2022 EUROPEAN MEDICAL DEVICE AND DIAGNOSTIC REGULATORY AFFAIRS CONFERENCE
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Notified Body Perspective on MDR Conformity Assessement Experience

Journey, Challenges, Lessons Learned

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DQS-Medizinprodukte GmbH

Agenda

- DQS-Med in a brief
- The Presentator
- Strategic Approach for Techfile Applications
- What the MDR not explicitely states, but MDM‘s need to know
- Common Pitfalls in TF Submissions
- How to avoid X-tra Loops

In a brief

DQS-Med in a brief

- Subsidiary of DQS Holding GmbH
- A World Leading Certification Body
- 1st accredited ISO 9001 Registrar in Germany
- ~ 3200 assessors worldwide
- Spin-off as independent entity in 2008
- 16th NB under MDR, designated Aug., 8th, 2020
- ~ 1600 customers, ~ 250 Assessors, ~ 100 FTE‘s
- 13485/ MDD / MDR / MDSAP (TCP III/ UKCA pend.)

The Presentator

What MDR not explicitely states but MDM‘s need to know!

Appearently :

PostMarket is key (PMS, PMSP, PMSR, PSUR,PMCF)

Premarket seems to have lower priority

The opposite is true!

The MDR expects from MDM‘s to put any possible effort into the validation of :

- Product (incl. SaMD) – Safety and Effectiveness
- Processes (Production, Sterilisation, Transport)
- Material Properties (Compatability, Biocomp., CMR-Substances)
- Computer Systems

What the MDR not explicitely states....

…. but MDM‘s need to know!

Appearently :

PostMarket is key (PMS, PMSP, PMSR, PSUR,PMCF)

Premarket has lower priority (1 citation)

The opposite is true!

The MDR expects to put any possible effort into the validation of

- Product (incl. SaMD) – Safety and Effectiveness
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What the MDR not explicitely states, but MDM‘s need to know

The Presentator

- Born 1958
- Degrees in EE (1984), MBA (1997)
- 36 years experience

  2/3rd in Electronic Industry, 1/3 in Medical

  thereoff 3/4 in CA, 1/4 at MDM‘s

  R&D, Quality, Production, Marketing, GM

Ex NBRG-Chair (Recommendation Group)

Since 7/2018 : DQS-Med, Head of Notified Body AMD

Strategic Approach for Techfile Applications

Strategic Approach for TF Applications

The Approach from a NB standpoint is simple:

- **TF-Review is most critical with ~ 70% of the load**
- **Reviewer base has been significantly reduced due to Qualification and Impartiality Req‘s**
- **Demand balancing is key, not primarily for profitability, but for availability at all**
- **A generic demand calculator will illustrate the challenges**

Strategic Approach for TF Applications

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- **Demand balancing is key, not primarily for profitability, but for availability at all**
- **A generic demand calculator reflecting the MDR provisions for TF Reviews will illustrate the challenges**

Assessor Capacity Demand Configurator

Risk class			Year 1	Year 2	Year 3	Year 4	Year 5	Cycle 1 : Total	Year 6	Year 7	Year 8	Year 9	Year 10	Cycle 2 : Total
	Audit Type		Cert.	S1	S2	S3	S4		Recert.	S1	S2	S3	S4	
	FTE's													
	Audit Days	0	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
III	No. of TF's		0,00					0,00	0,00					0,00
IIbimp.	No. of TF's		0,00					0,00	0,00					0,00
IIb	No. of (Level 4 CND) categories with 1 TF		0,00					0,00	0,00					0,00
	No. of (Level 4 CND) categories with 2 TF's		0,00	0,00				0,00	0,00	0,00				0,00
	No. of (Level 4 CND) categories with 3 TF's		0,00	0,00	0,00			0,00	0,00	0,00	0,00			0,00
	No. of (Level 4 CND) categories with 4 TF's		0,00	0,00	0,00	0,00		0,00	0,00	0,00	0,00	0,00		0,00
	No. of (Level 4 CND) categories with > = 5 TF's		0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
IIa	No. of MDA/MDN categories with 1 TF		0,00					0,00	0,00					0,00
	No. of MDA/MDN categories with 2 TF's		0,00	0,00				0,00	0,00	0,00				0,00
	No. of MDA/MDN categories with 3 TF's		0,00	0,00	0,00			0,00	0,00	0,00	0,00			0,00
	No. of MDA/MDN categories with 4 TF's		0,00	0,00	0,00	0,00		0,00	0,00	0,00	0,00	0,00		0,00
	No. of MDA/MDN categories with > = 5 TF's		0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Is,m	No. of TF		0,00					0,00	0,00					0,00
Ir	Regardless of No. of TF's		0,00					0,00	0,00					0,00
		Total	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**	**0,00**

