# Best Practices

## Medical Device Technical Documentation


**Address**

Aligned AG
Tellstrasse 31
CH-8004 Zürich

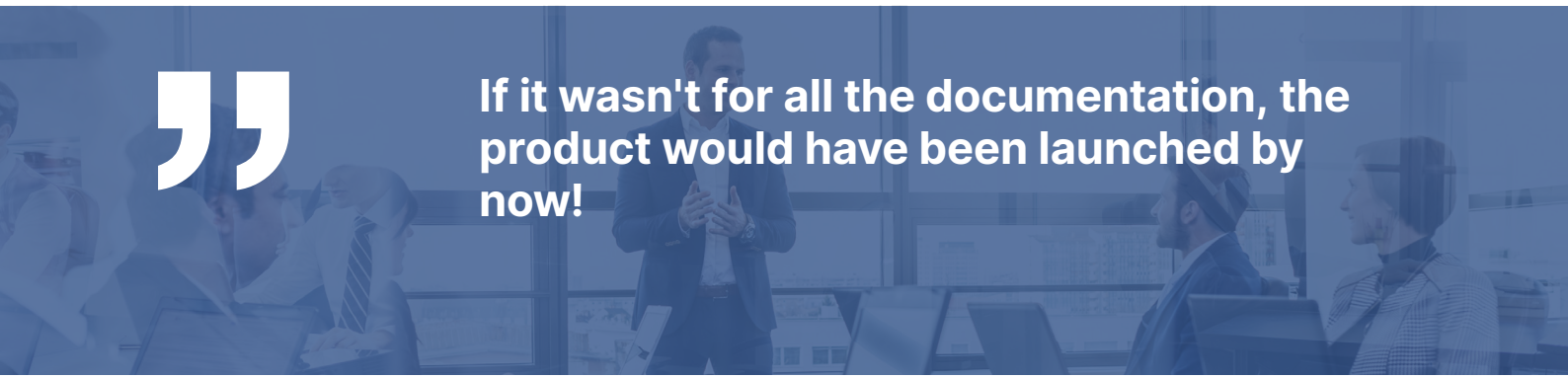
**Phone & Fax**

Phone: +41 (0)44 312 50 20
Fax: +41 (0)44 312 50 20

**Online**

sales@aligned.ch
support@aligned.ch
info@aligned.ch
www.aligned.ch


aligned



**If it wasn't for all the documentation, the product would have been launched by now!**

We are all familiar with the medical device development documentation and the impact it has on our projects, how it seems to erode time-lines and lure away resources from important development tasks.

For medical devices, up to 50% of the total development effort is placed in documentation activities. As the projects progress and as the documentation effort grows, it becomes a daunting task to keep the documentation updated and consistent.

# The iterative course of a development document

The ever-increasing amount of medical device regulations is often pointed out as the major reason for making the development documentation compilation such a dreaded activity. It is true that many regulations require extensive documentation to enhance patient safety, but they are far from the only villain in this drama.

Let us consider the typical actions of creating a version of a document:

Write → Review → Sign

This process looks straight forward and simple. We write the document, then review and release it in accordance with our development process. The procedure consists in creating the target document but also generates a certain administrative overhead when documenting that the process has been performed correctly.

As the project progress, this process is repeated a number of times during the course of time.

