Understanding how to understand QMS in

QMS wrapper™

Welcome to qmsWrapper™[1]!

qmsWrapper is built to help companies work in manner that will help them meet ISO Standards compliance in particular ISO 13485:2003 (2016 is in progress) and the FDA's QSR's (Quality System Regulations) for medical device companies.

Implementing qmsWrapper does not automatically make companies Regulatory or ISO compliant. qmsWrapper is an enabler technology that helps companies work more effectively as a team in an manner that makes it much easier and more likely to achieve the goal of ISO Standards Compliance.

However, companies must still implement for themselves all aspects of the compliance requirements as set by the Standards Regulations they aim to achieve. For example, qmsWrapper does not include a Quality Manual as required by most ISO Standards. However, for ISO 13485: 2003, it does include many of the work processes and the forms that are.

Each company must adapt qmsWrapper to its own particular needs, QMS processes and requirements. qmsWrapper helps Company's achieve these goals by enabling a management style, pioneered by UVA Research Corp, and incorporated into qmsWrapper, called Managing Through Quality™, or **MTQ** for short.

MTQ is not QMS. Rather, **MTQ** supports QMS. What's the difference? QMS specifically focuses more on quality outcomes, whereas **MTQ** is about the workflow processes that lead to those quality outcomes.

Note: almost any Quality Standard can be respected or enabled[2].

[1] qmsWrapper, qmsWrapper.com, Wrapper, WrapperApp, **Managing Through Quality**, **MTQ**, are trademarks of UVA Research Corp. and all right reserved worldwide.

[2] qmsWrapper enables project management based quality system compliance by teams. Compliance still requires full adherence to all the regulations contained in the Standard.

With **MTQ**, quality management is integrated with project management rather than implemented as a separate management layer in other words, **MTQ** is sewn into the fabric of team function so everyone works together using quality as the trigger, not only for how team works together, but also for compliance.

Quality reporting becomes more transparent thereby reducing the paperwork burden normally associated with Regulatory and ISO compliance.

To achieve **MTQ**, qmsWrapper combines the various modules including Quality Management, Project Management, Document Management, and Team Communications into one all-inclusive, integrated software. Integral to each is the preservation of process, the workflow, that is the proof of compliance adherence. But its focus is not purely on compliance but rather on fostering good management built on good teamwork, using quality as the glue that binds them into one process – and this is what makes compliance possible and easier. And this is the essence of **MTQ**.

Now that you understand the concept of qmsWrapper and **MTQ**, let's get a better understanding of the inner workings.

How **MTQ** is organized within qmsWrapper?

To the user, qmsWrapper presents itself as separate functions so they can better understand how the various functions work. qmsWrapper contains different elements including:

1. Team communication, a chat (and soon an optional Voice and Video app), that allows teams to communicate together, it is tied to projects, document storage, QMS and the calendar. In other words, it is integrated into all aspects of qmsWrapper
2. Project Management, a straightforward understandable project management software with all the essentials[2]

---

[2] By essentials we mean meet the needs of 99% of the needs most companies want. Wrapper is not everything to everyone… but it is essential to most.

3. A sophisticated Document Management System, that integrates not only with the project management, on a project by project basis, but also includes the user's desktop. A desktop App integrates directly into the project file structure. This is very unique and very useful to users. Do take a close look at it, as it's pretty impressive. On the surface it might look like a "dropbox" type app, but look again, its way more and its connected to the projects.

4. The calendar which connects users and projects to dates, deadlines and meetings. The online meetings can be recorded and saved in each project, topic, or both, thereby enabling easy follow-up for either management or compliance reasons. Meeting include agendas, with follow-to-completion functionality.