*Top-Level Approach - Not considered: Sterile, UAA, PSUR, X-tra Loops, Admin.

3 Levels of MDM‘s modulated

1 Man-Band :
1 FTE, 1 Ir TF

Risk class			Year 1	Year 2	Year 3	Year 4	Year 5	Cycle 1 : Total	Year 6	Year 7	Year 8	Year 9	Year 10	Cycle 2 : Total
	Audit Type		Cert.	S1	S2	S3	S4		Recert.	S1	S2	S3	S4	
	FTE's	1												
III	Audit Days	4,5	4,50	1,50	1,50	1,50	1,50	10,50	3,00	1,50	1,50	1,50	1,50	9,00
IIIbim.p.	No. of TF's		0,00					0,00	0,00					0,00
	No. of TF's		0,00					0,00	0,00					0,00
IIb	No. of (Level 4 CND) categories with 1 TF's		0,00					0,00	0,00					0,00
	No. of (Level 4 CND) categories with 2 TF's		0,00	0,00				0,00	0,00	0,00				0,00
	No. of (Level 4 CND) categories with 3 TF's		0,00	0,00	0,00			0,00	0,00	0,00	0,00			0,00
	No. of (Level 4 CND) categories with 4 TF's		0,00	0,00	0,00	0,00		0,00	0,00	0,00	0,00	0,00		0,00
	No. of (Level 4 CND) categories with > = 5 TF's		0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
IIa	No. of MDA/MDN categories with 1 TF		0,00					0,00	0,00					0,00
	No. of MDA/MDN categories with 2 TF's		0,00	0,00				0,00	0,00	0,00				0,00
	No. of MDA/MDN categories with 3 TF's		0,00	0,00	0,00			0,00	0,00	0,00	0,00			0,00
	No. of MDA/MDN categories with 4 TF's		0,00	0,00	0,00	0,00		0,00	0,00	0,00	0,00	0,00		0,00
	No. of MDA/MDN categories with > = 5 TF's		0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Is,m	No. of TF		0,00					0,00	0,00					0,00
Ir	Regardless of No. of TF's	1	1,50					1,50	1,50					1,50
	Total		6,00	1,50	1,50	1,50	1,50	12,00	4,50	1,50	1,50	1,50	1,50	10,50

