Technical Documentation Under MDR 2017/745

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Our Speakers

Daniëlle has more than 15 years of experience in the medical device industry and has been hands-on in international registrations, post-market surveillance, clinical evaluations, and risk management.

With her background in Biopharmaceutical Sciences and experience gained when working for the Medicines Evaluation Board of the Netherlands for 5 years before transferring to the medical device industry, she enjoys working in the medical device field to ensure regulatory compliance while supporting market access.

Daniëlle Sleegers
Director of Regulatory Affairs & PRRC
MedEnvoy Global

Our Speakers

Salman has been in the medical devices industry for over 20 years and has worked in R&D, Manufacturing, QA/RA within the medical devices industry and subsequently worked over a decade as Lead Auditor / Technical Reviewer for reputable European Notified Bodies including LRQA, SGS and NSAI, etc. Salman's notable credentials include:

- Member of ISO 13485:2016 standard development technical committee TC 210
- Recognized Lead / Principal Auditor by International Register of Certified Auditors
- Certified Regulatory Affairs Professional [RAC] # 09144585
- MDSAP Certified Lead Auditor
- QMS Lead Auditor and Technical Documentation Reviewer [MDR 2017/745]

Salman Raza – MEng, MBA, MS

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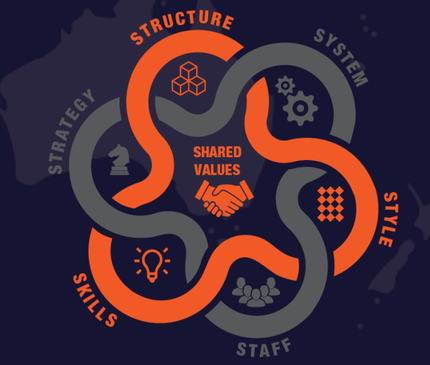

Agenda

1. Auditing Technical Documentation Under MDR 2017/745
2. Fundamentals – Discussing Tricky Audit Topics to Avoid Common NCs Identified During the Audits
3. Conclusion

Technical Documentation (TD)

Under the MDR

Poll #1

Description of Assessment, Documentation, and Product

- Description of Assessment / Scope
- Documentation Submitted Technical Documentation details **(Annex II/Annex III)**
- Description of Product on Certificate
- Content of Declaration of Conformity **(Annex IV)**
- Generic Product Details
- Significant Change to Existing Device
- Previous and Similar Generations **(Annex II.1.2)**
- Market History
- Principle of operation and its mode of action and core performance claims **(Annex II.1.1.d/Article 7)**
- Key Functional Elements **(Annex II.1.1.J)**
- Device used in combination **(Annex II.1.1.h)**

UDI, Medical device Justification, Classification, GSPR, Standards

- UDI **(Annex VI Part C)**
- UDI DI/ UDI PI **(Annex VI Part C)**
- Medical Device definition **(Article 2)**
- Intended Use and Intended Users **(Annex II.1)**

- Classification **(Annex VIII)**
- GSPR **(Annex I)**
- Absence of Human Origin Tissues
- Machinery Directive 2006/42/EC **(Article 1)**
- Standard / Common specifications Used

Risk Management, Device V&V and Device Manufacturing

- Risk Management **(GSPR 3 and Annex II.5)**
- Risk Analysis Methodology and Risk Management Plan **(GSPR 3,4,5,)**
- Device design stages **(Annex II.3/GSPR 10/GSPR 14)**
- Specific device design aspects
- Compatibility with substances (fluid/drug delivery), devices used to deliver medicinal substances **(GSPR 10.3)**
- Compatibility **(GSPR 14.1)**
- Software
- Sites involved in manufacture (Annex II.3.c)
- Manufacturing of the device
- Testing of Devices at Surveillance Audits

Packaging/Shelf Life, Labelling and Instructions for Use

- Packaging integrity and Shelf life
- Device cleanliness and manufacturing
- Content of Labelling and Instructions for Use **(GSPR 23.1)**
- Information on the label **(GSPR 23.2)**
- Information on the packaging which maintains the sterile condition of a device
- Information on the IFU **(GSPR 23.4)**
- Machinery Directive 2006/42/EC **(Article 1)**
- Implantable devices – Implant Card **(Article 18)**

Materials and Biological Risk, Nanomaterials and Substances absorbed by/dispersed in human body