5. The QMS module, which is connected to all the other modules

Example: creating a task in To Do List you can connect with QMS
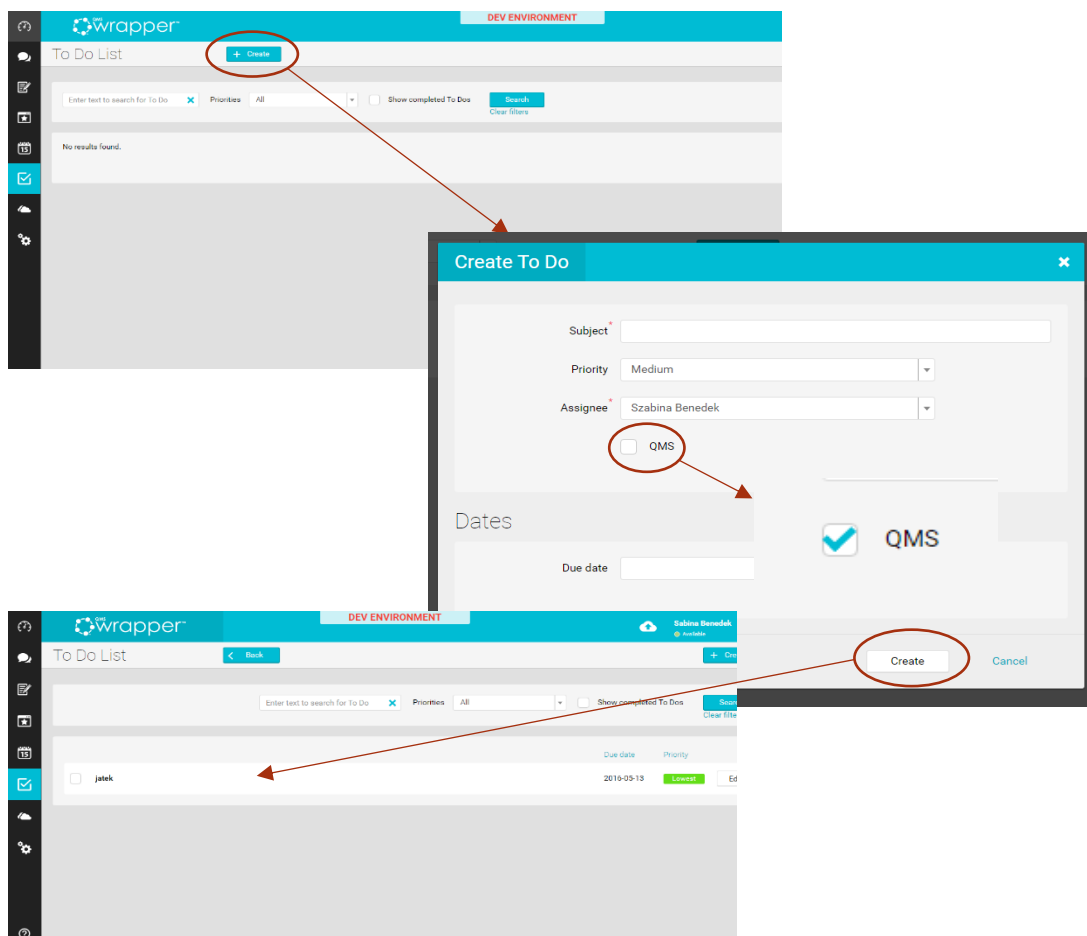
Connecting the Dots…

The Wrapper communications module enables users to chat with each other whether one-on-one, within groups, or by Topic (project related).

All chats can be saved and documented for compliance purposes and attached to a project, topic, user or issues, they relate to. For follow-up, chats are saved as meeting minutes, where they can then be used for the follow-up meetings. You can even create an agenda and tasks for the next meeting which is a big issue in compliance. An agenda issue not resolved in one meeting, gets carried over into the agenda of the next meeting.

From a chat you can also create follow-up task, "to-do's" or action items for follow-up.

