Innovation, not administration

6 steps to easier Design History File Management

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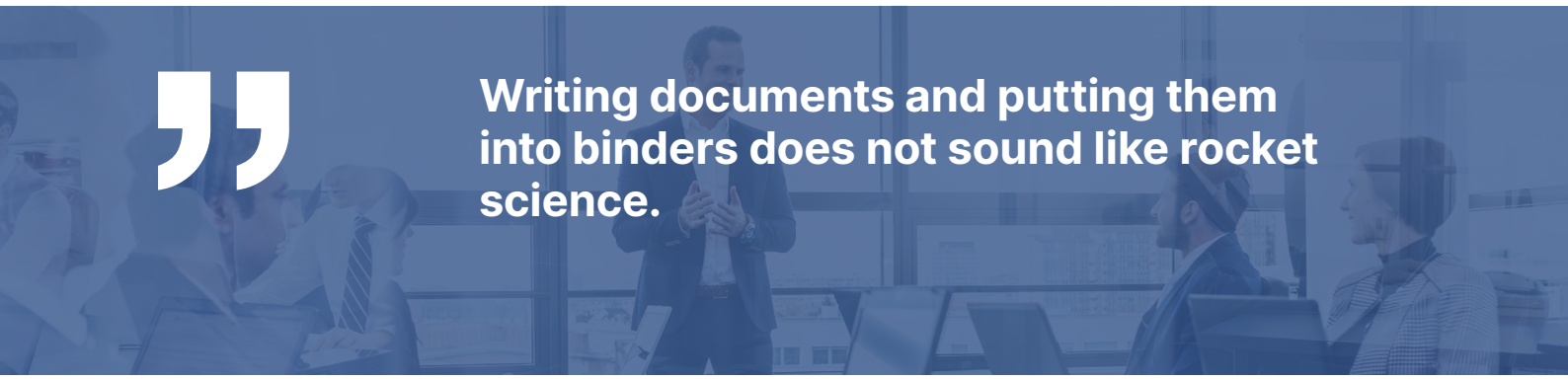


> **Writing documents and putting them into binders does not sound like rocket science.**

Nevertheless, many of us have experienced how the Design History File management turns into a both complex and cumbersome activity.

As the DHF documents change over time, we enter a reoccurring loop of having documents modified, reviewed, signed-off and archived. Although this procedure is explicitly required by many regulations and helps us bringing order and structure to our work, a substantial effort is needed to keep the DHF complete and consistent.

Surprisingly enough, as long as regulatory demands are met, the documentation process itself is seldom scrutinized for efficiency improvements. We are convinced that great savings can be made in this area.

Effective handling of the DHF will reduce costs, shorten timelines and free up resources for other tasks. In this best practice guide, we will cover a few simple but rewarding steps, aimed to minimize the required effort by reducing overhead and rework while continuously keeping an eye on the documentation completeness and consistency.

Is this the latest version of the PRD?

Do not put traceability information in the requirements document. The requirements document contains your product requirements. These are documented according to the prerequisites of your Quality Management System which in turn is inferred from Medical Device norms and regulations.

The regulations also stipulate that “adequate evaluation of conformance between [..] categories“ must be proved. In laymen’s term this is called “traceability”.

It is very tempting to add traceability information to your requirements document, i.e. to include the traces from the requirements to their respective Design Control Item (such as specifications or tests). On the surface, it seems like we add useful contextual information to the requirements.

However, the requirements usually stabilize much earlier in the project than the traceability. Exposing your requirement documents to this asymmetry will cause the document to be out of date for most of the project duration.

