医疗器械设计开发合规性所涉及的 DHF/DMR/DHR

DHF – Design History File

The DHF is the design history file.

DHF 是设计历史文档。

As you go through the design anddevelopment process foryour medical device, the documentation that you createis going to be containedhere.

它包含在完成医疗器械的设计和开发过程时所创建的文档。

According to the FDA, thedesignhistory file shall contain or reference the records necessary todemonstratethat the design was developed in accordance with the approved designplan andthe requirements of this part (21CFRPart 820.30). Each

manufacturer shall establish and maintain aDHFfor each type of device.
根据 FDA 的规定，设计历史文件应包含或引用必要的记录，以证明设计是根据批准的设计方案和 21 CFR Part 820.30 的要求制定的。每个制造商应为每种类型的器械建立和保存 DHF 文档。

The actual idea of the DHF is fairlystraightforward. Inpractice, that can be a bit of a challenge if you don’t compileit as you go.
DHF 的实际意图相当简单。如果你在实践中不去编写它，这可能是一个挑战。

You need to include or provide a referenceto all of therecords related to the activities you did during the design anddevelopmentprocess.
你需要包括或提供你在设计和开发过程中所做的活动有关的所有记录。

That means you need all of the user needsand designinputs you came up with at the start of the project.
这意味着你需要在项目开始时提出的所有用户需求和设计输入。

All of the design outputs that yougenerated to build thedevice.
为制成器械而生成的所有设计输出。

All of the designverificationand validation protocols and reports.
所有的设计验证和确认的方案和报告。

Plus, all of design reviews that went alongwith all ofthat…and don’t forget everything for transferring the device tomanufacturingtoo.
此外，与此相关的所有的设计评审…不要忘记把器械转移到生产的过程。

Once you’ve gotten all of those documentscompiled intoyour DHF, the next acronym that needs to be tackled is the DMR.
一旦将所有这些文档编写到 DHF 中，需要解决的下一个首字母缩略词就是 DMR。

DMR – Device Master Record

The DMR is the device master record.
DMR 是器械主记录。

Everything you need to know to build andtest the deviceis contained here.
它包含了制造和测试器械所需的一切。

According to the FDA, the DMR foreachtype of device shall include, or refer to the location of, thefollowinginformation:
根据 FDA 的规定，每种医疗器械的 DMR 应包括或提及以下信息的位置：

(a) Device specificationsincluding appropriate drawings, composition,formulation, componentspecifications, and software specifications;
器械规格，包括适当的图纸，成分，配方，组件规格和软件规格;

(b) Production processspecifications including the appropriate equipmentspecifications, productionmethods, production procedures, and productionenvironment specifications;
生产工艺规范，包括适当的设备规格，生产方法，生产程序和生产环境标准;

(c) Quality assuranceprocedures and specifications including acceptancecriteria and the qualityassurance equipment to be used;

质量保证程序和规范，包括验收标准和使用的质量保证设备;

(d) Packaging and labelingspecifications, including methods and processesused; and

包装和标签规格，包括采用的方法和工艺;

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

安装，维护和维修程序和方法。

Each manufacturer shall ensure thateachDMR is prepared and approved in accordance with 21CFRPart 820.40.

每个制造商应确保每个 DMR 按照 21 CFR Part 820.40 进行准备和批准。

Some parts of this should sound a lot likewhat you justgot done compiling in the DHF.

这里的部分内容很像刚刚提到的 DHF 的编写。

The device specifications, packaging and labeling specificationswere part of the design outputs you created earlier.
器械规格，包装和标签规格是你之前创建的设计输出的一部分。

The production process specifications werepart of the designtransfer youdid earlier as well.
生产工艺规范是之前做过的设计转换的一部分。

Even the quality assurance procedures andspecificationswere created earlier, because those include defining theacceptance criteriawhich is part of design output.
质量保证程序和规范也是早些时候创建的，因为其中包括作为设计输出一部分定义的接受标准。

The good news is that the FDA only requiresyou toreference the required items, not duplicate them.
好消息是，FDA 只要求你参考所需的项目，而不是重复它们。