Contacts   Topics   Recent

add topic   add To Do   save   add/remove user
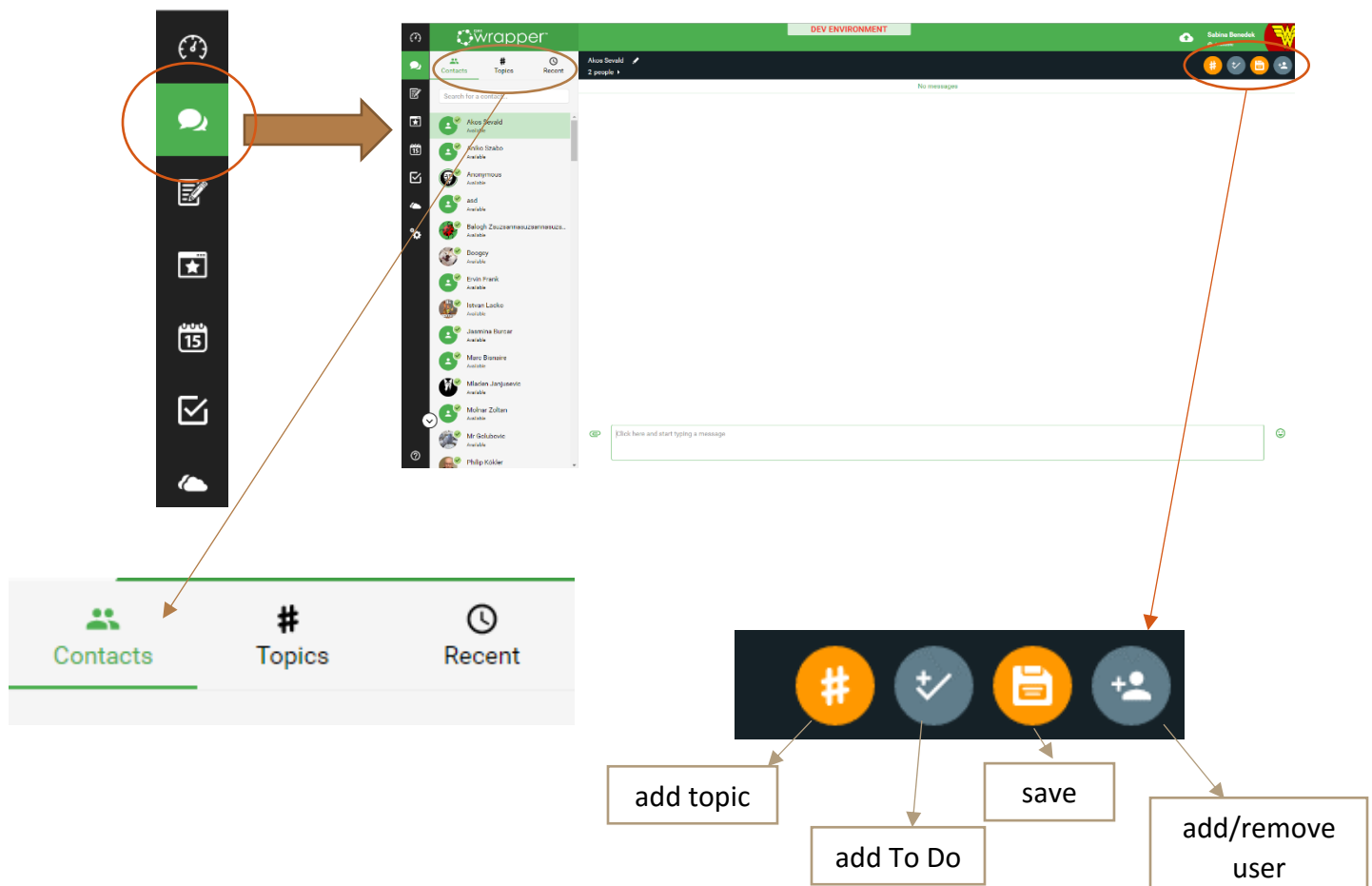
If a chat is related to a QMS issue, then, when saved, it will automatically trigger a QMS event which can then be monitored by the QMS manager who can quietly track the event and if required trigger a separate QMS task. For example, a chat related to a design change can trigger a QMS event which will trigger a DHF (Design History File) task for the appropriate manager, who must