There exist two widespread approaches to deal with this situation:

- **Repeatedly review and update the PRD document which, due to the repetitiveness, desensitizes your team from identifying the important changes.**
- **Abstaining from updating the PRD document which consequently leads your team to distrust the validity of the entire document, not just the outdated traces.**

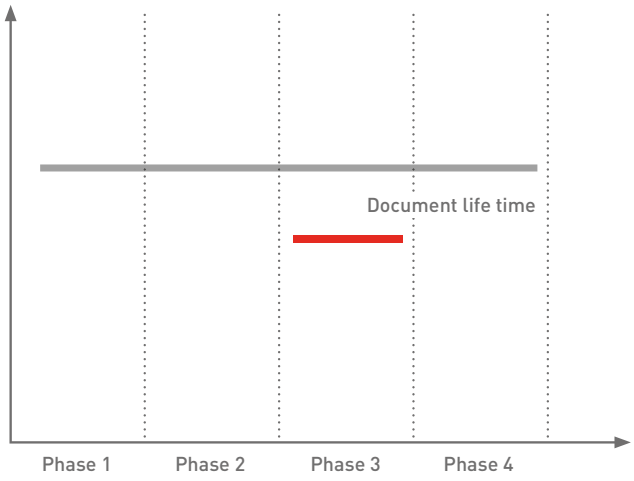
Document stabilization

The former approach will cause unnecessary overhead while the latter decreases confidence in the documentation, none being particularly productive.

Generally, this situation is applicable to any document containing artefacts that are traced (requirements, specifications, risks, tests etc.). Striving for content stabilization and early document closure is a good DHF practice. This is obtained by a deliberate selection and grouping of DHF content according to when the content is created and stabilizes during the project life cycle. The lesson here is: Do not mix artifact content and traceability information in the same document. Keep the traceability information in separate documents.

Best practice 1: Do not mix content that stabilizes at different phases in the same document. Strive to match the creation and early closure of the documentation with the stabilization of its content.

Example: Do not add traceability information in the requirements document.



Repetitivitivity

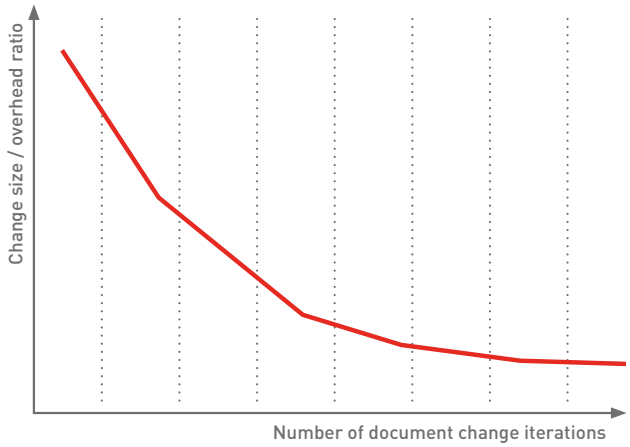
As you may already have experienced, many documentation activities are reoccurring throughout the project. Classic examples are:

- **document reviews**
- **document release procedures**
- **change-request handling**
- **performing test cases**

The Quality Management System usually prescribes how these activities should be performed in order to stay compliant with medical device regulations. Unfortunately, it is equally common that the regulatory aspect totally dominates the design of these procedures, while completely ignoring how the design affects the practical workload when performing the activity.

All DHF documentation activities contain some degree of administrative overhead and we can usually separate any DHF documentation activity into a part which is overhead and a part that constitutes to the actual core content.

As the project progresses and the activities are repeated, the administrative overhead stays close to constant for each execution. As the content stabilizes, the scope of each content change tends to diminish and as a result, the further the project proceeds, the larger the overhead portion of the total effort is.



The sensation of excessive paper-shoveling therefore often emerges as the project end draws near.

There are several ways to mitigate this problem. The first is to take a good, hard look on the prescribed process and investigate if there are possibilities of stripping away any excessive documentation requirements or activity steps. In these cases, it is often beneficial to bring executors (R&D personnel) and designers (Quality personnel) together. The executors can highlight which documentation steps are being particularly time consuming and the designers can make sure that modification to the process does not violate any regulations.

Automate reoccurring tasks

A second approach is to automate the overhead aspects of the activities as when possible, with the aim to focus valuable human resources on enhancing the actual content instead of diverting them to automatable administration.

