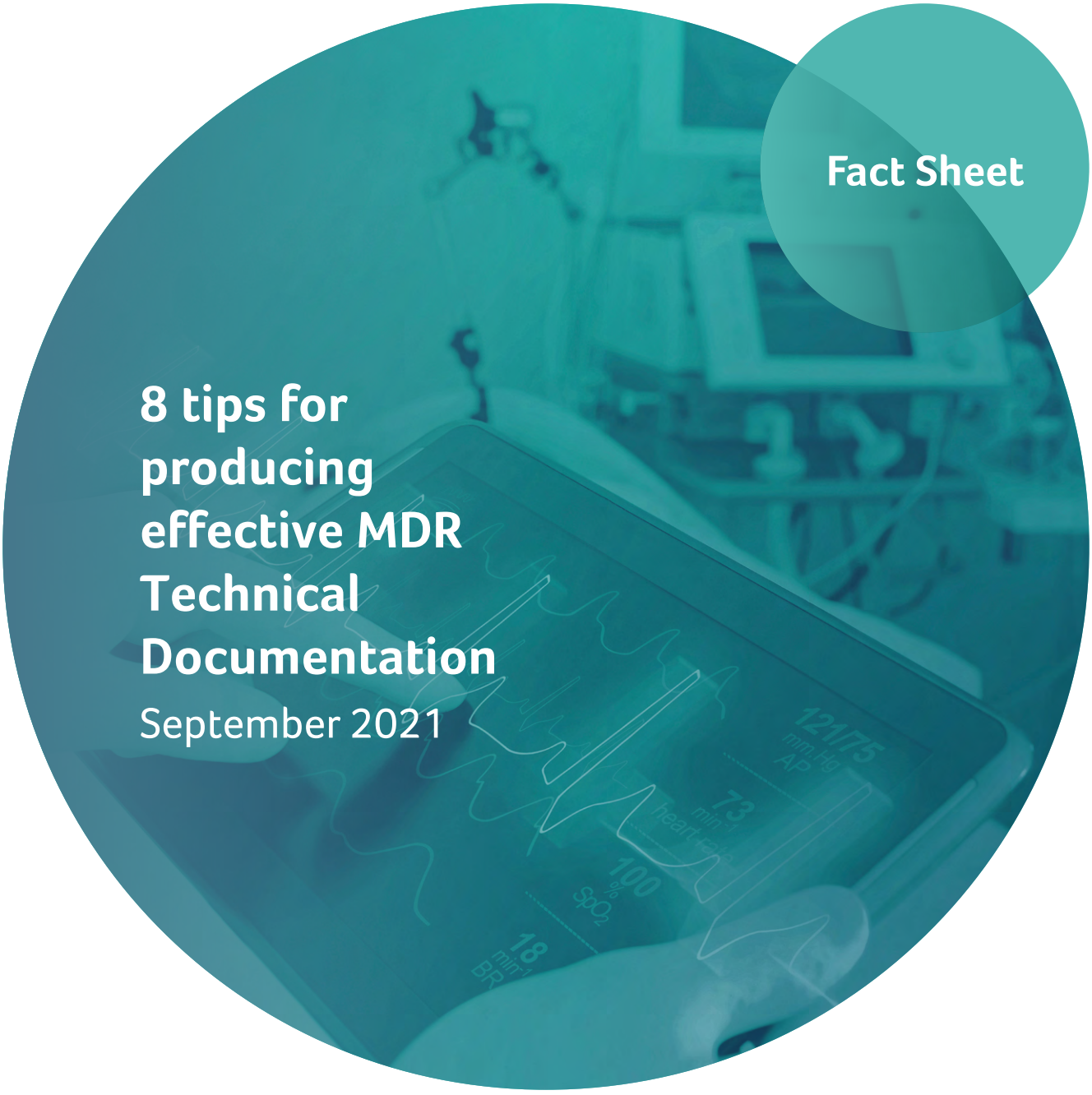
Congenius



Fact Sheet

8 tips for producing effective MDR Technical Documentation

September 2021

Smart consulting,
enhanced medical solutions.

Producing effective MDR Technical Documentation

Technical Documentation: Who benefits from getting it right?

Effective Technical Documentation (TD) provides **manufacturers** with their own central information source regarding their medical device. Secondly, accurate TD can reduce the review time spent by **notified bodies**. And thirdly, concise and comprehensive TD makes the job of **auditors** significantly easier.