then review the change and update the required documents, including Requirement, Design and Verification and
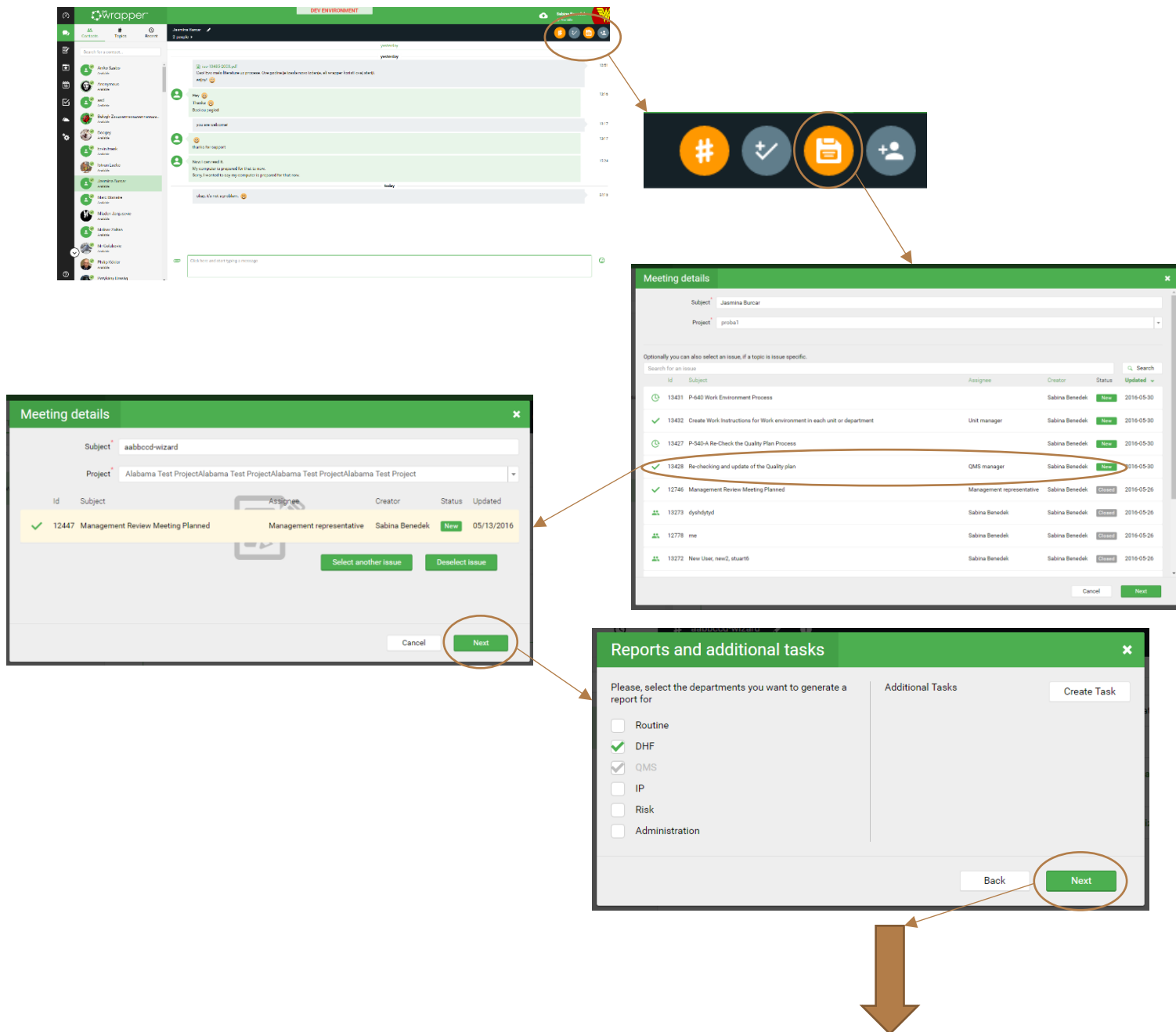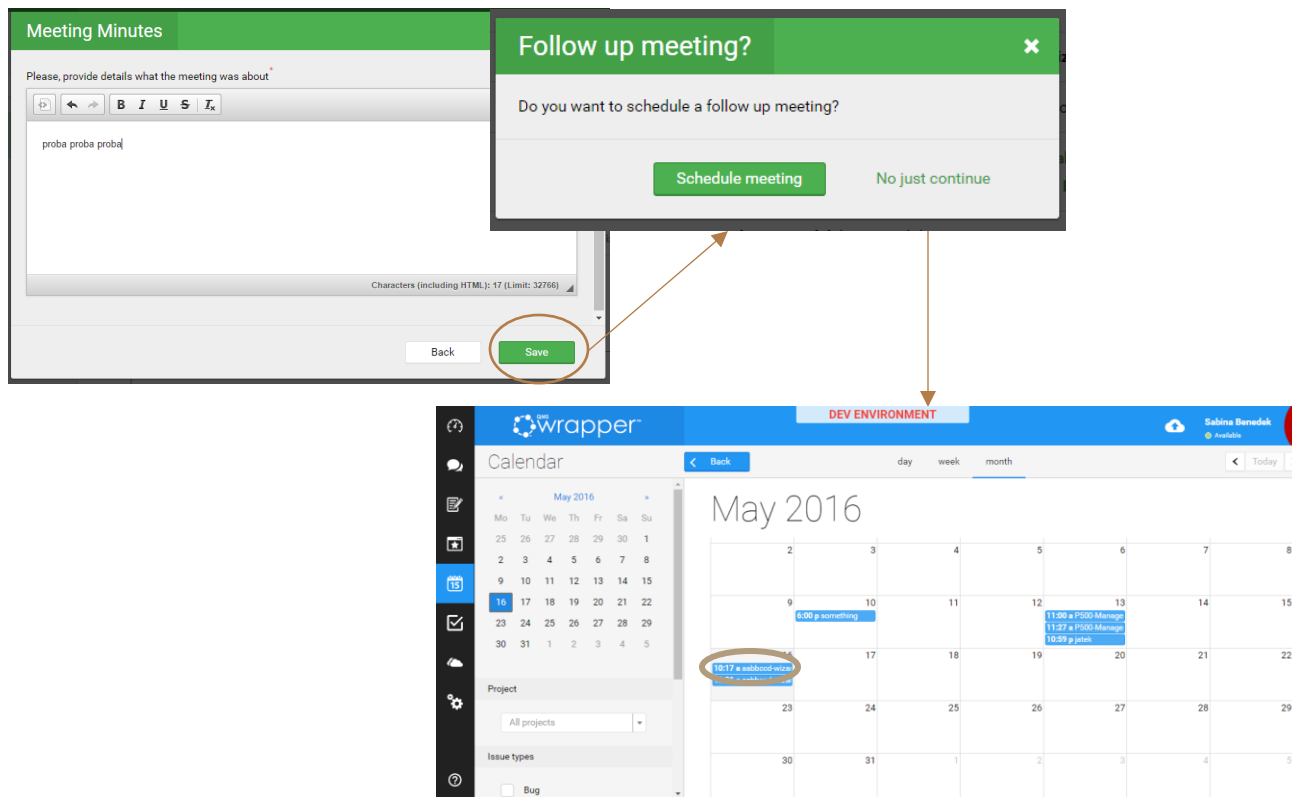
Validation. As each task is completed, the QMS process moves to the next level. When the QMS process is complete, in all its parts, the QMS manager will get a task to review it and authorize and or approve the change or process. If any other approvals are required, they are triggered and followed-up on.