SME :
80 FTE, 8 Cl. III TF‘s

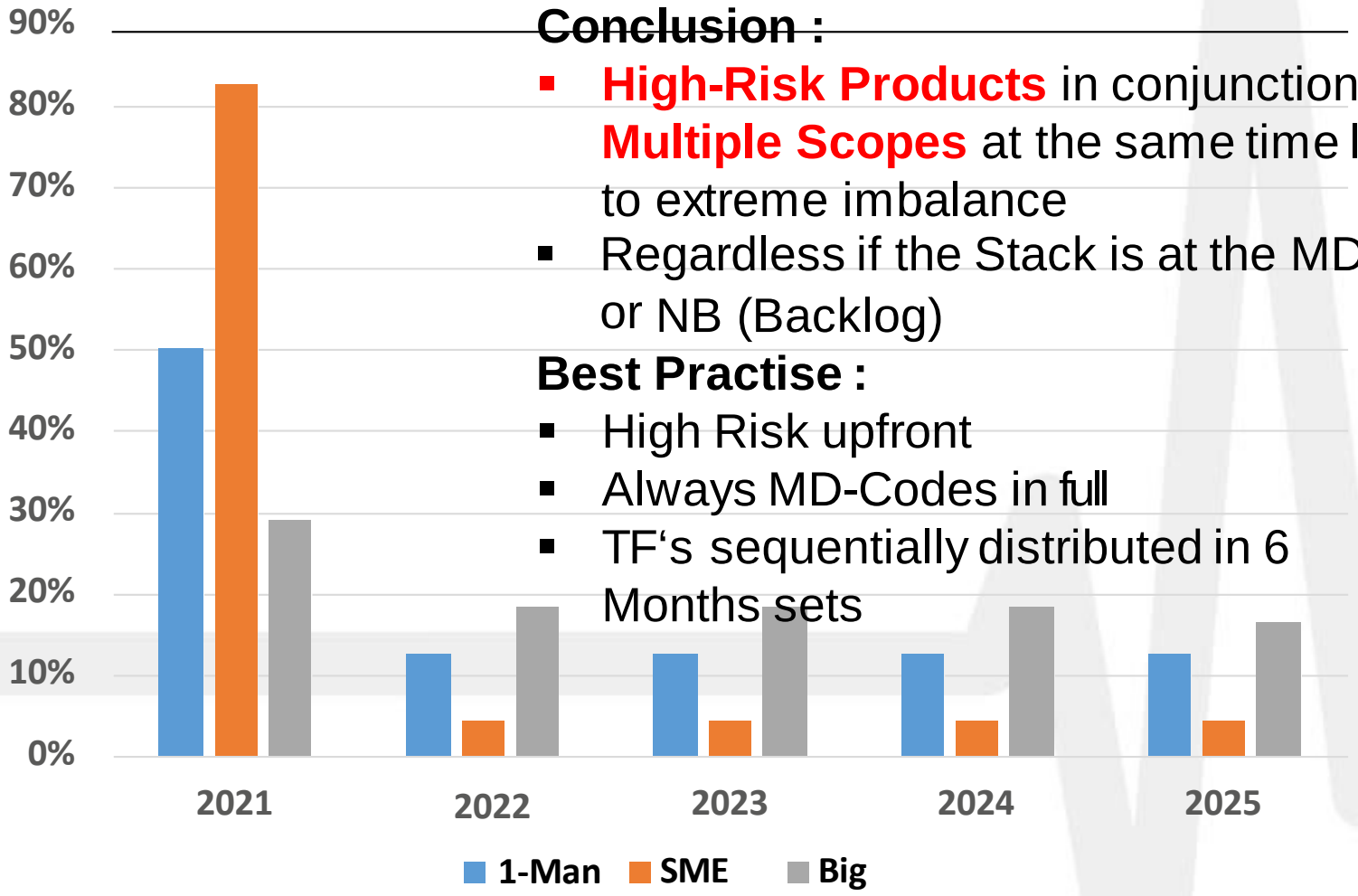
Risk Class			Year 1	Year 2	Year 3	Year 4	Year 5	Cycle 1 : Total	Year 6	Year 7	Year 8	Year 9	Year 10	Cycle 2 : Total
	Audit Type		Cert.	S1	S2	S3	S4		Recert.	S1	S2	S3	S4	
	FTE's	80												
III	Audit Days	12	12,00	4,00	4,00	4,00	4,00	28,00	8,00	4,00	4,00	4,00	4,00	24,00
IIIbim.p.	No. of TF's	8	64,00					64,00	64,00					64,00
	No. of TF's		0,00					0,00	0,00					0,00
IIb	No. of (Level 4 CND) categories with 1 TF's		0,00					0,00	0,00					0,00
	No. of (Level 4 CND) categories with 2 TF's		0,00	0,00				0,00	0,00	0,00				0,00
	No. of (Level 4 CND) categories with 3 TF's		0,00	0,00	0,00			0,00	0,00	0,00	0,00			0,00
	No. of (Level 4 CND) categories with 4 TF's		0,00	0,00	0,00	0,00		0,00	0,00	0,00	0,00	0,00		0,00
	No. of (Level 4 CND) categories with > = 5 TF's		0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
IIa	No. of MDA/MDN categories with 1 TF		0,00					0,00	0,00					0,00
	No. of MDA/MDN categories with 2 TF's		0,00	0,00				0,00	0,00	0,00				0,00
	No. of MDA/MDN categories with 3 TF's		0,00	0,00	0,00			0,00	0,00	0,00	0,00			0,00
	No. of MDA/MDN categories with 4 TF's		0,00	0,00	0,00	0,00		0,00	0,00	0,00	0,00	0,00		0,00
	No. of MDA/MDN categories with > = 5 TF's		0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Is,m	No. of TF		0,00					0,00	0,00					0,00
Ir	Regardless of No. of TF's		0,00					0,00	0,00					0,00
	Total		76,00	4,00	4,00	4,00	4,00	92,00	72,00	4,00	4,00	4,00	4,00	88,00

