QMS wrapper™

qmsWrapper Best Practices

Document Management

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We all know that one colleague who is so organized that he can always find any document, let it be from 3-years ago or 8, he will find it in a fraction of a minute.

In this document we collected best practices to help you develop advanced document managing skills:

a) **Follow rules** that you set up with the help of **naming** convention.

b) Set up a **simple and clear structure of projects**, subprojects that are mirrored in the document management module.

c) Every main device has its own **QMS folders** with separate folders for different topics, such as: **standard literature (with requirements etc), submissions, FDA feedback,** etc.

d) Using Project versioning amongst other benefits, also keeps the **latest versions** in front and hides the obsolete off site.

In the following we will detail the above mentioned pints with examples. The first chapter is describing the basic thematic of Naming Convention, and the second chapter includes advanced examples of **best practices regarding storing documents in your qmsWrapper**.

If you are familiar with the concepts of Naming Convention, please feel free to jump straight to the second chapter.

i. First Chapter: The basics of Naming Convention

Naming convention is a set of rules for choosing the subject (sequence of characters) of a document for identifiers which demotes types, functions and other entities in documentation.

Many companies have established their own set of conventions, but if your company is not promoting following set rules, you should have a plan at least for yourself: how to get organized and be able to find anything in no time. Some of the potential **benefits** that can be obtained by adopting a naming convention include the following:

- Reduce the effort needed to read and understand document titles

  Enable other team members to quickly navigate between the documentation that follows the naming standards. (This is especially handy when a new colleague comes onboard, or a colleague is leaving and somebody has to take over his work)

- To provide additional information (i.e., metadata) about the use to which an identifier is put. (Additional information about what the document is about, what it relates to, etc.)
- To help formalize expectations and promote consistency within a team.
- To enhance clarity in cases of potential ambiguity.
- To enhance the aesthetic and professional appearance of work documentation (for example, by disallowing overly long names, comical or “cute” names, or abbreviations).
- To help avoid “naming collisions” that might occur when the work documentation of different departments is combined. (or work documentation of different devices)
- To provide meaningful data to be used in project handovers.
- To provide better understanding in case of document reuse after a long interval of time.

Challenges

The choice of naming conventions can be an enormously controversial issue. Even with known and well-defined naming conventions in place, some organizations may fail to consistently adhere to them, causing inconsistency and confusion. These challenges may be exacerbated if the naming convention rules are internally inconsistent, arbitrary, difficult to remember, or otherwise perceived as more burdensome than beneficial.

There are some fundamental elements to all naming conventions, such as: the length of identifiers, letter case and numerals, usage of multiple-words, way of separating words, etc… More on naming convention online, for example on Wikipedia: https://en.wikipedia.org/wiki/Naming_convention

ii. Second Chapter: Best Practices - Storing Your Documents in qmsWrapper

In the following we will go through the basic steps of familiarizing with the Document Management module, followed by some advanced examples and pro tips for having a neat QMS documentation.

Basic knowledge of document management layout: https://documentation.qms-wrapper.com/content/storage

Basic knowledge about working in Document Management module: https://documentation.qmswrapper.com/content/work-storage

Now that you are familiar with the basic components and functions of the Document Management module, lets move to advanced details.

Practical examples with handling your Document Management

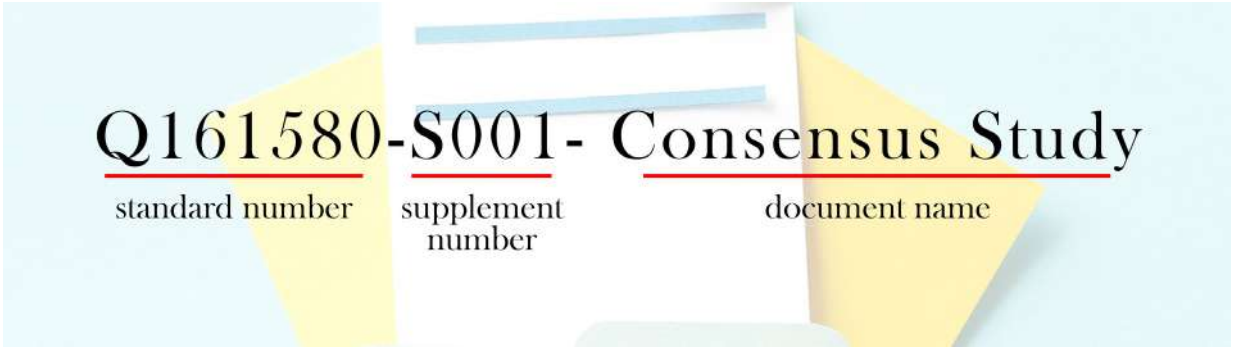
1. Decide the rules you are going to follow with your naming convention, for example:

1.1. All standard related documents will start with the **name of the standard**, etc.

1.2. If date goes into the document name in which format (and everyone in the company will follow and use the same agreed format).