Technical Documentation requirements under the Medical Device Regulation (EU) 2017/745 (EU MDR) are more extensive than under the Medical Device Directive (MDD).

This fact sheet provides 8 useful tips on how to produce Technical Documentation under the EU MDR to facilitate an easy journey to device delivery and registration.

But first, this is where you can find the EU MDR Technical Documentation requirements:

For a **description of the content** of your EU MDR TD, see:

- Annex II Technical Documentation
- Annex III Technical Documentation on post-market surveillance

For **requirements concerning manufacturers** regarding TD creation, access and maintenance, see:

- Article 10: sections 4 and 8
- Article 11: section 3
- Article 15: section 3b

For **how a notified body will assess your TD**, see:

- Article 45
- Article 52
- Annex IX

For the **postmarket surveillance elements of your TD**, see:

- Article 83
- Article 84
- Article 86
- Article 88

8 tips on how to produce effective MDR Technical Documentation

1. Determine your TD structure

After considering the content requirements for your TD, you need to determine how to structure your MDR TD template.

Option 1

Insert the additional MDR requirements into the existing MDD TD structure to save time.

Option 2

Follow the EU MDR structure and numbering laid out in Annex II and III of the EU MDR to ensure all MDR requirements are met, including that the TD be presented in a "clear, organised and unambiguous" manner.

2. Use EU MDR terminology

Aligning with the terminology used in EU MDR when you build your TD template and populating it with evidence will help meet the requirement of a "clear and unambiguous" TD. It'll help to clearly show the link between the provided evidence and the requirements in audits or during a Notified Body review.

To use EU MDR terminology effectively you should **clearly determine and define how these terms are used** in relation to your devices. e.g. determining and documenting which products fit the definition of a medical device / which are their accessories, or how to determine key functional elements for your devices or novel features.

3. Group your devices efficiently

You can utilise the below as appropriate to your devices:

Group an entire product family of devices into one TD, to help the reader understand the use of the devices within a system.

Group together devices of a similar type that are all used with other devices across product families e.g. accessories / instruments used with a variety of other devices.

Group devices within one family of products into their own TD based on characteristics like sterility, single use versus re-usable, software versus hardware, etc.

4. Strive for consistency

Clear and effective TD demonstrates consistency. To achieve this:

- ✓ **Refer to your devices** in your TD consistently (e.g. use the device names and device article numbers as they appear on the labels)
- ✓ **Align the classification of your devices** with the way it is presented in each section (e.g. the device description section, the section on design, packaging or biocompatibility)
- ✓ **Ensure that the information in your TD lines up with the evidence** in the GSPR, Clinical Evaluation Report and Instructions for Use
- ✓ **Maintain a consistent approach for your technical files** across your device portfolio regarding terminology, rationales and data presentation.

5. Copy or reference information

Copying information:

✓ Advantage	✗ Disadvantage
Copying information from other documents into your TD will ensure that all information is centrally contained and readily available for review.	Copying can be more time consuming due to unnecessary duplication. It also leaves room for potential errors and warrants more frequent updates.

Referencing information:

Since the EU MDR requires Technical Documentations to be kept up to date, referencing information in other documents (e.g. labels, IFUs, clinical evaluation reports, drawings or design documents) may prove more effective, as long as these documents can be easily made available to Notified Bodies for review.

6. Involve subject matter experts early on

Letting experts from respective teams (other than the Regulatory Affairs team) **populate evidence for each section of the TD** as appropriate may prompt greater ownership and a more efficient use of resources – since each expert knows their field best, they will be able to provide their evidence more easily.

7. Provide easy access for the EAR

Under EU MDR, the **European Authorised Representative** requires access to the TD documents. Therefore, it may be advantageous to utilise an appropriate Product Life Cycle management system to store and manage your TD, which offers easy access to all necessary parties.

8. Future proof your MDR TD

Build for change management: When determining the format and structure of your TD, keep in mind ease of updating when changes occur. This can be done through implementing robust ties between DHF documentation and your TD, for example through a Product Life Cycle Management system that automatically feeds DHF documents into the TD, or by using references to documents as opposed to duplicating information from DHF documents in your TD.

Learn from audits and be flexible: Requirements from Notified Bodies for Technical Documentations may change, so ensure that your process remains flexible enough to account for those changes, and allows you to adapt to learnings from audits and technical file reviews, new guidance or best practices.

Should you require assistance with a regulatory challenge, please don't hesitate to get in touch – we'd be happy to help.

Congenius AG
Riedstrasse 1
CH- 8953 Dietikon

congenius.ch