Technical File Self-Assessment

Finding inefficiencies in your Medical Device Technical File

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To illustrate how you can analyze your own processes and identify potential documentation inefficiencies, try to complete the following three example exercises.

Analyzing re-occurring documents

Is there any specific document type that exists in a large number of instances in your Design History File, such as Test Cases or Review Protocols? If so, which document type is it?

Document Type: .....

How large part of the total DHF does these document make up (in percent)?

Percentage of DHF: .....

What would need to change in your organization in order to cut the time of creating and releasing this particular document radically, say with 50% and still remain compliant?

Example changes:

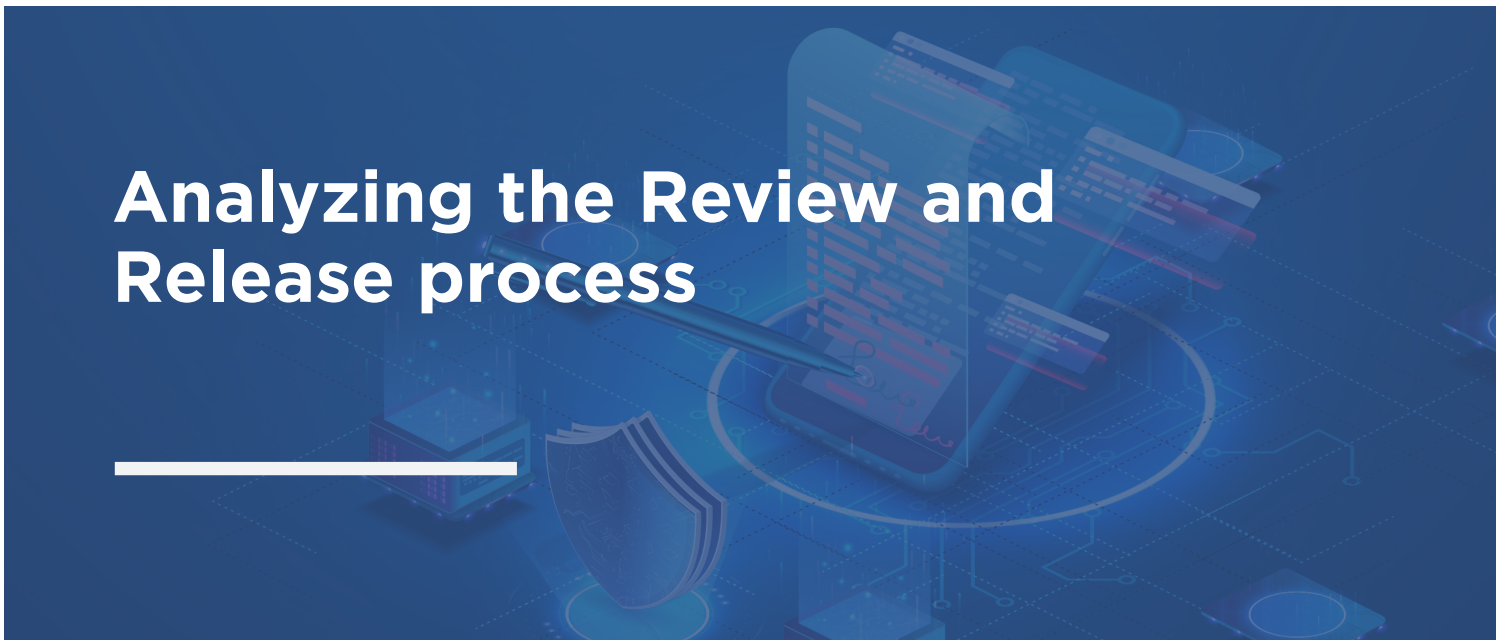
- Changes to the template?
- Changes to the number of people involved?
- Changes in the review and release process?
- Changes in the workflow of handling the document?
- Addition or modifications of supporting software tools?

List the changes you have identified:

Identified changes: .....

Can any of these changes be implement until next Friday?

Easily implemented changes: .....



Analyzing the Review and Release process

Consider a recent document that you were involved releasing. How long did it take to complete the review and release, i.e. from when the review invitation was sent out until the document was placed in the DHF after the release (the date of placing it into the DHF)?

Duration from review invitation to completed release:

Compare this time with how long it took to actually write/update the document. What is the ratio?

Time to review and release / time to write:

Analyze the different stages in the review-release process. In which stage does the document spend the most time before proceeding to the next stage?

Time consuming stage:

What is, in your opinion, a reasonable maximum duration for the formal review and release of a document?

Target max duration:

What needs to happen in your organization in order to cut the review and release process duration radically, say with 50% and still remain compliant?

- A different workflow?
- Different document templates?
- Involving less people?
- Using less signatures?
- Applying electronic signatures?
- Digitalization of the process?

Identified changes:

Analyzing Review Findings

Take a number of recent review protocols, preferably from reviews where representatives from the quality department participated. Go through the recorded review findings. How many of the findings were content relevant? How many were formal errors (incorrect version, wrong dates, incorrect references, errors in headers, footers, table of content etc.)?

Content relevant findings:

Formal error findings:

Focusing on the formal errors;

- How could these occur?
- Why where they not obvious to the author?

Reasons for formal errors:

- Are there ways these errors could have been avoided by changing the underlying document template?
- Can the source of the formal error be removed from the document template all together without damaging compliance?

Identified changes in order to omit formal errors:

About us

These exercise are examples of methods we use to identify and eliminate documentation inefficiencies.
If you would like to know more about how Aligned assists clients in speeding up their documentation process, please contact us.

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