1.3. Will the document include 510k numbers: In the example "Q161580-S001- Consensus Study" the first number is the standard, the S001 indicates the supplement number (it could be S002, S003, etc), and the last one is the document name.

1.4. Will you put space between the words, or dash, or nothing, etc. (and everyone in the company will follow and use the same agreed format).



2. Add Tags when importing new document to the Storage, or add Tags to already existing documents:

Both simple **Tags** and **QMS Tags** are available for all users for use.

2.1. Decide what Tags will you use to further enhance sorting, identifying, and filtering documents (for example "S001" or "Audit2023", etc. can be filtered with Advanced Search options, and also can create reports with the Reports module). More on Tags: https://www.qmswrapper.com/blog/qms-tags

2.2. QMS Tags: QMS managers have the right by their role to create QMS Tags in the following route: QMS Module/Manage QMS Tags/Create New QMS Tag. More on QMS Tags: https://documentation.qmswrapper.com/content/manage-qms-tags

3. Use Search and Advanced Search features.

In Storage module there are 2 search options:

3.1. **Simple search**: clicking the magnifying glass icon will search on the page you are currently at.

3.2. **Advanced Search**: clicking the button will open a window with multiple-search options, put your parameters and click search, the function will search amongst all data on the Storage.

4. Use Clear Set of Projects and Sub-Projects

The layout of your Projects and sub-projects will be automatically mirrored in the document management module. In the document management module, you can manually create additional folders for further categories.

4.1. **Create separate projects** for: different devices, projects for the main parts of your different devices, for clinical studies of the different devices *one for England, one for USA, etc., then separate for the cybersecurity of different devices, HelpDesk, Marketing, etc.

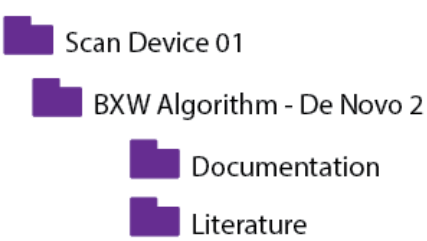
4.2. **Create separate sub-projects** in each main development project, for example: "BXW Algorithm – De Novo 2" has a main project, sub-projects would be: BXW 510k activity (with an identifier: PRESUB), BXW Algorithm Implementation (with an identifier: JAVA), BXW Algorithm Cybersecurity (with an identifier: CYBERFDA), etc.

5. Use a Clear set of Folders and Sub-Folders

5.1. Create **new folders and sub-folders** if you expect multiple documents to store in it, don't create unnecessary folders or sub-folders.

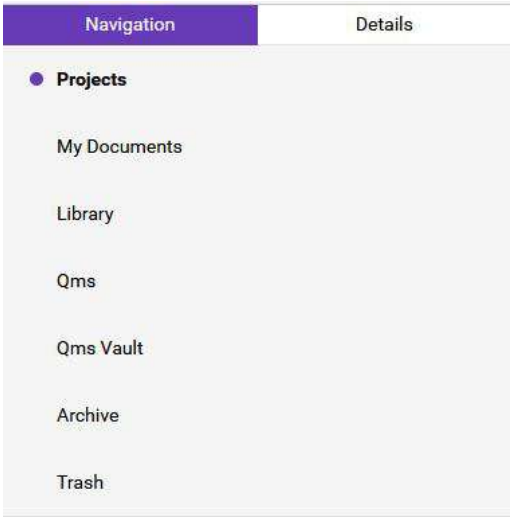
5.2. In the Storage module you will add further folders to the "BXW Algorithm – De Novo 2" sub-project, such as:

5.2.1. "BXW Algorithm – De Novo 2 **Documentation**" (where you might store in separate sub-folders the submissions, then the feedbacks, different descriptions, any additional information, etc.),



5.2.2. **Literature** (where you will have separate folders such as Standards (guidance, guidelines, set rules that you download on the specific standard), Databases, Demographic (for different references, statistics, checklists), Publications (any external publication on your area), Regulatory requirements, Standards, etc.