Biggie:
5K FTE‘s, 36 IIa/bTF‘s

Risk Class			Year 1	Year 2	Year 3	Year 4	Year 5	Cycle 1 : Total	Year 6	Year 7	Year 8	Year 9	Year 10	Cycle 2 : Total
	Audit Type		Cert.	S1	S2	S3	S4		Recert.	S1	S2	S3	S4	
	FTE's	5000												
III	Audit Days	33	33,00	11,00	11,00	11,00	11,00	77,00	22,00	11,00	11,00	11,00	11,00	66,00
IIIbim.p.	No. of TF's		0,00					0,00	0,00					0,00
	No. of TF's		0,00					0,00	0,00					0,00
IIb	No. of (Level 4 CND) categories with 1 TF's		0,00					0,00	0,00					0,00
	No. of (Level 4 CND) categories with 2 TF's		0,00	0,00				0,00	0,00	0,00				0,00
	No. of (Level 4 CND) categories with 3 TF's		0,00	0,00	0,00			0,00	0,00	0,00	0,00			0,00
	No. of (Level 4 CND) categories with 4 TF's		0,00	0,00	0,00	0,00		0,00	0,00	0,00	0,00	0,00		0,00
	No. of (Level 4 CND) categories with > = 5 TF's	3	12,00	12,00	12,00	12,00	12,00	60,00	12,00	12,00	12,00	12,00	12,00	60,00
IIa	No. of MDA/MDN categories with 1 TF		0,00					0,00	0,00					0,00
	No. of MDA/MDN categories with 2 TF's		0,00	0,00				0,00	0,00	0,00				0,00
	No. of MDA/MDN categories with 3 TF's		0,00	0,00	0,00			0,00	0,00	0,00	0,00			0,00
	No. of MDA/MDN categories with 4 TF's	1	3,50	3,50	3,50	3,50		14,00	0,00	0,00	0,00	0,00		0,00
	No. of MDA/MDN categories with > = 5 TF's	3	10,50	10,50	10,50	10,50	10,50	52,50	10,50	10,50	10,50	10,50	10,50	52,50
Is,m	No. of TF		0,00					0,00	0,00					0,00
Ir	Regardless of No. of TF's		0,00					0,00	0,00					0,00
	Total		59,00	37,00	37,00	37,00	33,50	203,50	44,50	33,50	33,50	33,50	33,50	178,50

*Top-Level Approach - Not considered: Sterile, UAA, PSUR, X-tra Loops, Admin.