→ Write → Review → Sign ┐

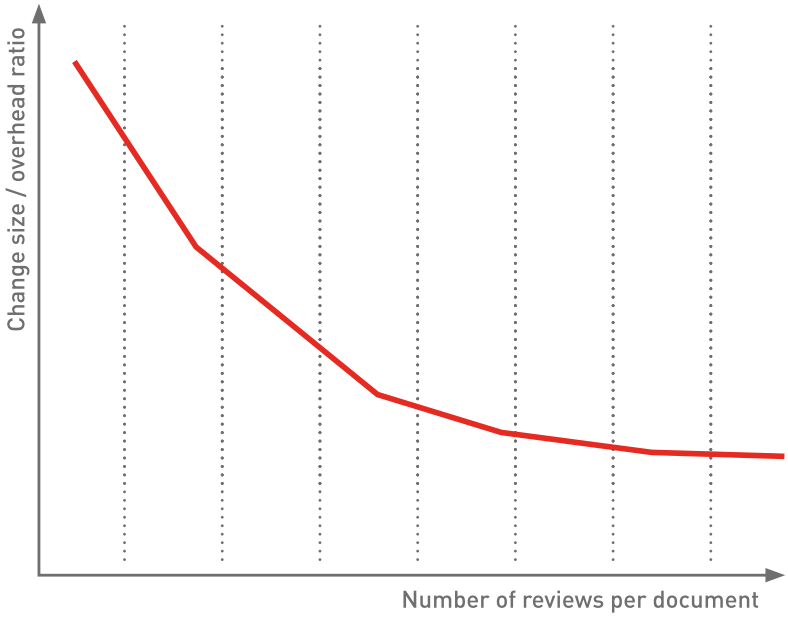
Any reason that requires us to go over the document again, be it the introduction of a design change, updating the document template, a milestone closure, will invoke the process described, including the administrative overhead. Regardless of the size or importance of the update, the administrative overhead is close to constant for every iteration.

# Didn't we just review this document?

The document review is an excellent instrument to gather refreshing insights and spur constructive discussions. Unexpected and important findings, crucial to the project success emerge from these meetings. This is the reason why formal reviewing is a mandatory cornerstone in many medical device regulations.

However, the regulations do not differentiate between small or large, important or unimportant updates. We can assume that, for a document being updated several times during the project, most changes to the document content is done in the early reviews. The longer the project progresses, the smaller are the changes made to the document. As a result, the ratio between change size and administrative overhead decreases for every additional review.

# Endless paper-pushing




No wonder that the feeling of endless paper-pushing increases in the later stages of the project. The cynical team member now complains that it would be better to delay the documentation until the project is completed.

In an effort to come to terms with this situation, let's consider the iterative nature of the medical device documentation process and reflect on:

1. How can we reduce the administrative overhead?
2. Is there a way to avoid unnecessary iterations?

# Consider repetitiveness when designing the documentation structure

When setting up the documentation process, including templates and SOP:s, keeping the iterative nature of the documentation process in mind is a good starting point. There might be aspects of the documentation structure that do not appear cumbersome at first sight but emerge as major contributors to administrative overhead once the process is repeated.

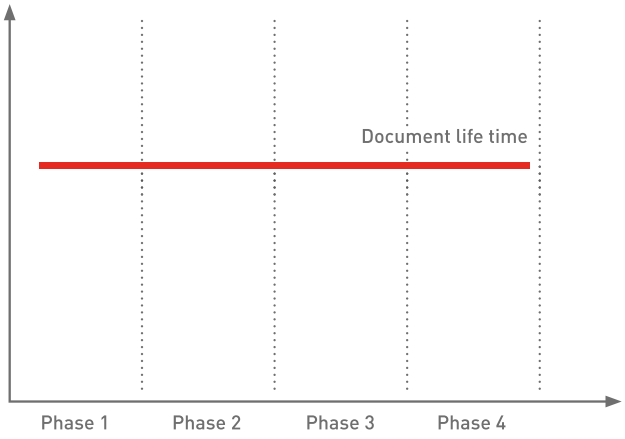
# Validate the document structure

The designers of the documentation processes are seldom the same people who eventually have to generate content and compile documents. Consulting the team members producing the document content might uncover potential sources of overhead hidden in the documentation process. This is also a good time to designate concrete content generation tasks to the individual team members to avoid confusion about who-does-what further down the line.

It might also be a well spent effort to validate the documentation process with real life examples, paying extra attention to the effects of iterating through the update-review-signature process several times.

