IVDR I Legislative act (31)

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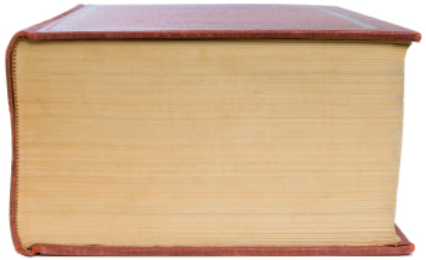
Introduction - Legislative Act

MDR, IVDR



"The **risk management system** should be carefully **aligned** with and **reflected** in the **clinical evaluation** for the device, including the clinical risks to be addressed as part of clinical investigations, clinical evaluation and post-market clinical follow-up. The risk management and clinical evaluation processes should be inter-dependent and should be regularly updated."

Ref: MDR I Legislative act (33), IVDR I Legislative act (32)

Risk management system

- Entire life-cycle of the product
- Continuous iterative process
- Regular, systematic updating
- Aligned and reflected by clinical evaluation
- Aligned and reflected by post-market follow-up

Ref: MDR/IVDR Annex I, GSPR 3

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Risk management system

Use
EN ISO 14971:2019
to support your work

Ref: MDR/IVDR Annex I, GSPR 3

Safe and effective device

- Acceptable risks
- High level of safety
- Benefits to the patient
- Generally acknowledged state of the art

Ref: MDR/IVDR Annex I, GSPR 1

Risk acceptability

"…reduce risks as far as possible without adversely affecting the benefit-risk ratio…"

- Acceptance criteria for individual risk
- Acceptance criteria for overall residual risk

Ref: MDR/IVDR Annex I, GSPR 2

Overall residual risk

- Method defined in the plan
- Acceptability criteria
- Inform the user on any residual risks

Ref: MDR/IVDR Annex I, GSPR 4 & GSPR 8

Benefit-Risk analysis

- Benefits to the patient and/or user
- For the overall residual risks
- Confirmed by the clinical evaluation

Ref: MDR/IVDR Annex I, GSPR 8

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Inform the user on

- Intended use
- Warnings, cautions
- Information for correct use
- What to do or not do to avoid risk or minimize risks
- Significant residual risks

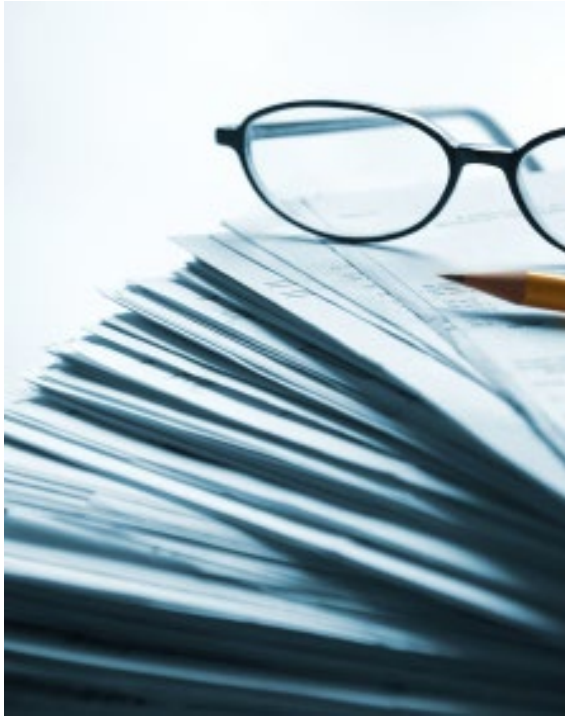
Ref: MDR Annex I, GSPR 4 & 23; IVDR Annex I, GSPR 4 & 20

Systematic post-market follow-up

- Post-market surveillance
- Aligned and reflected with risk management
- Active data collection
- Systematic & regular risk update

Ref: MDR Article 83; IVDR Article 78

Last but not least, in the technical documentation



document:

- Benefit-risk analysis
- Solutions adopted
- Results of the risk management

Ref: MDR/IVDR Annex II, Technical documentation (5)

Make sure that

Risk management system

- Life-cycle approach
- Regular and systematic update
- Aligned and reflected by clinical evaluation
- Aligned with post-market surveillance

