DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

(*http://Elsmar.com/Forums/showthread.php?t=41690*)

QE 11th June 2010 11:44 AM

DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Dear all coves

Can some one explain by definition what is a difference between a DMR, DHF and DHR. Here is how FDA defines them

DHF :
§ 820.30(j) Design history file.
Each manufacturer shall establish and maintain a DHF for each type of device.
The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.
II. DEFINITIONS
§ 820.3(e) Design history file (DHF) means a compilation of records which describes the design history of a finished device.

DMR :
DEVICE MASTER RECORD
Title 21 CFR 820.3(j) states a "Device master record means a compilation of records containing the procedures and specifications for a finished device." A Device Master Record (DMR) is a comprehensive record of all of the procedures and instructions required to manufacture each type of glove. A DMR contains or refers to the location of documents for manufacturing and processing activities, such as procurement, processing, labeling, test and inspection, and packaging. The DMR also contains information on the design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, acceptance criteria, packaging, and labeling of a finished glove.

DHR :
Sec. 820.184 Device history record.
Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information:
(a) The dates of manufacture;
(b) The quantity manufactured;

(c) The quantity released for distribution;
(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;
(e) The primary identification label and labeling used for each production unit; and
(f) Any device identification(s) and control number(s) used.

MIREGMGR 11th June 2010 12:04 PM

Re: Dmr vs dhf vs dhr

DMR = all the documentation for design and manufacturing of your current product. Assumes all processes and decisions are fully documented.

DHF = past versions of all the records in your DMR. Assumes a fully change-controlled, systemic approach to documentation.

DHR = all your production batch records. Assumes that nothing happens in Manufacturing without appropriate work orders, and that all actions and decisions are documented.

arios 11th June 2010 12:09 PM

Re: Dmr vs dhf vs dhr

I would had used the same definitions you posted to answer the question.

In few words:

DHF: are the records that describe the design process and its changes for a device over the time

DMR: could be considered the output of the DHF, is the set of specificatios developed for design and manufacturing

DHR: is the evidence that a lot, unit or batch was manufactured in accordance with the DMR. You just listed the specifics of what the DHR is meant to include.

Over the time, the performance of a device could result in improvements to the desigm, so, it can be said that the DHR could eventually become an input that will be reflected on the DHF

Hrbtfbn 14th September 2010 07:12 PM

Re: Dmr vs dhf vs dhr

So if your device remains original with no changes, then your Device Master Record would be considered your current Device History File.

Laura Halper 24th September 2010 12:30 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Oops, not exactly:
"So if your device remains original with no changes, then your Device Master Record would be

considered your current Device History File."

In FDA nomenclature, there is no "Device History File". There is a Design History File, and there is a Device History Record, but there is no Device History File. The nomenclature is confusing.

Here's my simple definition for DHF, DMR, and DHR.

The Design History File explains how you developed the recipe for making your device.

The Device Master Record is the recipe itself (specifications, work instructions, inspection procedures, etc.) for making the device.

The Device History Record is the evidence that a particular unit, batch or lot of devices was made according to the recipe.

QA compliance

10th November 2010 10:32 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

:applause: Excellent answer! That is what I would have said.
I just want to add the in your DHR, also include setup sheets per operation that were used for THAT PARTICULAR job.

geno27

11th November 2010 05:19 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

The DMR contains the documentation necessary to produce a device. The final design output from the design phase, which is maintained or
referenced in the DHF, will form the basis or starting point for the DMR. Thus, those outputs must be referred to or placed in the DMR.

The total finished design output includes the final device, its labeling and packaging, and the DMR that includes device specifications and drawings, as well as all instructions and procedures for production, installation, maintenance, and servicing.

The DHF, in contrast, contains or references all the records necessary to establish compliance with the design plan and the regulation, including the design control procedures. The DHF illustrates the history of the design, and is necessary so that manufacturers can exercise control over and be accountable for the design process, thereby maximizing the probability that the finished design conforms to the design specifications.

andymo13

3rd February 2011 10:12 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Hi everyone,

I´m still confused about where to keep which document: do I put the Validation documentation into the DHF or DMR? Because these documents show (among other things) that the product complies with the regulations.

Or am I totally wrong? :confused:

Thank you in advance for your answers

MIREGMGR 3rd February 2011 10:34 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Quote:

*In Reply to Parent Post by **andymo13*** (Post 417012)
do I put the Validation documentation into the DHF or DMR?

At the company where I work, we don't worry about whether a particular file or storage location is called DHF or DMR. Our focus instead is on assuring that we retain everything that should be part of the DHF and DMR, and that we have a complete definition of where every retained record/document is located.

Our validation records, because they were very expensive to produce and have a uniquely broad importance to the legal marketability of our product range, live on a set of shelves in the Engineering Manager's office.

