10 Things You Must Know About Updating Your Technical Files to Comply with EU MDR

Thursday, July 26, 2018 1:30 - 2:30pm EST
# TODAY’S MEETING

## AGENDA

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## PRESENTER

Sameer Jaiswal is a PRP Consultant - EU MDR Subject Matter Expert. He has over two decades of experience working in the global medical device industry with companies such as Abbott Laboratories, Boston Scientific and Fujifilm Medical Systems. During his career, Sameer has been responsible for the clearance of numerous class II and class III devices in over 70 countries including major markets such as the US, EU, China and India. Currently, Sameer is consulting with a number of medical device companies seeking to comply with the demands of EU MDR.
1. NEW LIFE-CYCLE APPROACH

ROUTINE UPDATING OF TECHNICAL DOCUMENTATION THROUGHOUT
2. SIGNIFICANTLY MORE PRESCRIPTIVE OF REQUIRED CONTENT

- Remain Alert to Publication of New Common Specifications
- New Sections on PMS
- More Detailed QMS Requirements
### Essential Requirements Checklist Revamped

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<th>Essential Requirements</th>
<th>Applicable to the Device?</th>
<th>Method Used to Demonstrate Conformity</th>
<th>Method Reference</th>
<th>Reference to Supporting Controlled Documents</th>
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<td><strong>I. General Requirements</strong></td>
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| 1 Devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose, taking into account the generally acknowledged state of the art. They shall not compromise the clinical condition or the safety and health of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include:  
- reducing as far as possible the risk of use error due to ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and  
- consideration of the technical knowledge, experience, education and training, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users). |
| 2 The solutions adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. The manufacturer shall apply the following principles in the priority order listed:  
  (a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;  
  (b) eliminate risks as far as possible through inherently safe design and manufacture;  
  (c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and  
  (d) provide training to users and/or inform users of any residual risks. |
| 3 The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer’s instructions. When no lifetime is stated, the |
4. REVISED DECLARATION OF CONFORMITY

- Additional Safety and Performance Requirements
- Additional Requirements for Tech Documentation, QA, Clinical Eval, and PMS
- Consult with Health Authorities and Expert Panels
- More Demanding and Considerably Longer
5. TECHNICAL DOCUMENTATION MUST BE SEARCHABLE

This should include:

- Device description and specification
- Information supplied by the manufacturer
- Design and manufacturing information
- Safety and Performance Requirements
- Risk/benefit analysis and risk management
- Product verification and validation (including preclinical and clinical data).
- Additional requirements on the technical documentation regarding Post market surveillance is provided in the Annex III
6. THE BAR HAS BEEN RAISED FOR CERs

- CERs need to be reassessed
- Updates to CERs may also trigger updates to Instructions for Use; make sure they are in alignment
- Clinical investigations must be conducted within the constructs of the new legislation (EU MDR Annex XV)
- Must also align with the clinical evaluation plan
- Post-market clinical follow-up (PMCF) will no longer be a “check-the-box” activity
- Summary of safety and clinical performance must be updated “at least” annually
Examples Where Equivalence Argument Has Been Rejected:

- Devices are judged to be alternate treatments
- Composed of different materials in contact with tissues resulting in different biological response (e.g. biologic vs. synthetic)
- Dissimilar material form (e.g. sheets vs. granules vs. foam)
- Dissimilar principles of operation (e.g. stop bleeding by pressure vs. natural hemostasis vs. included medicinal agent)
- Vastly different absorption profiles (e.g. non-absorbable devices claimed to be equivalent to absorbable ones)
- Different clinical uses (e.g. hemostasis vs. aid to wound healing)
- Only clinical data available for equivalent device is for off-label use
8. RISK MANAGEMENT & CLINICAL EVAL CLOSELY INTERTWINED

- Risk management no longer separate and apart from the clinical evaluation process
- Documentation must clearly show a close alignment between risk management concepts and clinical evaluations
9. EXPECTED LEVEL OF EXAMINATION RAISED

- Expectation for notified bodies to provide a clinical evaluation assessment report (CEAR)
- Some devices, analysis of notified body’s CEAR by “expert panels”
- Competent Authorities notified of device that receives a certificate post-conformity assessment involving an expert panel
10. NEW DATA SUBMISSION REQUIREMENTS

- The technical documentation on the products will need to be updated (e.g. technical file – Annex II, Declaration of Conformity – Annex IV, point 3, etc.)
- Must submit to a central UDI database
- Must be stored and traceable
- UDI information must be placed on label and/or package
- Must clearly disclose any residual risks
KEY QUESTIONS TO CONSIDER

● Does your document management process enable the technical documentation to be organized and readily searchable, and be kept up to date throughout the device life cycle?
● What new documents do you need to include in your technical documentation?
● Do you have processes to monitor the adoption of new standards or common specifications, or changes to existing standards or commons specifications?
● How do you assess the effect of such new or revised common specifications on your technical documentation?
Determine exactly which materials need to be compiled.

Review all existing documentation in support of meeting the applicable Essential Requirements of the Directive(s). Evaluate and identify gaps or deficiencies in your documentation.

Compile your EU Technical File or Design Dossier, with internal peer review.

Determine applicable testing requirements and standards for your device.

Review your clinical data, compile a Clinical Evaluation Report (CER), and facilitate a Risk Assessment as necessary.

Review your proposed labeling and Instructions for Use.
EU MDR TRANSITION TIMELINE

2016
EU MDR Formal publication

2017

3 year transition period
Pre-implementation: Formal procedure for translation of consolidated regulatory text to all EU member languages

2018
EU MDR implementation

2019

5 year transition period
Pre-implementation: Formal procedure for translation of consolidated regulatory text to all EU member languages

2020

2021

2022
EU IVDR implementation

EN ISO 13485:2016 release date

EN ISO 13485:2016 becomes mandatory