Device Master Records and Medical Device Files – How Do They Compare?

FDA requires the use of a Device Master Record (DMR) for Medical Devices. The ISO 13485:2016 standard; however, now includes a Medical Device File (MDF) requirement. What are DMRS? What are MDFs? How do they compare?

This White Paper focuses on Medical Device compliance per 21 CFR 820.181 for DMR and ISO 13485:2016 § 4.2.3 for MDF documentation. The intent is to demonstrate how these compare, as well as how a single system can fulfill the requirements of each.

What is a Device Master Record (DMR)?

21 CFR 820.3 (j) provides the following definition:

Device master record (DMR) means a compilation of records containing the procedures and specifications for a finished device.

It is further discussed in 21 CFR 820.3 (g) Design output. *The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.*

21 CFR 820.181 Device master record explains that each manufacturer shall maintain DMRs, including preparation and approval per 21 CFR 820.40. The DMR for each device type shall include or refer to the location of:

(a) *Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;*

(b) *Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;*

(c) *Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;*

(d) *Packaging and labeling specifications, including methods and processes used; and*

(e) *Installation, maintenance, and servicing procedures and methods.*

What is a Medical Device File (MDF)?

MDF is included in ISO 13485:2016 § 4.2.3. This standard requires the organization to establish and maintain one or more MDF for each medical device type or medical device family, containing or referencing documents generated to demonstrate conformity to requirements. The MDF content shall include, but is not limited to:

a) *General description of the medical device, intended use / purpose, and labelling, including any instructions for use;*

b) *Specifications for product;*

c) *Specifications or procedures for manufacturing, packaging, storage, handling and distribution;*

d) *Procedures for measuring and monitoring;*

e) *As appropriate, requirements for installation;*

f) *As appropriate, requirements for servicing.*

How Do DMR and MDF Compare?

DMR and MDF requirements are very similar. Although there are slight differences in how they are outlined from the FDA regulation to the ISO standard, the overall intent is the same. Each system is requiring the Medical Device manufacturer to provide a "recipe" (essentially), per Medical Device Type, or Medical Device Family. This "recipe" includes the details required to build the Medical Device.

Single DMR / MDF System

For Medical Device companies that are both FDA Registered and ISO 13485:2016 certified, it's possible to create a single system that addresses the requirements for both DMR and MDF. Within this single system, the following content, per Medical Device Family / Type is applicable:

1. Title and General Description of the Medical Device, including intended use / purpose;

2. Labeling, including Instructions For Use (IFU);

3. Device specifications, including appropriate drawings, Bill of Materials (BOM), component and software specifications, etc.;

4. Production process specifications, including procedures / methods for manufacturing, packaging, labeling, storage, handling / distribution, equipment specifications and environment specifications;

5. Quality Assurance / Measuring and Monitoring / Inspection procedures, including specifications / acceptance criteria and required equipment; and

6. As appropriate, installation, maintenance and servicing procedures / methods / requirements.

All of these items, in a single file, can be lengthy. Where appropriate, take advantage of the option given by FDA and ISO to reference the location of the relevant documents. For example, the methods / procedures in this "recipe" to build this device, are likely located within the company Document Control program. In this regard, the DMR/MDF can be created with device specific content (Numbers 1-3 above) and can make reference to the procedural content (Numbers 4-6 above) located in Document Control. The references can take the form of references to Document Control, listing specific procedure numbers and titles. One more option, is to create a Process Flow Chart per Medical Device Type / Family, capturing all related Document Control procedure references. Include the Process Flow Chart in the DMR / MDF and maintain as appropriate.

It is also possible for the DMR / MDF to be a single document, referencing the location of each item described in Numbers 1-6 above. It is important to remember; however, that the DMR / MDF must be approved and maintained.

Summary

The FDA requires Medical Device Manufacturers to prepare, approve and maintain DMRs per Medical Device Type. Similarly, ISO 13485:2016 requires Medical Device Manufacturers to establish and maintain a MDF per Medical Device Type or Medical Device Family. Each of these is very similar in requiring the manufacturer to provide a "recipe" per Medical Device Type / Family, including the details required to build the medical device. Where applicable, it's possible to create a single system that addresses the requirements for both DMR and MDF.

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