QMS wrapper™

qmsWrapper Best Practices

Implementation agenda for setting up the QMS

www.qmswrapper.com

This document is summarizing the necessary steps of the initial **QMS implementation**. Please note: there are separate topic-oriented best practices documents that are covering the steps of how to work in the different modules.

The 8 steps of your QMS implementation

1. Setting up the **company profile** (in the ***Settings/System*** tab)
2. **Adding users** (in the ***Settings/People tab/Users***)
3. **Defining company roles** from scratch or based on existing Organizational chart (in the ***Settings/People tab/Groups-System Roles***)
4. Establishing **Approval Workflows** based on company needs (in the ***Settings/Approval Workflows***)
5. **Setting up the project** that is related to QMS Implementation (or use the General Administration project) - in Project Management Module
6. **Organizing and uploading existing documentation** to the Storage in a folder of a project that is created for QMS implementation:
    - o Overview of existing documentation,
    - o Creating sub-folders (folder for SOPs, WI, templates, general documents, etc.),
    - o Placing the documentation in appropriate sub-folders,
    - o Sending documents through predefined approvals.
7. **Adjusting Processes** according to company procedures:
    - o Adjusting processes steps (in the ***Settings/Processes*** tab)
    - o Adjusting process documentation (templates) - uploading new ones or adjusting the pre-built ones.
    - o Adjusting process roles (the assignees of certain steps in the process workflows)
8. **Establishing Quality Manual** using qmsWrapper Interactive Quality Manual Creator Tool (new from scratch or based on the company's existing one). The Quality Manual PDF generated using this tool is saved under the General Administration project by default, but you can easily move it elsewhere if preferred.

This is the guide how to set up the system based on the QMS. Then it comes to run an actual work in the software.

Overview of handling projects and necessary documentation:

In this section we will touch **3 topics**:

1. **Creating projects**
2. **Handling SOPs**
3. **Managing DHF, DMR, DHR**

Please note: there are specific topic-oriented best practices documents to cover each above-mentioned topics in great detail. In this document we will touch only the surface.

1. Creating Projects

You'll organize your work **per projects**. (Please refer to *"qmsWrapper Best Practices- Project Management"* document)

Best Practice recommends to work with small, manageable projects. Create **separate projects for the main parts** of your medical device, another for the software included, another for cybersecurity, for marketing, etc. Admin or project lead will add members that are relevant for the particular project, all users will have access to the projects according to their role-permissions given by the Admin. (Note: roles can be also specified on a project -level.)

Projects are issue driven, user can create and assign tasks to other project-member users. Projects are also process driven. Process driven means that the system assures that your team is working based on your predefined SOPs.

For example, when it comes to handle CAPA related to the D&D of your device, you'll start the CAPA process from that project and the P-850 CAPA process will drive the users through the entire workflow, through the workflow that was previously defined and approved by the Quality Manager. The CAPA process will assign the tasks from the workflow to the users/assignees who need to deal with the various steps, including the templates that need to be filled (assignees will get email notifications, and software notifications on their Dashboard about their new assignments).

2. Handling SOPs:

In qmsWrapper there are 3 sets of pre-built templates that are prepared by following the **ISO13485, 14971 standards**:

2.1) Word format templates under the route: *Storage/Projects/Templates* (these are Word documents, treated in the software as files). These templates, are SOPs prepared to follow the ISO 13485,14971/9001 standards, these can be used on their own, or user can start a process and include these templates in the process.

2.2) Workflow Processes under the route: Settings/Processes (these are flowchart processes, treated in the software as sequence of tasks). Many of the default Workflow Processes that are included in the software already have some of the Word format templates attached in one of their steps as a mandatory attachment. These processes were also built to follow the standards

2.3) Forms under the route: Settings/Forms (these are interactive software forms (with checkboxes, tables, radio buttons, etc.), can be converted to pdf or excel). Forms can be also attached to any task or to a workflow process.