My take is that it's permissible to keep DMR and DHF records in intermixed form in a single file/storage location, as long as a potential user or auditor of those records is readily able to discern which are latest-dated or highest-version-numbered and therefore by definition "DMR", and which are prior and therefore by definition "DHF". We have records other than those pertaining to validation that are retained on that basis.

Laura Halper 3rd February 2011 10:51 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Validation documents should be part of the Design History File. The FDA defines two kinds of validation -- design validation and process validation. 21CFR 820.30(g) discusses design validation as part of the design control process (and therefore, part of the Design History File).

Although the FDA discusses process validation in 820.75, and not as part of the design control process, it should be one of the steps before you release the product to market. I would consider it to be part of the Design Transfer activities, and so part of the Design History File.

There is a linkage between the Design History File and the Device Master Record. Sometimes the design validation and/or process validation reveal issues that must be addressed before the product is introduced to the market. For example, if the design is modified as a result of the design validation to make it more user-friendly, then the new drawings etc. would be part of the Device Master Record. Or for example, if you find during process validation that the assembly steps must be modified in order to insure that acceptable products are consistently made, then the new assembly procedure would be part of the Device Master Record.

In a nutshell: The Device Master Record is the "recipe" for making the device. The Design History File explains how you developed the recipe.

The Device History Record demonstrates that a particular unit/batch/lot was made according to the recipe.

Laura Halper 3rd February 2011 10:57 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

I just saw MIREGMGR's response (we must have been composing at the same time). So let me clarify that even with my approach, you may keep the physical documentation separate from the DHF or the DMR. The FDA allows both the DHF and the DMR to reference the records -- the DHF and the DMR do not have to house the actual record themselves.

sagai 7th February 2011 08:38 AM

Re: Dmr vs dhf vs dhr

This subject will never die out :) :) :)

gexaka 10th February 2011 03:44 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Hi

You are validating the design for all products. Validation data are in the DHF. For each device, you use procedurs in the DMR to verify that the system meets specs. The results go in the DHR. Does that help?

George

gexaka 28th February 2011 11:56 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Hi

Not sure I understand your question completely. Are you asking about including production bacth records in the DHR, or are you asking that production batch records go in the DMR?

George

Tedster 16th March 2011 10:37 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Quote:

In Reply to Parent Post by ***MIREGMGR*** (Post 417020)
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is called DHF or DMR. Our focus instead is on assuring that we retain everything that should be part of the DHF and DMR, and that we have a complete definition of where every retained record/document is located.

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If I understood the question, you should "put" or at least reference the Validation records into the Design History File as Validation (as well as verification) must be an element of your design process for both FDA and ISO 9001 compliance. In our case verification is done in house (check design input vs design output) and validation is completed by our customers (does the prototype meet their needs).

Our Device Master Record consists of the bill of materials, router and relevant process and inspection work instructions.

Batch records become part of our Device History Records.

charchar

24th February 2012 03:46 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Your validation documents should be implemented into your DHF.

markhbarbieri

19th April 2012 04:19 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Hi,

I recently purchased a great book that I'd like to recommend which will probably answers most of the questions regarding DHF, DMR, and DHR. The book is called, "Mastering and Managing the FDA Maze." It's about $30 bucks on Amazon, and well worth it.

With regards to your validation documentation question, the validation plan documentation would be placed into your DMR (specifications) and the verification and validation testing results/summary, would be a part of your DHF. However, I have seen some approaches where individuals reference the validation plan in the DHF as well as the DMR. It is unlikely that an inspector would issue a 483 for having a validation plan in the DMR and the DHF.

sagai

19th April 2012 05:07 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

It is interesting, there are only about 15 posts and almost 8ooo viewings, this subject does interest the industry I guess :)

Ronen E 19th April 2012 07:22 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Quote:

> *In Reply to Parent Post by* ***markhbarbieri*** (Post 478622)
> *Hi,*
>
> *I recently purchased a great book that I'd like to recommend which will probably answers most of the questions regarding DHF, DMR, and DHR. The book is called, "Mastering and Managing the FDA Maze." It's about $30 bucks on Amazon, and well worth it.*
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> *With regards to your validation documentation question, the validation plan documentation would be placed into your DMR (specifications) and the verification and validation testing results/summary, would be a part of your DHF. However, I have seen some approaches where individuals reference the validation plan in the DHF as well as the DMR. It is unlikely that an inspector would issue a 483 for having a validation plan in the DMR and the DHF.*

I fail to understand the relevance of a validation plan to the DMR. The DMR is supposed to be the "recipe" for making the device, so how do validation plans contribute to it? In my understanding both the validation plans and validation summary reports should be included (or referenced) in the DHF.

If anything, I would say that validation reports are more relevant to the DMR, because these may prescribe established process parameters and settings.