If you were really organized in thecreation of your DHF,it’s going to be really easy to reference that locationin your DMR.
如果你准备了要创建的 DHF，那么在你的 DMR 中引用它将非常容

易。

The difference between the DHF and the DMRis in thatfirst letter – design vs. device.
DHF 与 DMR 之间的区别在于第一个字母- 设计与器械。

The DHF is focused on the history of thedesign andensuring it was done according to the FDA regulations.
DHF 侧重于设计的历史，并确保按照 FDA 的规定进行。

The DMR is focused on the device andensuring you have allof the necessary items to build, test, package, andservice it.
DMR 侧重于器械，确保拥有制造，测试，包装和维护所有必需的项目。

Now that you’ve designed the device (DHF)and have therecipe to build and test it (DMR), it’s time to actually make thedevice.
现在你已经设计了该器械（DHF）并且拥有了“处方”来构建和测试它（DMR），现在是时候制造器械了。

That’s when the DHR comes into play.

也就轮到 DHR 发挥作用了。

DHR – Device History Record

The DHR is the device history record.

DHR 是器械历史记录

Everything you did to make the device iscontained here.

它包括制造器械所做的一切事情。

According to the FDA, the DHRshallinclude, or refer to the location of, the following information:

根据 FDA 的规定，DHR 应包括或参阅以下信息：

(a) The dates of manufacture;生产日期

(b) The quantity manufactured;生产数量

(c) The quantity releasedfordistribution;交付数量

(d) The acceptance recordswhichdemonstrate the device is manufactured in accordance with the DMR; 证明器械的制造符合 DMR 的检验记录

(e) The primary identification labelandlabeling used for each production unit; and

主要的标签和对应每个产品的标签;

(f) Any uniquedeviceidentifier (UDI) or universal product code (UPC), and any otherdeviceidentification(s) and control number(s) used.

任何唯一的器械标识符（UDI）或通用产品代码（UPC），以及使用的任何其他器械标识和控制编号。

Each manufacturer shall establishandmaintain procedures to ensure that DHR's for each batch, lot, or unitaremaintained to demonstrate that the device is manufactured in accordancewiththe DMR and the requirements of this part.

每个制造商都应建立和保存程序，以确保每个批次或单位的 DHR 都能确保证明该设备是按照 DMR 和本部分的要求制造的。

The device history record is literally thehistory of thedevice.

器械历史记录字面意思就是是器械的历史。

Everything that you complied in the DMR wasused to makethe device.

制作设备的所有内容都编写在 DMR 中。

The history and information on how you madethe device

inaccordance with the DMR is stored in the DHR. Much like the DHFis the historyof the design, the DHR is the history of the device.
根据 DMR 制作设备的历史和信息都记录在 DHR 中。就像 DHF 是设计的历史一样，DHR 是设备的历史。

DHF vs. DMR vs. DHR

While these three acronyms can seeconfusing and easilyinterchangeable when you first hear them, if you look atthe actual terms,they’ re surprisingly descriptive.
虽然这三个缩写词在你第一次听到时可能会感到困惑并且很容易混淆，但如果看一下实际的术语，它们会有惊人的描述性。

DHF - Design History File DHF-设计历史文档
DMR - Device Master Record DMR –器械主文档
DHR - Device History Record DHR –器械历史记录

You start with the history of the design,which leads tothe record of how to build and test the device, which leads tothe history ofthe device you actually made.
从设计的历史开始，引向构建和测试器械的记录，再引向制造设备的

实际历史。

If you’re like me, the part you mix up themost is whenthe D stands for design vs. device.

你可以像我一样，最容易混淆的部分是 D，代表设计和器械。

I keep them straight by remembering that Ineed a file forthe design and a record of the device.

我是这样记的：我需要一个设计的文档和器械的记录。

When I see the R at the end, I know it’sdevice related.

当我看到最后的 R 时，我知道它是与器械相关的。

Hopefully that simple trick will help clearup anylingering confusion.

希望这个简单的技巧会有助于消除长久的困惑。