Safe and effective device

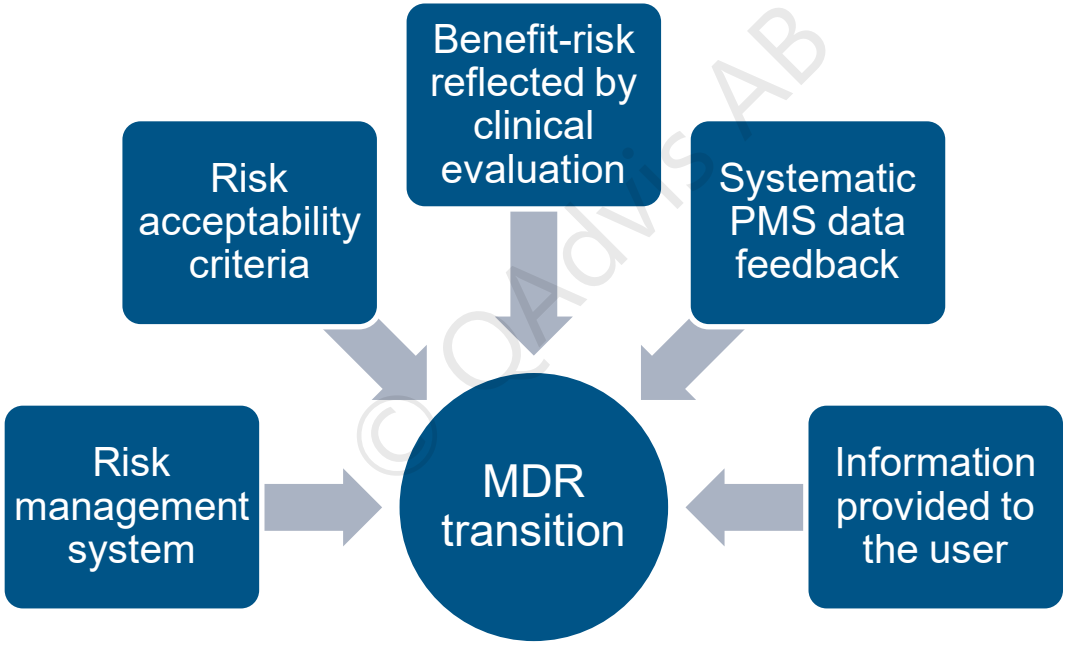
- Reduce risks as far as possible
- Use all available control options
- Benefit-risk for overall residual risk

Inform the user

- Intended use
- Correct use of product
- Information for safety
- Disclose most significant residual risks

Use EN ISO 14971:2019 to support your work!

Wrap up



Use EN ISO 14971:2019 to support your work!

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Risk Management

Intresserad av att veta mer?
Vi håller kurs om 2 dagar på nedan datum!

- **7-8 oktober 2020**
- **16-17 februari 2021**

www.swedishmedtech.se

QAdvis services

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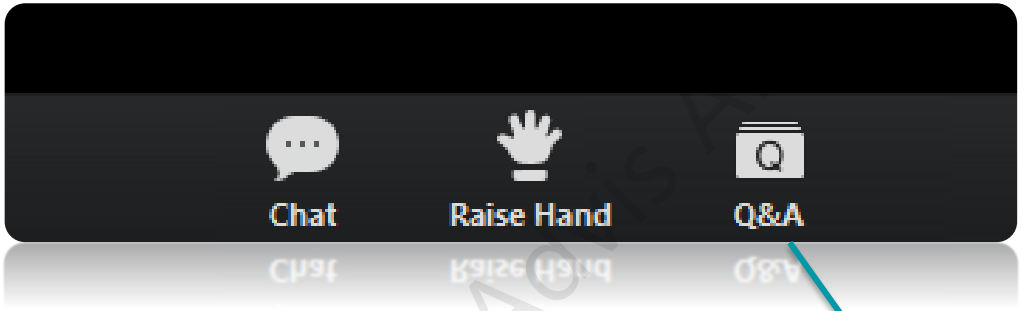
- Product specific workshop
- GAP analysis and implementation plan IVDR/MDR
- Quality Management System
- Auditing
- Risk management
- Clinical evaluation
- Courses – see our webpage

www.qadvis.com/courses-and-seminars/

Questions & answers



Questions via "Q&A"

(Other questions: cristina.barkman@qadvis.com)

Evaluation

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