All 3 sets are editable, and can be tailored to your specific needs, or you can create band new ones from scratch. (For specific assistance schedule a call on: **contact@qmswrapper.com** or read more online on the qmsWrapper User Manual site: for example, here is a link for reading more about the Process Editor: https://documentation.qmswrapper.com/content/process-editor)

Examples of how to handle SOPs:

a. A **Word template can be an SOP in itself**... for example, fill this in, when this happens.

b. A **process can be an SOP**, a series of events that enable you to do some actions. Start this process, do the actions.

c. A **process can have multiple Word Templates or Forms attached** to it that are required to be completed, it can be assigned to a person or group or role, and require the assignee to do something, for example Task X.

Let's see for example handling a CAPA: There is a capa template in the *Storage/Project/Templates*, F-850 CAPA, you can choose to fill in every section of the

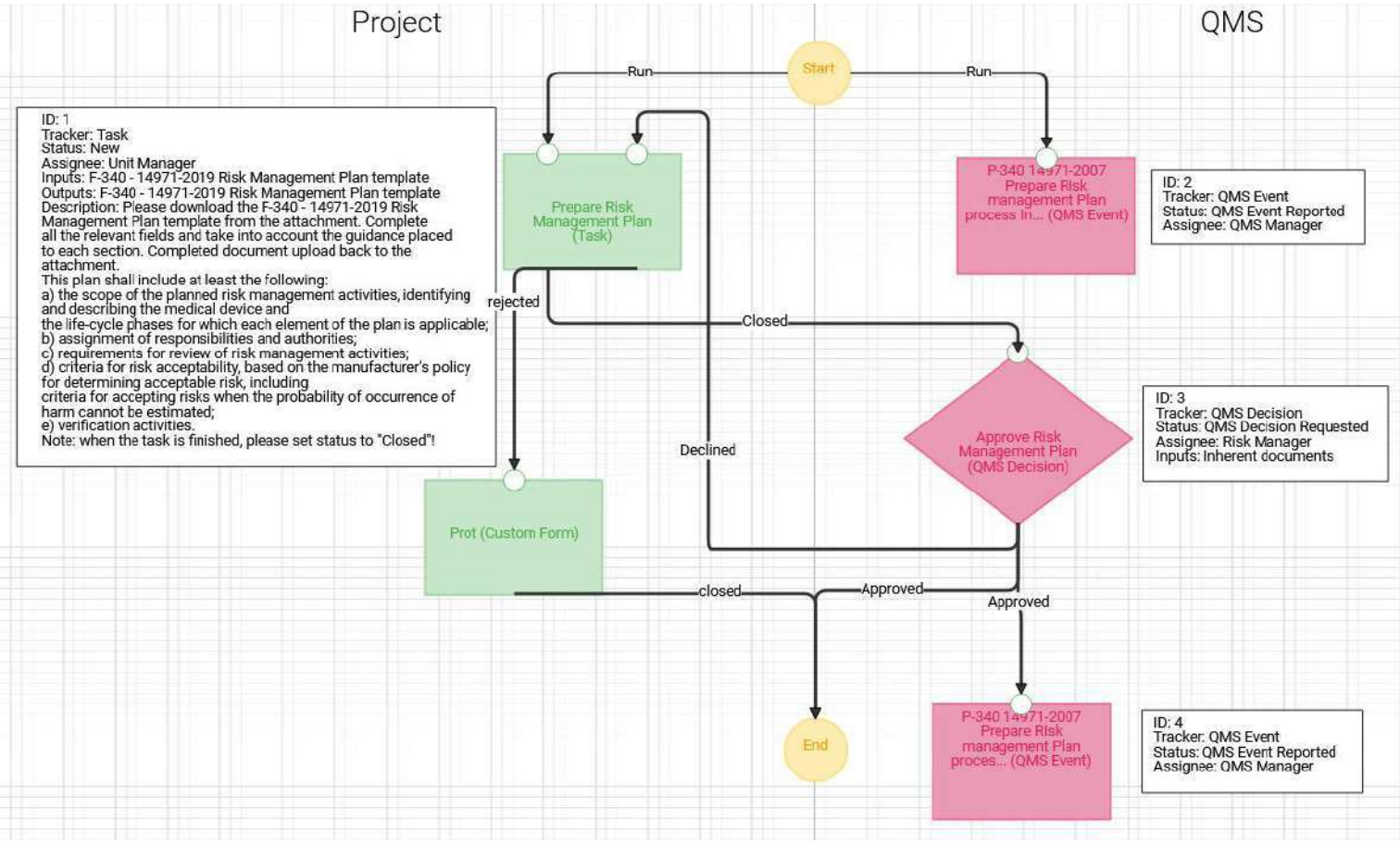
form manually (qms manager and other users together, or only qms manager, depends on the roles), or you can choose to run the process P-850 CAPA, when you open the preview of the process you can see that it already includes the template F-850 and the process hints (white textbox next to each step) are guiding the user through the steps, presenting which role should fill up which section of the template.