QMS tasks are never lost, they must be completed "full-circle" and approved at some level. At all levels they are tracked and automatically recorded. Until they are closed, such QMS tasks are scheduled for follow-up meetings until closed at a QMS meeting. Unresolved tasks are automatically added to the regular QMS meeting agenda.

Wrapper is all about follow-up and follow-through.

The beauty of the system, is that the two users who started a process, don't have to chase it down through all its downstream steps and don't have to document the many layers of approvals or complete multiple forms. To them, it is all a transparent process.

These processes are defined by the ISO and compatible for use within FDA's QSR.

For the QMS manager, they don't have to chase team members for signatures or more likely just trying to figure out that a QMS change has happened in the first place. You know what I'm talking about here…

And this is the beauty of qmsWrapper. It all happens pretty seamlessly as if part of the Normal Project Workflow.

The paper chase needs no hounds.

QMS can capture and follow-through on these events. Users don't have to worry about them. Management, is informed of them. That's **Managing Through Quality**.

The QMS checkbox – User triggered QMS Event.

At a basic level, when the PM (project manager) or any user for that matter, creates a project task, or a sub-task they can either invoke one of 44 predefined ISO-13485/QSR processes, with more coming every week, or use a normal task issue and tick
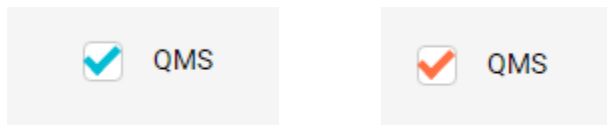
the QMS checkbox.

The Task QMS checkbox is the simplest and easiest way to trigger a QMS event. It flags for the QMS Manager that this issue needs their attention. It can be triggered in a number of ways, through a completion threshold, a date, or any number of triggers.

QMS checkbox events appear in the QMS section of Wrapper as an event that needs QMS attention, either some approval is required or simply acknowledging that the task is at a certain point and requires, or not, some action on the part of the QMS Manager or designated person. Its simple and straightforward. It is subtle unobstructed compliance.

A QMS checkbox event can also attach a QMS form to it, that the user can then complete and forward as required. A copy of the completed QMS form resulting from a QMS checkbox event will always be part of the history and recorded in the QMS Module.

But let's face it, users hate to fill out forms, so the QMS checkbox event will flag a QMS event for the QMS manager than can then create a QMS task for completing the required form and assign it to the appropriate team member. Pretty nifty huh!

From the QMS manager side, the QMS checkbox events appears in the project it is originated from. All projects created in the Project Management Module have a "mirror" project in the QMS module, where all QMS events for that project are tracked, recorded and actioned (it does not include all the regular project tasks and events).

The complete history of all QMS events for that project can be later save, printed or outputted as required. All QMS forms can be printed, including the work process showing what work was completed that results in the completion of the form.

Each projects history, whether normal events or QMS events can be printed and or outputted as required.

QMS Processes – the soul of pre-defined compliance

A second, but much more powerful option for QMS compliance are QMS Processes. QMS Processes is essentially a series of predefined QMS task or events that must be completed in sequence as defined by the ISO Standard, in particular for ISO 13485:2003 (2016 in progress) and compatible with FDA's QSR (Quality System of Regulations, 21 CFR 820 sections related to medical devices).

These ISO defined processes show the various events, in sequence, that need to be completed to meet the minimum ISO Standards. They are selected by either the project manager or the user and simply dropped into the project at the appropriate point.

The QMS process then automatically fills in all the subsequent tasks, reporting, workflows, managers, users and thresholds and triggers that are required, by the ISO standard. As one QMS Process defined event is closed, the next is automatically triggered and initiated and this continues until the Process is complete - all in accordance with the ISO Standard.

DEFAULT SETTING: qmsWrapper has already prepared 44 QMS Processes in accordance with the most common default setting that best meet the ISO requirements. However, you can use the Process Editor to change and modify them to meet your own particular requirements BUT it is highly recommended that you start by using the defaults.

When a QMS process is selected for use, you can be sure it meets all the compliance requirements for that process. qmsWrapper also has an optional add-on which qmsWrapper users can subscribe to, to ensure that qmsWrapper and the Processes are validated for use in accordance with ISO 13485: 2016. This can also be used by you to help validate it your own "intended use" in accordance with FDA QSRs.

Although QMS Processes meet the ISO Standard, users & managers alike must still complete their individual tasks as required of course, to ensure practical compliance.

The QMS Process Editor (available Mid-2016) will allow QMS managers to edit and modify existing QMS Processes and create new ones thereby allowing you to custom fit them to your particular requirements or adapt them to any ISO or QSR standard as required.

Document Management (DM) – An Essential QMS function

The DM module is pretty transparent to the user. It is however extremely complex beneath the surface as it automatically keeps files by project, conversation or both.

There are two pieces to DM. The Storage module found in the UI, and a desktop application called WrapperApp.

DM requires no setup. When you create a project, it is automatically mirrored in DM. Create a Sub-project and it is also mirrored in DM.

Access rights are set by role, so users with a specific role can edit their own files, but not delete them. Deletions are controlled by the Admin and the policy they establish. User files can be deleted from view but never truly deleted. Only an admin can permanently delete files.

Every document in DM is version controlled[3] and subject to the version control policy set by the Admin of the system.