Best practice 2: Bring the Quality and R&D department together and analyze the procedures of reoccurring tasks to strip away unnecessary administrative steps. Automate reoccurring tasks.

Examples: Use software tools for review management and change handling. Reduce the number of signatures needed to release a document.

Document Reviews

Document Reviews are one of the most effective ways to proactively reduce costs and trim timelines. Early identification and correction of errors can lead to substantial costs savings. Correcting a specification in a document is far less expensive than redesigning a hardware component further down the line.

"You can use an eraser on the drafting table or a sledge hammer on the construction site."

- Frank Lloyd Wright

But if document reviews are such potential goldmines, why are they perceived as dreary, tedious and exhausting? Maybe you have experienced the review a 300 page risk assessment?

We are all too familiar with these "Death-by-Review" sessions. As the meeting drags on, attention slips, results in a declining quality of the review output.

The most productive way to handle this problem is to:

- **Recognize that several sessions are needed for the first review and accommodate for it accordingly by reviewing smaller portions in each meeting.**
- **After the initial review, implement effective change control in order to swiftly identify parts that have changed since the last review.**
- **During sub-sequential reviews, restricting the review scope to the things that have actually has changed since the last review.**

If, on the other hand, the review scope is kept comfortably small, but the consequence is a very large number of reviews, then every little extra administrative step required by each review execution accumulates into a large administrative burden through the repetitiveness of the work. In these cases, we can fall back on the Step 2: automate tasks and trim away excessive activities.

Best practice 3: When reviewing, focus on changes.

Example: Use software tools to track and analyze changes of individual Design Control Items.

The conventions in Risk Management

Of all DHF categories, the one task that causes the most heated discussions during implementation is Risk Management. The ISO 14971 “Medical Devices – Application of Risk Management to Medical Devices”, is the established industry standard since 2000. It articulates the required steps needed to setup and fulfill a compliant Risk Management. However, it deliberately refrains from defining a particular risk assessment technique to be used.

By explicitly not mentioning hard requirements on the “how”, the manufacturer is left to choose his own preferred method. Most risk assessment techniques are largely subjective and configurable. In the example of an FMEA approach, the manufacturer is free to define parameters such as:

- **number of severity and probability levels**
- **the use of a qualitative or quantitative probability approach**
- **the method of estimating probabilities**
- **the calculation formula of Risk priority numbers**
- **the threshold selected for unacceptable risk**

Whereas most other DHF Design Control Categories such as verification and validation have an objective and scientific basis, it is often easy to forget that risk assessment techniques essentially are subjective and based on conventions selected by the manufacturer. From a regulatory point of view, one set of conventions is not necessarily better than another, as long as the requirements of ISO 14971 are satisfied.

And this is what we often experience during the risk assessment work. Many individuals spend extended periods of time attempting to accurately assign a probability of a not yet experienced event for a not yet manufactured product. Large assessment variations are found when different people perform similar tasks. Long discussions are invested in exploring the relative merits of a five level or a ten level severity scale, all in the glory of establishing the most true risk assessment technique.

So if the nature of conventions and subjectivity have these effects on the practical work, what best practices can we extract from experience?

First of all, set up your process using a set of conventions that do not violate ISO 14971. Since the standard is deliberately vague on how to set up your risk management practices, this should essentially not be a problem (even though there are exceptions, such as the infamous notion of reducing risks “as far as possible.”)

Stick to your conventions

Second, if you are working closely with and are relying on a particular notified body for audits and certificates, it is very probable that they have preferences on which conventions to use. It can be well worth the trouble to selectively align your conventions with their preferred practices.