- Device construction – raw materials **(Annex II.1.1.k)**
- Substances **(Annex I / GSPR 10.4)**
- Use of alternative substances **(GSPR 10.4.2)**
- Biocompatibility **(GSPR 10)**
- Nanomaterials **(Rule 19 Annex VII MDR (EU) 2017/745)**
- Substances absorbed by or dispersed in human body **(Rule 21 Annex VIII MDR (EU) 2017/745)**

TD Assessment

The Fundamentals

Poll #2

Medical Device Definition – Article 2

- Confirm how device under review is a medical device per MDR Article 2 definition
- ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
  - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
  - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
  - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

Medical Device Definition – Article 2 (Cont.)

- And which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
- The following products shall also be deemed to be medical devices:
  - devices for the control or support of conception;
  - products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in this section

Manufacturers must qualify their product as a medical device!

Poll #3

Device Classification – Annex VIII

- Product Classification and Rule:
  - Review the 22 Classification Rules listed in MDR Annex VIII and provide a justification for the selected classification and rule of your device(s)
- Classification will fall under Class I, Class IIa, Class IIb or Class III
- One of the 22 Rules will be selected to justify the Class selected
- **Example**: A medical device that is software which provides information which is used to take decision with diagnosis and does not have an impact that could cause death or an irreversible deterioration of a persons' state of health or a serious deterioration of a persons' state of health or a surgical intervention would be considered **Class IIa per Rule 11.**

Do not leave it to reviewers' imagination or discretion. Present your case with conviction!

Poll #4

Risk Management

- Risk Management Files
  - Risk Management Plan
  - Risk Analysis
  - Overall Residual Risk Evaluation
  - Risk Management Review Report
  - Post-Production Activities
  - For recertification, risk analysis must be updated annually
  - For significant changes, the risk analysis must be reviewed for updates

Must demonstrate that Benefits outweigh risks and risk mitigations have not compromised the benefits.

Content of Labelling & IFU

- **Label Location:** on the device itself
- **Labels Formatting:** provided in human readable format/RFID/bar codes
- Correct use of symbol
- Language requirements per Annex II.2
- **EIFU:** IFU can be provided electronically per EU 2021/2226
- **Information on the Label:**
  - name/trade name of device
  - Device Identification
  - Manufacturer
  - Authorized Representative
- If the device contains:
  - Medicinal/Animal/Human Tissue
  - CMR or Endocrine disrupting substances
- Lot Number / Serial Number
- UDI Carrier
- Shelf life
- Date of Manufacture
- Storage and/or handling condition
- Sterilization state/Method
- Warning
- Single Use devices / Reprocessed single use device
- Custom Made devices / Clinical Investigation
- Devices absorbed or locally dispersed

Content of IFU & Labelling (Cont.)

Information on the IFU:

- Name/trade name of device
- If the device contains:
  - Medicinal/Animal/Human Tissue
  - CMR or Endocrine disrupting substances
- Storage and/or handling condition
- Sterilization state/Method
- Single Use devices/Reusable devices/Compatibility with other devices
- Devices absorbed or locally dispersed
- Intended Purpose, Indications, Contra-indications, Patient Target Group and Intended Users
- Clinical benefits and Link to SSCP
- Performance Characteristics
- Information on associated software and accessories
- Contra-indications, Undesirable side-effects and Residual risks
- Usability Information
- Preparatory treatment or Handling
- Training and user qualification
- Installations
- Devices Supplied Sterile/sterilized before use
- Device emits radiation for medical purposes
- Precautions and limitations of use in case of malfunction or reasonably foreseeable influences
- Implantable devices
- Disposal
- Used by Lay Person
- Products without intended medical purpose
- IFU Version and date of issue
- Incident reporting requirements
- Implant Card
- Hardware requirements (for Software Devices)

Continuous Updating Data

- Bio compatibility
- Electrical Safety/EMC
- Any other standard/state of the art

Poll #5

Takeaways - Conclusion

- There must be clear and visible comments/rationale for all the regulatory requirements; even if they're not applicable, it must be identified as N/A with a rationale.

- Do not assume that it's common knowledge.

- **Remember!**
- It's not the assessment of what you, the reviewer, or the industry know.

It's the assessment of what the file is telling the reviewer!

Poll #6

Thank You For Listening!

Questions?

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