WrapperApp complement the Storage (DM) in qmsWrapper. It is a desktop app that can be used to directly access Project Files and a user's own documents stored in Storage (DM). It keeps a local copy of what is Storage. Whatever project a user has security access to, it shows in the WrapperApp as a "local" directory. Users can access Document and Project files without having to upload and download them from Storage all the time. A Synchronizing function keeps the local Projects and User Documents updated with Storage automatically.

The WrapperApp is available for Windows, 32 and 64 Bit versions, Mac and Linux. It requires Java (latest version). It has an auto update function to keep it current.

The WrapperApp can be used by users for all their files or Documents, thereby providing them with an online and off-site backup. It is similar to other cloud storage software with one major benefit, it is fully integrated into the Projects and the QMS. No simple sharing here... Dropbox type of sharing is so... primitive by comparison.

---

[3] Version Control of Documents produced by 3rd parties can be tricky to version control especially because Word for example can auto save every 5 minutes. Each auto save copy would be saved, which is crazy and a 1 MB document could quickly become a 100 MB storage problem with no benefit. For complete details on how Version control is implemented, please see: https://www.qmswrapper.com/features
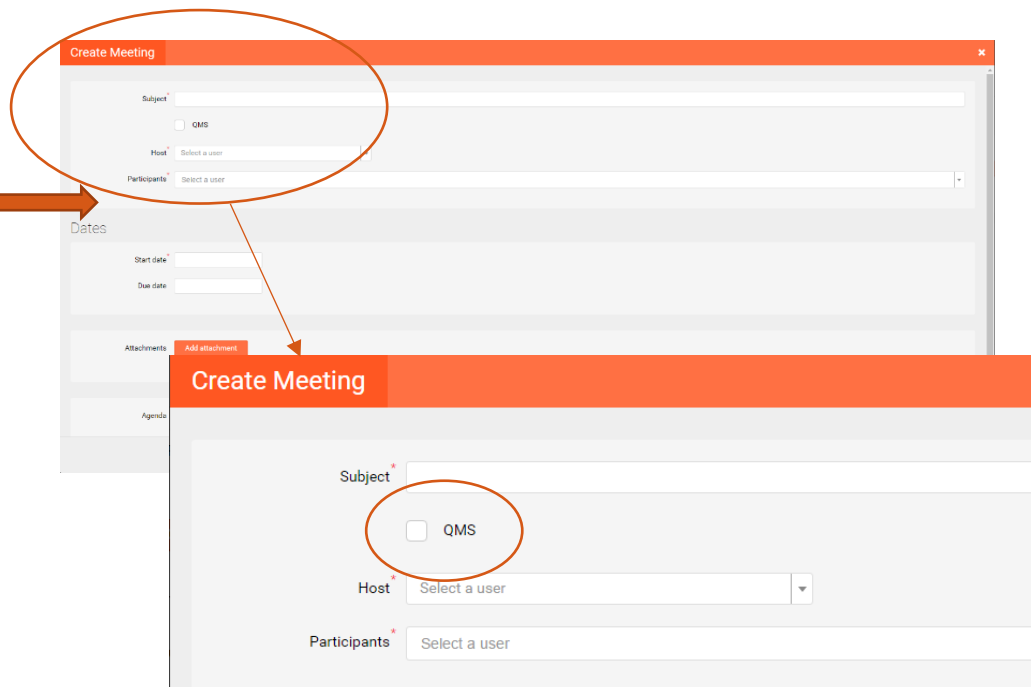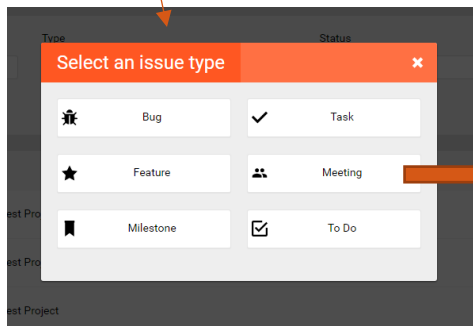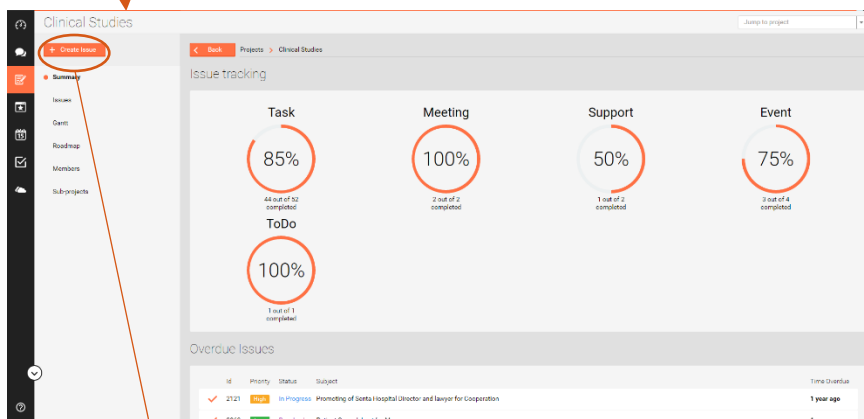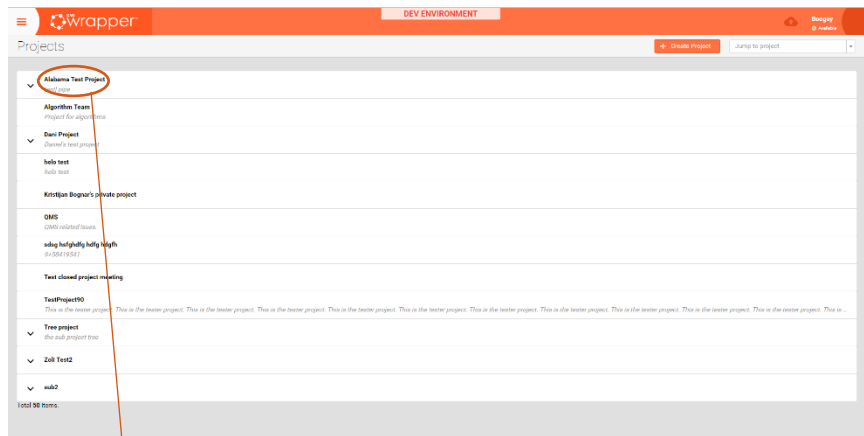
A Sample Project with QMS integration