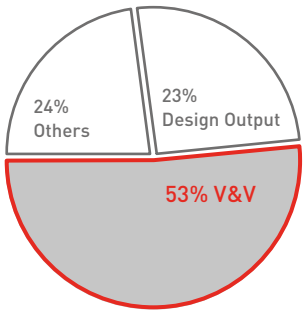
Third, as with many other best practices in this paper, we experience that the conventions and working methods established by the manufacturer are selected for their regulatory merit only, completely disregarding the impact they have on the practical work load. Again, it is often the case that the department that designs the process and selects the conventions (read: the quality department) is not the same group of people that have to perform the actual work and therefore is not aware of how a one set of conventions produces a significantly higher workload than another. Therefore, if two sets of conventions have the same regulatory impact but one generates less documentation work, then that is the preferred convention set to choose.

Best Practice 4: Recognize that risk assessment techniques are essentially subjective and based on conventions. There is no "right" way. However, some conventions cause more documentation work than others.

Example: Be observant when discussions arise during risk assessment sessions. Are these discussions attributed to unrealistic expectations on the conventions applied?

The bulk of the work: Verification & Validation

In a real-life example of a DHF consisting of 136 binders (10 meters of shelf space), 73 binders or 53% of the total documentation was verification documentation i.e. test plans, test results, test reviews etc. This is consistent with our experience: the Design Control Categories generating the most paper work is V&V.



However, test cases being of a highly recurring character, analyzing the V&V process, templates and work tasks for optimization might show some significant potential savings in terms of time and resources spent on documentation.

Here are a few noteworthy starting points:

The optimal length of a test case

Should one aim to generate many short test cases or fewer but longer test cases? Since each test case involves a certain overhead in terms of setting up and initializing the system, it seems preferable to have long test cases, generating as much test coverage as possible in order to compensate the set-up overhead.

On the other hand, one detected error might fail the entire test case where 95% of the steps actually work. Furthermore, verifying the future fix for that single error forces you to rerun the entire test case. A long test case might further complicate the communication between tester and developer since it is easier to read and understand a shorter test case rather than a longer.

In our experience, the optimal size of a test case is between 10 and 20 test steps. There is no particular science to this. We have just seen that this is a practical size of a test case as a work package.

Keep test environment separate from the test instructions

There is usually a requirement that the test case document should facilitate the possibility of reproducing it at a later stage. As a result, the entire execution environment of the test case is parameterized and documented as a part of the test case. Therefore, we sometimes find test case templates where the test environment constitutes more than 50% of the documentation. However, even though it is notorious for the function being tested to change as soon as the

50% of the total DHF

test case is written, the test environment is less prone to such frequent changes. Furthermore, the test environment is often the same for several test cases in a test suite. It might therefore be a good idea to document the test environment separately and refer to it from the test cases.

The right level of detail

Describing the test steps in high detail may have its merits. There might be a particular test point that you need to cover or a high risk area that needs some extra attention. However, a lower level of detail has the benefit of being less exposed to volatility. A very detailed test step has, apart from taking more resources to write, a higher risk of being in need of an update as soon as anything in the function or user interface changes which leads to increased maintenance costs.

If you suspect that the function or feature you are testing has not yet stabilized, a lower level of detail is to be preferred. You can always add more details later on!

Reviewing and releasing the test case/signatures

At some point, the test case probably needs to be reviewed and signed-off before it can be executed. Since test cases are going to be created in such abundance, it's utterly important that this process is trimmed down to only that which is essential.

First of all, remember that collaboration is always faster than reviewing. Therefore, make sure testers and developers are in close collaboration. This will minimize the effort of bringing everyone up to speed once the review takes place.

Secondly, find an efficient method for sign-off, release and archiving the test case into the DHF. Any reduction of work in this process will pay off 100-fold throughout the project.

Best practice 5: The V&V documentation may make up more than 50% of the total DHF. The V&V documentation mainly consists of test cases and test results. Any optimization of the test case documentation process will bring large savings both in terms of time and resources.

Examples: Write test cases of reasonable length (preferably shorter than longer) and with reasonable level of detail (preferably lower than higher). Separate the documentation of the test environment from the test instructions. Optimize the sign-off and release procedure.