Ronen E 19th April 2012 07:28 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Quote:

> *In Reply to Parent Post by* ***sagai*** (Post 478628)
> *It is interesting, there are only about 15 posts and almost 8ooo viewings, this subject does interest the industry I guess :)*

It's easier to focus on non-important administrative definitions than on actual device-affecting thinking...:lmao:

Heck, the important things about all this documentation is that it (a) exists, (b) has sufficient good content, (c) is properly controlled and (d) is able to be found in a timely manner, when required; not so much how the files are called and which references which documents. Disclaimer: The FDA may view it differently :)

CreMindES 11th June 2012 06:04 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

I want to add that IMHO the only way to make it cause as little pain as possible, is to make sure it also helps your development and documentation, ensuring that it only adds minimal extra effort to maintain it.

ssz102 11th June 2012 07:14 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

this thread are useful for me, i learn it
thanks for you sharing

rdesmond 6th September 2012 10:34 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Hello. We are a contract manufacturer. When we perform Process Validation, should we place the protocol & report in our DMR or DHR? Of course, our customer receives a copy for their DHF, however I wasn't sure for ours. I assume?? the same answer will also hold for Equipment Qualification protocols & reports, yes? Thanks a bunch!!:bigwave:

MIREGMGR 6th September 2012 10:44 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Quote:

> *In Reply to Parent Post by* ***rdesmond*** (Post 494139)
> *Hello. We are a contract manufacturer. When we perform Process Validation, should we place the protocol & report in our DMR or DHR?*

In your part of the device DMR.

As a contract manufacturer, you have primary responsibility for those aspects of your processes that are proprietary to you and therefore not fully controllable by your customer(s). Records related to your responsibilities go into your DMR for the product. Your customer also has a DMR for the product, containing records for those matters that they control and that they source on the outside and can effectively control, such as design and (in some cases) materials qualification.

The DHF is maintained by the party responsible for the device design, and contains information on that design from the beginning and including all iterations, modifications and developments, but usually doesn't include the current product design which is documented instead in the DMR.

The DHR is maintained by the party responsible for manufacturing, or in a contract manufacturing relationship, sometimes jointly and sometimes in duplicate fashion by the customer and the contract manufacturer respectively.

Ronen E 6th September 2012 06:46 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Quote:

> *In Reply to Parent Post by* ***rdesmond*** (Post 494139)
> *Hello. We are a contract manufacturer. When we perform Process Validation, should we place the protocol & report in our DMR or DHR? Of course, our customer receives a copy for their DHF, however I wasn't sure for ours. I assume?? the same answer will also hold for Equipment Qualification protocols & reports, yes? Thanks a bunch!!:bigwave:*

Definitely not in the DHR.

IMO also not in the DMR.

I think you could simply create a file designated "Process Validation & Equipment Qualification", and keep it there, as simple as that. Just make sure all your SOPs are aligned with that arrangement, and that any one with proper clearance (FDA, your staff etc.) is able to gain access to these documents quickly and effortlessly, for as long as required. See also my previous post in this thread.

Contrary to common belief, regulation doesn't have to go against common sense.

Cheers,
Ronen.

Huyen 17th October 2012 12:48 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Quote:

> *In Reply to Parent Post by* ***Ronen E*** (Post 494209)
> *Definitely not in the DHR.*
>
> *IMO also not in the DMR.*
>
> *I think you could simply create a file designated "Process Validation & Equipment Qualification", and keep it there, as simple as that. Just make sure all your SOPs are aligned with that arrangement, and that any one with proper clearance (FDA, your staff etc.) is able to gain access to these documents quickly and effortlessly, for as long as required. See also my previous post in this thread.*
>
> *Contrary to common belief, regulation doesn't have to go against common sense.*
>
> *Cheers,*
> *Ronen.*

Dear All,

We just produce the sample of medical device for Customer from US (we are from Vietnam). Our company plan to certify FDA in next year. However, when Customer audit us, they ask to have DHR procedure inplace, we are almost unclear about it, Can anyone help to share the format or template of it
Must appreciated ..

lfrost 19th October 2012 03:57 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

"Dear All,

We just produce the sample of medical device for Customer from US (we are from Vietnam). Our company plan to certify FDA in next year. However, when Customer audit us, they ask to have DHR procedure inplace, we are almost unclear about it, Can anyone help to share the format or template of it
Must appreciated .. "

The DHR, and all of it's components, tells how the device was made to the specifications of the DMR. The DMR, and all of it's components, tells how the device was manufactured to the specificatons of the DHF. The DHF tells of the steps taken to design the device.

You should be aware that your device needs to be listed and registered with the FDA before you market your device in the USA. You do not need to "certify" your device with the FDA unless it is class III or a required class II device which need a 510(k) PMA approval.