Let's walk through the creation and setup of a qmsWrapper project and highlight how to include QMS achieve to **MTQ**.
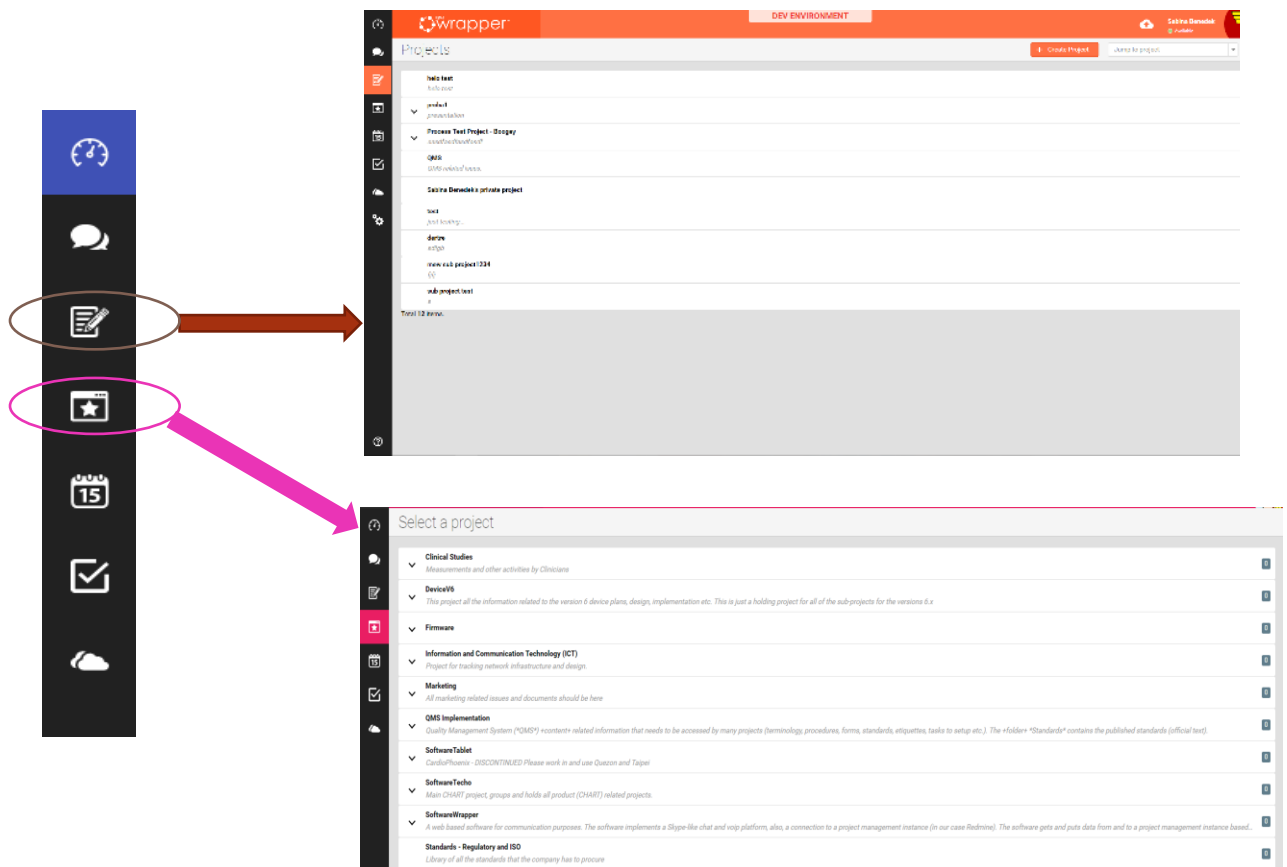
Example: connecting projects, meetings, tasks and other with QMS

QMS Processes – The heart of compliance

qmsWrapper processes follow the ISO guidelines and definitions, where defined, in support of the ISO requirements. In ISO 13485:2003 the ISO Standard organizes Processes by Function, which in their infinite wisdom, they also divided into number categories to help us better understand the type of QMS issue it is related to.