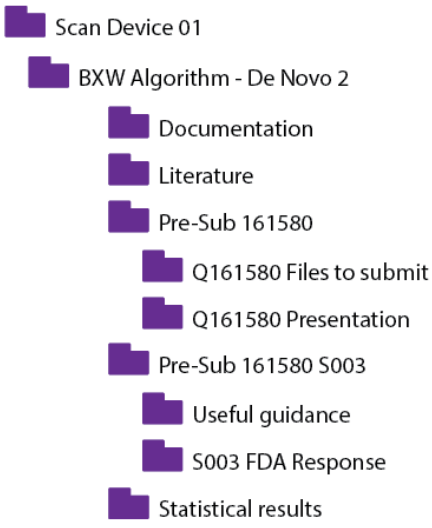
5.2.2.1. Others might use the **Library folder** (non project specific) to keep regulatory guidance that they download regarding their EU CE, MDR, FDA etc. submissions, or to keep different publications regarding the company.



5.2.3. **Pre-Sub 161580**, with sub-sub-folders, such as: Q161580 Files to submit, Q161580 Presentation, Q161580 Responses, Q161580 – Supplements, etc.

5.2.4. **Pre-Sub 161580 S003**, with sub-sub folders such as: useful guidance, S003 FDA Response, Pre-sub final to send, etc.

5.2.5. **Statistical results**, etc.



5.3. **QMS implementation** might also be a separate sub-folder, it may include: Work instructions, Employee cvs (or can go to Library), Job descriptions, Processes, Trainings. QMS folder acts like a filter , a type of help for the QMS manager.

5.4. You might open a sub-folder for **Submissions specific documents**: you might put here the document that you need to modify to fit the standard requirements: different standards require different layout and specifics such as:

- Specific names
- Page numbering
- Font (way type is allowed in the document)
- Different tables
- Headers
- Approvals (the layout of the approvals how they want them to be presented)
- Etc
- If you know in advance what standard you aim for, check their specific requirements for handling documents and naming documents, etc. and start to apply their rules from the beginning of creating your documentation.

System folders

In every Project and Sub-project there are some **automatically generated system Folders**, these are generated on the demand of the software and they have functional purposes. Most of the system folders are owned by the organization, so deleting these folders are disabled, this serves the purpose to ensure that the related project will run properly.

System folders examples:

A) "**Issues**" Folder

- It is not generated immediately; it is generated when the first time a user creates an issue, then the system automatically creates the folder in the Storage menu to store any connected document (for example: attachment to a created Task).
- Stores any document added as an attachment to an issue, however best practice says to import your documents first to a designated folder in the Storage module and not straight from your computer to an issue. This will force you to follow the document structure that you built, and set healthy habits to keep being organized. (Same goes for the Chat module, import your documents

first to a designated folder in the Storage, and attach the document from there to the chat discussion).

- Attach docs straight to issue or to chat only if the doc is kind of unimportant, such as: partial results that will have a full document later.

B) "**Project Plan**" Folder

- Put here your: Quality plan dox, Design plan dox, checklist or stuff that the standard require.

C) "**DHF**" folder

- while creating each project you have an option to check "Create a DHF for this project" checkbox. It will automatically create Design History File folder within Storage (in a projects folder), where you can keep your files related to design history, but files need to be added manually, such as sub-sub-folders for: Design Change, Design Input, Design Output, Design Review, Design Transfer, Design Validation, Design Verification, FDA Revise, Risk Analysis, etc.
- Other solution for updating Design History File automatically is to use the Traceability Matrix feature. If you run your project through this feature, you will get your DHF in one place in a table form, updated, which can be exported to Excel with all the attached files.

D) "**Matrices**" Folder

- The folder "matrices" is for the Traceability Matrices which are related to the particular project.

6. Use Versions for projects and sub-projects

Using versions have multiple benefits, for example you might want to open a new version of a particular project if you have to apply some major updates or modifications, and for example:

a. From the regulatory point you need to **keep the original untouched**.

b. The new folder will have different documents etc. and you would like to **avoid collisions or doubling**.

c. If you don't want to **recreate the whole project** just have a new version of it.

d. It's easier to find related documents if a **version has a set timeframe**.

Let's see an **example with versioning:**

User wants to create a Bug type of issue for a project named "BXW Algorithm – De Novo 2", when he opens the versions of the project, he can see that there were new versions added periodically to the project, let's say yearly. When opening the version called "2022a" he can see that there were 5 bugs reported, documented, and corrected in that version.

a. New bugs will go to the latest version, but

b. You can document your bugfixes retroactively: When you are writing the DHFs you can go and check which bug belonged to which version. Same goes for the features.

(Bugfixes, etc fixes can be documented retroactively. At any time, you can open a new issue for these and document their history, because important is that they get documented, not the date when you opened the issue and got them documented.)

You can always close an old project version, so it is off site, and only the latest ones will be displayed to work with.

Contact us for company specific questions, we can help you at any stage.

Best regards,

The qmsWrapper HelpDesk Team
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