# Aim for early document closure

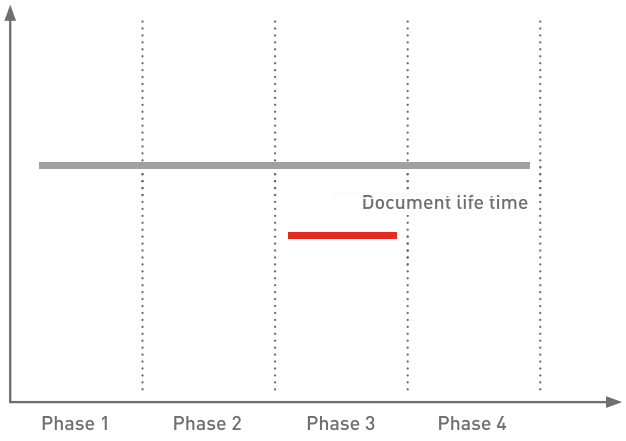
Documents are often drafted in one development phase and released in another. This often, quite correctly, reflects that the complete picture is not known at the time of document creation and that the document naturally evolves as the project matures.




Yet, the longer it takes fora document to reach its final state, the more reviews are likely to target the document. Therefore, it can be a wise choice to consciously define the intended document content in a way that allows the artifact to be completed sooner rather than later.

One of our customers insisted on keeping the traceability from requirements to specifications in the product requirements document. The idea was to pick up the PRD at any time and get informed about, not only the requirements, but also the current trace coverage.

As it turned out, the requirements quickly stabilized in the early phases but the traces to specifications did not, simply because that information was not available until much later. A nice idea from a manager turns into a nightmare for the people trying to keep the document up-to-date. As a result, the PRD constantly changed even though the requirements did not. Separating content in a way that makes a document span over fewer phases will potentially reduce the number of update iterations.



# Assessing documentation completeness and consistency

It usually does not take long until the project documentation is so large and changes so frequently that it is impossible for any one person to manually assess the current level of completeness and internal consistency.

Due to the medical device regulations requirement for traceability, a very large number of references between development documents quickly emerge. While a change alters parts of the documentation, it is essential to verify if referenced parts are affected by the update. A massive effort is needed to track down the ripples caused along the chains of references.

Where textual references are used, typically being unidirectional, the referred object does not “know” or show any sign that it has been referred to, an endless labor of back-tracking and correct the referring parts ensues.

By applying traceability tools with integrated change control. this type of work can be radically reduced. State-of-the-art traceability software can track down and highlight change chains throughout the documentation. Inconsistencies are automatically detected and brought in to light, making it easier to handle them.

# Restrict reviewing to changes

Being able to assess completeness and consistency of the development documentation can reduce the review effort by making it possible to focus on the things that have actually changed. This may sound trivial but it is remarkable how often lengthy review discussions emerge on content that has already been covered by previous reviews.

Use an appropriate software tool to filter out the things that changed since the last review including meta-information such as why and by whom the change was made. Present this delta content to the reviewers and leave out the rest. This will permit review chunks of manageable size, avoiding a “death-by-review" situation caused by a 500 page document.


# Conclusion

Compiling and managing the medical device development documentation is a considerable part of the development effort. One important explanation for this lies in the iterative nature of the documentation process where the size of the administrative overhead is constant in every iteration.

To minimize the administrative overhead and reduce the number of iterations, reflect on the following options:

- **When setting up the documentation structure and process, consider that documents will be created iteratively and that administrative overhead will increase relative the benefit of updates.**
- **Involve the team member performing the practical documentation work to detect and eliminate unnecessary administrative overhead in the documentation process.**
- **Match document creation to the phase where its content is created and aim for early closure.**
- **Use appropriate automation tools to assess documentation completeness and consistency.**
- **Try to restrict reviews to the things that changed since the last review.**

After analyzing your documentation process along these lines, the most promising actions to take will soon emerge. If performed correctly, you will be well on your way towards a more efficient documentation process.