Agenda

- DQS-Med in a brief
- The Presentator
- Strategic Approach for Techfile Applications
- What the MDR not explicitly 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 explicitly states but MDM‘s need to know!

Apparently:

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 (Compatibility, Biocomp., CMR-Substances)
- Computer Systems
What the MDR not explicitly states....

.... but MDM‘s need to know!

Apparentely:

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

Premarket has lower priority (1 citation)

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- Processes (Production, Sterilisation, Transport)
- Material Properties (Biocomp., CMR-Substances)
- Computer Systems
What the MDR not explicitly 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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- 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 reflecting the MDR provisions for TF Reviews will illustrate the challenges
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*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

<table>
<thead>
<tr>
<th>Risk Class</th>
<th>Cert. S1</th>
<th>S2</th>
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#### SME:
80 FTE, 8 Cl. III TF’s

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<th>Risk Class</th>
<th>MDA/ MDN Categories with 1 TF</th>
<th>MDA/ MDN Categories with 2 TF’s</th>
<th>MDA/ MDN Categories with 3 TF’s</th>
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#### Biggie:
5K FTE’s, 36 IIa/b TF’s

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<th>Risk Class</th>
<th>MDA/ MDN Categories with 1 TF</th>
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### 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

<table>
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<tr>
<th>Structure</th>
<th>TF Share</th>
<th>Initial cost (Year 1)</th>
<th>Delta Cycle 2/1</th>
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<td>13%</td>
<td>50%</td>
<td>90%</td>
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<tr>
<td>SME</td>
<td>70%</td>
<td>82%</td>
<td>95%</td>
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<tr>
<td>Biggie</td>
<td>63%</td>
<td>30%</td>
<td>90%</td>
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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
- Biocompatibility
- 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
- Validation Test Report: no Risk-ID for specific Test
- Usability 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 successful 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)