Load Share over the Certification-Cycle



Conclusion :

- **High-Risk Products** in conjunction with **Multiple Scopes** at the same time lead to extreme imbalance
- Regardless if the Stack is at the MDM or NB (Backlog)

Best Practise :

- High Risk upfront
- Always MD-Codes in full
- TF‘s sequentially distributed in 6 Months sets

If not well distributed : Tsunami coming every 5 years

Structure	TF Share	Initial cost (Year 1)	Delta Cycle 2/1
1-Man	13%	50%	90%
SME	70%	82%	95%
Biggie	63%	30%	90%

Conclusion :

- TF share dominant beside Ir
- Unfavourable cost distribution (Liquidity)
- No Cycle-Volatility

Strategic Summary

- **Reduce your risk by early application**
- **Do not join the MDM‘s applying after 26.05.2023**
- **Apply latest in Q3 / 2022 with Priority on High Risk / Main Revenue base**
- **Apply in descending risk class order**
- **Keep in mind : CAB‘s cannot cope with a capacity peak of 300% and idling between the peaks**

Common Pitfalls in Submission

Common Pitfalls in TF Submission

- **Window brushing** of MDD-Techfiles
- **Divergent Interpretation of Requirements**
- Differing expectations in terms of **acceptance levels**
- Systematic NC‘s due to **Gaps in QMS Provisions**

But also:

Lack of **adopted stringency** at TF-Assessor, Reviewer and Certification Board Level

CAPA Action Plan Topics

Generic Issues

Biocompatability

IFU

Usability Process

Hazardous Substances

GPRS

Clinical Evaluation

DoC

Labelling

Supplier Quality Control

Production Processes

Verification- / Validation Testing

Intended Use / Purpose

Usability Process

- User Groups in Usability File not precisely defined
- Lack of information about mitigation of safety critical User Errors and if repetitive tests have been passed
- Validiation Test Report : no Risk-ID for specific Test
- Usabilty for connected devices not covered

GPRS

- Checklist imprecise
- Reference to (non-) / harmonised Standards lacks Rev.-No. / publication date and specific requirements (Subclauses)
- No GAP-Analysis if preceeding Version was used
- Lack of Methodology / References for Objective Evidence
- Link between UDI-DI and Variants missing
- Missing / Incomplete / outdated References to applicable Directives / Standards / Guidance papers
- Traceability for Implementation of Annex III Req.‘s
- Electrical/ Mechanical Safety as well as functional / essential Performance tests inadequate

Clinical Evaluation

- **Impartiality Declaration / proven clinical Competence of assessors**
- **CER inadequate, specifically equivalence principle**

Recently one of the major Topics of German DA (ZLG) from Surveillance Activities of the NB

Production Processes

- Production Flowcharts unreadable
- Lack of Process validation
- Software PP not documented
- Production Information incomplete / incorrect
- Place marker as reference
- Worker Instructions for Production Processes missing
- Lack of BOM
- schematic set-up / flowchart for production line missing
- Details of process controls and final inspections missing
- Validation report missing or not applicable for MDR

Verification- and Validation Tests

- Tests failed or classified as non-critical
- Unclear actions for sucessful passing repetitive tests
- Lack of scope for Impact parameters on Validation
- No worst case approach
- Mixture of Verification and Validation activities
- Lack of real world validation e.g. clinical environment

Summary

- Beside of sloppyness and unsufficient, internal Reviews before uploading the TF specifically the evolutionary Approach for any Topic of the MDR shows room for improvement.
- Also DQS-Med took that approach during the designation application and faced substantial mitigation loops and delays
- The regulation is a new regulatory Framework striving for the mitigation of all potential discrepancies before introducing the product to the market in order to make PMS somehow managable.
- This demands in virtually all topics on product level a substantially higher level of meat to the bone, compared to MDD
- MDM‘s unaware about this fact, might just suffer under a single Major Non-conformities, but occasionally with up to 50 subjects.

How to avoid x-tra Loops

How to avoid x-tra Loops

- **Do not rush – a one week TF peer review beside of the PRRC is a good investment**
- **Consider a trial TF-Review before applying for all**
- **Learn in Webinars about specific NB expectations (some also in English)**