All 3 above mentioned example options are leading to the same result (fill the Word template manually, or attach it to a Workflow Process), in the end the user will have a completed CAPA form.

Process Builder/Editor Tool:

A process would contain all the necessary steps to successfully handle a "situation" in a way that satisfies the **ISO13485/14971/9001** standard requirements. The process will trigger all defined steps in a sequence (as assignee completes one step, another will be triggered). In this case, all stages are defined as issues. Within each stage you can add file attachment, which will be stored in the corresponding Folder in the general Storage.

Please refer to following image:



Following Started Processes:

Processes can be started through any of the projects or through the designated **QMS modules** (capa, nonconformity, training, change management, customer feedback, suppliers).

Progress of a process can be **followed from the QMS Module**, the QMS module is also organized per projects. *QMS Module/particular project/Started Processes/* will be displayed in a **Kanban layout** where user/qms manager is able to go into the finest details to investigate what work was done.

For following the overall progress of a processes regardless of the projects where they have been started, use the **Report module**.

3. Managing DHF, DMR, DHR – the Agile Methodology- Traceability Matrix

qmsWrapper supports **Device Master Records**, **Device History Records**, and **Device History Files**.

There is a great overlap between all 3, but user can easily keep them separated in different folders, or following them in Traceability Matrices with all their references.

qmsWrapper includes built-in **document controls** that support electronic signatures, allowing the **quality manager to review and approve** changes to the **DHF, DHR and DMR** with the click of a button.

In a **Traceability Matrix** the DHF, DHR and DMR documents can include or reference the required materials, with qmsWrapper the user can securely store medical device records where they can be easily referenced in a short **DMR** document.