Hope this helps...:2cents:

CoveSwimmer 21st October 2012 06:13 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

1 Attachment(s)
The attachment should clarify the required documents.

nilesht 23rd October 2012 07:25 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

:rolleyes:This is really good resource on info about DMR

Lulumathew 26th November 2012 07:26 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Could any one help me understand what is Lot History Record? Is that same as Device History Record?

sagai 26th November 2012 07:32 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Where is that terminology coming from?
Cheers

MIREGMGR 26th November 2012 08:45 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Quote:

*In Reply to Parent Post by **Lulumathew*** (Post 502365)
Could any one help me understand what is Lot History Record? Is that same as Device History Record?

I'd think yes, for a product that is produced in batches or lots.

Laura Halper 26th November 2012 10:35 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

The FDA uses and defines the term "Device History Record". I would guess that "Lot History Record" is just an in-house term for the same record. If the Lot History Record includes manufacturing and inspection records that show that the requirements of the Device Master Record (e.g., specifications, drawings, formulations, acceptance criteria) were met for a particular lot, then it is functioning as the Device History Record.

Lulumathew 26th November 2012 11:40 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

I was searching for the list of artifacts required for FDA/CE filing and I came across this terminology Lot History Records for Production equivalents.

Ronen E 27th November 2012 05:37 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Quote:

*In Reply to Parent Post by **Lulumathew*** (Post 502457)
I was searching for the list of artifacts required for FDA/CE filing and I came across this terminology Lot History Records for Production equivalents.

Sounds strange. :confused:

If by "filing" you refer to premarket clearance, then AFAIK both FDA and the EC system don't require specific lots records (i.e. in a 510k submission or a technical File).

If you referred to something else, plaese clarify.

Cheers,
Ronen.

potato124 28th November 2012 04:56 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

I think it depends on the organization. Here is how I would recommend thinking about it:

DHF: proof that the design and manufacturing are safe (basically 510k + process validations)

DMR: recipe on how to make the device (work instructions, routers, BOMs, etc)

DHR: proof that you made the product correctly for a specific lot

MFerguson 25th March 2013 11:59 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

First of all - apology for being a newbie to this forum.

From an activity perspective - we have collaboration tasks, we have interim drafts, we have interim review minutes, we have release documents (including the change request form + release approvals).

Questions - for the formal 'DHF'
1 - are all items - including the interim drafts and collaboration tasks included in the DHF?
or
2 - formal DHF is limited only to the release files and the signed release approval request?
and
3 - do we continue to show prior release history, or, DHF should be latest current release only?

And depending on answers - what hard-copy records need to be preserved? (we are a small start-up and could not afford the elegant on-line doc records like a GrandAvenue).

Thx & help
[and apology if posing question in the wrong thread...]

sagai 25th March 2013 12:08 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

My opinion would be:
1., not necessarily
2., could be

3., release history should be part of the DHF, the latest released design to production is more like a DMR for me.

I think, one extremity could be is that you keep only a one page document listing all the document references those relate to the design of the final release of your device design and a single signature manifest that all documents approved and the design was authorized to be released.

But, that's purely an opinion, you should work out your own way.

Cheers

Aphel

3rd April 2013 09:14 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Hello!

How do you handle service reports (records according §820.200) in regard to DHR?

The regulation does not require, that service reports are part of the DHR - am I right?

Best regards,
Aphel

MIREGMGR

3rd April 2013 09:32 AM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

I assume you're going to save the records in any case, since 21CFR 820 establishes a requirement that the records exist and thus a basis for their inspection, and doesn't state a retention/disposal requirement which leaves you with the default life-of-the-product one. Given that, does it matter what legacy FDA term you apply to the record type? All FDA-required records are allowed to be kept on a distributed basis, as long as they're acceptably controlled and retained. Whether an inspector or auditor thinks your service records are part of the DHR, or maybe the DHF, or freestanding, you're good; they're in this file cabinet here.

Johan Bonefaas

23rd April 2013 04:07 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Our current DMR is a 7 chaptered list of all articles and items. But it's hard to keep it up to date or even complete. An option is to use create a DMR that serves as an index and looks like a christmas tree, so to speak. Using levels starting at the productspec or highest drawing number.
It would be nice to draw all relationships there are between documents or use Agile to do so. Does anyone have any experience in using the DMR as a BOM structure in Agile?

Thanks,
Johan

sagai

23rd April 2013 04:27 PM

Re: DMR-Device Master Record vs DHF-Design History File vs DHR-Device History Record

Johan,
I am not really getting your problem.
The DMR is for the finished design, whereas agile kinf of development is a method to carry on the design.
Cheers!

The time now is 04:05 AM. All times are GMT -4.
Your time zone can be changed in your UserCP --> Options.

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Discovering Change | Process Capability - Cp vs. Cpk | Histogram Animation | Process Loop Animation | Taguchi Loss Function
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