Project vs. Product Documentation

It is not uncommon that a medical device goes through a number of changes after its market introduction. After some time, a steady stream of patches, hot fixes, service packs, maintenance releases, solved obsolescence issues and regulatory adaptations finally make up the product.

From a regulatory point of view, the Design History File must clearly reflect this state. In principle, this does not seem to be problematic. After all, each change is carefully documented.

During the regulatory audit, it might therefore come as a surprise that the DHF turns out to be riddled with inconsistencies, incomplete sections, lost references and, on the whole, being unexpectedly obscure. How did we end up in this situation?

The answer might be found in the difference between documenting a project and documenting a product.

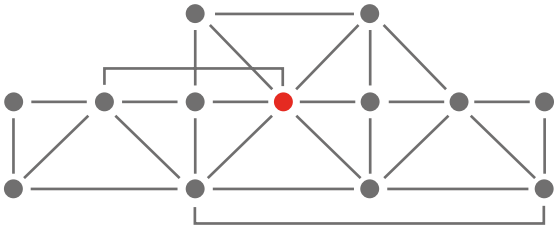
Most medical device companies organize their product development in projects. Normally, once the product has been launched, any post-market launch modification effort is set up as a new project being planned, staffed and documented separately from the original project. Thus, over time, the product itself is actually made up of the results from a number of projects.

From a documentation perspective, subsequent product releases are usually documented using some kind of delta approach i.e. rather than re-creating the complete DHF (including the modifications) a second time where only a small part is different from the original DHF, the existing DHF is amended with the modifications only. There is an intuitive appeal in handling the documentation this way. After all, the product was updated with a small set of modifications, as was the documentation. Moreover, restricting the documentation to the things that changed seems to trim the documentation effort down to the essential minimum. However, there are two elemental aspects of medical device development that prevent this approach from being successful.

The first is the intertwined nature of the Design History File resulting from the regulatory demand of “evaluation of conformance” a.k.a. traceability. Due to the

Keep a single DHF for the Product

fact that most artefacts of the DHF are linked, traced or referenced by one or more other artefacts, it becomes exceptionally difficult to operate on an isolated selection (our delta) of the documentation without severing these links. This further makes it difficult to reuse existing document throughout subsequent releases.



The second aspect has to do with the way the project documentation overlaps with the DHF documentation. The DHF documentation is simultaneously an output and a subset of the project documentation, which logically belongs with the rest of the DHF.

However, logistically, it is common to electronically and physically incorporate the DHF documentation with the rest of the project documentation. The result is a DHF being dispersed over several physical and electronic locations.

The difficulties resulting from this added complexity call for a practice where you explicitly operate on a single DHF over several projects. The recommended approach here is to move from a document centered to a database centered repository. The DHF artefacts will then "live" in the repository and allow reports to be generated, depicting the state and relations of the artefacts at a given moment. Use software tools to manage controlled versioning of artifact updates and to establish strict traceability control over all artefact links.

Best Practice 6: Keep a single DHF for the product, preferably both physically and electronically. Use software tools to manage versioning and tracing of individual Design Control Items.

Example: Use a single, versioned, project independent DHF Index.

Conclusion

Getting the Design History File together takes a considerable effort, often significantly more than initially anticipated. There is however great optimizations waiting to be discovered once you take a closer look at the DHF process.

We have in this paper covered six best practices that can be summarized as:

- **Do not mix artefact and traceability content in the same document.**
- **Involve team members performing the practical work when designing documentation procedure. They will help you detect and eliminate unnecessary administrative overhead.**
- **Focus the review meetings on the content that has changed.**
- **Select risk assessment conventions that minimize the work load.**
- **Up to 50% of the total DHF is V&V documentation. Any process improvement here will pay off 100-fold.**
- **Beware of the difference between DHF and project documentation. Keep the DHF in a single repository for all projects throughout the life cycle.**

We hope that these guidelines can generate some fruitful ideas on how your DHF process can be optimized and in the long run help you cut costs, free up resources and shorten timeline.