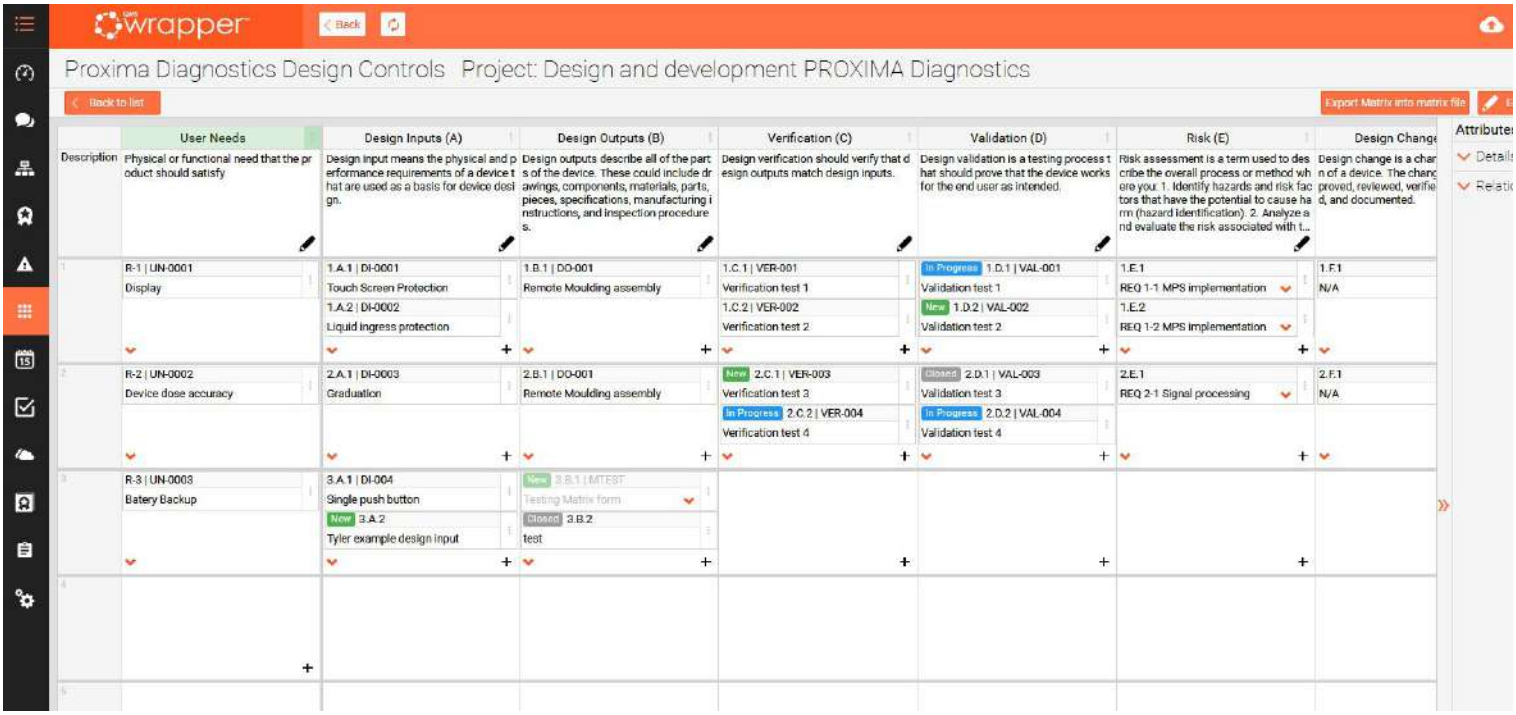
Traceability Matrix start:

(for more details please refer to the topic-specific "*qmsWrapper Best Practices-Traceabilty Matrix*" document)

Building a **Traceability Matrix** requires a bit of expertise, but can be manageable even to freshly-minted qms managers if a good basic layout is defined.

A short example: In the first columns the qms manager will define all requirements. Then, the requirement passes through development phase (development, integration and testing) , after the requirements goes to release. If the release is approved – flow ends for this requirement. If it isn't approved, or a change is required, then a new requirement is defined (for which the entire cycle begins again).

Please refer to this sample matrix:



In the **first column**, there are **defined requirements/user stories** (also, added sub-requirement column if main requirement is divided to smaller ones – this is optional).
You can **define your requirement with any available Traceability Matrix item** (for example Label item to state the requirement). Next, the Issue type item can be used, if your requirement is defined in some file (for example in your Word template) or you can use the Form Editor feature to make Forms which you'll use for defining requirements, then you can input those particular Form items.

The **next column** could be a **Development colimn**, where you'll insert development documentation (can be handled same as the requirements with all items).

If you have procedures in place, already defined that you follow through your development, you can use those. To make new process workflows please use the Process Editor feature, and start a process from this phase in the Matrix, once the process is designed it will lead you through the entire procedure flow with a single click.

Same refers to other phases – **Integration, Testing and Release**.

At the end, if you see that some **changes** are required, you can **de ine them in the last column** and describe your change.

After the changes were made, you'll define new requirements. You can even add **cross-reference** between items where change is defined with the new requirement.

For any further information please contact the qmsWrapper Customer Support team at: **contact@qmswrapper.com** or **tech.support@qmswrapper.com**

Best regards,
The qmsWrapper Helpdesk Team