Processes are numbered by their function as defined in the particular chapter of the ISO Standard it is found.

For ISO 13485:2003, the function and forms convention is as follows:

P-1	Scope
P-2	Normative references
P-3xx	Terms and definitions
P-4xx	Quality management system
P-5xx	Management responsibility
P-6xx	Resource management
P-7xx	Product realization
P-8xx	Measurement, analysis and improvement

Legend: the "P"-xxx defines a QMS Process. If an "F"-xxx then it would be a Form related to that QMS Process (by number).

The 1st number or #, (after the P-#xx) related to the chapter in the ISO the QMS Process relates to. In the table above, P-5xx is a QMS Process related to Management Responsibility.

The xx numbers, relate to individual processes. It is strongly recommended you do NOT change the provided defaults, listed below.

The Letters (see below), relate to parts of one QMS Process. This makes it easier to splits tasks and create more efficient forms and processes.

The following QMS Processes are defined and included in qmsWrapper.

Each QMS Process is "approved" by the "QMS roles" shown in the right column. ISO is a little "role" crazy and it can be quite a challenge for Start-ups and Smaller medical device Companies. However, it is possible to assign more than one role to one person. This is easily achieved through the Admin Setup Wizard. The trick is being smart about it.

Process #	Process description	Process Reporting Manager
P-420	Document Approval	
P-540-A	Re-Check the Quality Plan Process	
P-550	Assignment of the Management Team Process	
P-560	Management Review Meeting Process	
P-622-A	Preparing Job Description Process	HR Manager, QMS Manager, Unit Manager
P-622-B	Competence, Awareness and Training Process	
P-630-A	Infrastructure- Equipment Problem Report Process	
P-630-B	Infrastructure- Equipment Maintenance	
P-640	Work Environment Process	CEO, Management, QMS Manager
P-710	Planning of Product Realization Processes	Management, QAR Manager, QMS Manager
P-720-A	Customer related Processes- Requirements	Management, Marketing and Customer Support (MCS), QAR Manager, QMS Manager
P-720-B	Customer Related Processes- Contract Amendment	
P-722-A	Risk Management- Approach Process	Management, QMS Manager, Risk Manager
P-740-A	Purchasing Process	Purchase Manager, QMS Manager, Unit Manager
P-740-B	Purchasing Process- Supplier Regular Evaluation Process	
P-750	Control of Production and Service Provision Process	Office Manager, QMS Manager
P-752	Validation of Processes for Product Realization Process	CEO, QMS Manager
P-753-A	Identification and Traceability- Requirements	
P-753-B	Identification and Traceability	
P-754-A	Customer Property Process	
P-755-A	Preservation Property Process	
P-755-B	Preservation of Property- Regular Inspection Process	
P-760	Control of Monitoring and Measuring Devices Process	QMS Manager
P-820-A	Post Production Feedback Process- Regular Quality	Customer Service Leader, QAR Manager, QMS Manager
P-820-B	Post Production Feedback Process- Compliant Received	
P-822	Internal Audit Process	Auditor Team, Lead Auditor, QMS Manager
P-824	Monitoring and Measuring of Product Realization Process	QAR Manager, QMS Manager

P-830	Control of Non-Conforming Product Process	QAR Manager, QMS Manager
P-840	Statistical Techniques Process	Management, QMS Manager
P-841	Root Cause Analysis Process	Management, QMS Manager, RCA Team
P-852	Corrective Action Process	Inspector, Purchase Manager, QAR Manager, QMS Manager
P-853	Preventive Action Process	Inspector, Purchase Manager, QAR Manager, QMS Manager
P-854	Product Recall and Advisory Notice Process	

Note: A QMS Process can have more than 1 QMS Role, some have 2 and again others 3 or even 4, as required.

It is critical to understand that Processes are driven by the QMS Roles. Rather than define individual users in the QMS Process, the QMS Role is used and assigned to users. A role can therefore be assigned to any user, as appropriate.

Some users can be assigned multiple roles with no conflicts of interests or function, very useful for smaller companies. For example:

- CEO or President
- CTO and PTO (Chief, or Company, Technical Officer and Project Technical Officer)
- Reporting Manager (Snr Exec, Director, Division Manager, as appropriate for your team, etc.)

- QMS Manager
- QAR Manager (alternate, QMS Manager)

- Project Manager
  - Manager. A Manager within a Project (Not ISO defined, but defined within a project. Has certain functional rights, i.e. can create a sub-project)

- Risk Manager

- HR Manager
- Office Manager
- Purchase Manager

- Marketing and Customer Support (MCS)
- Customer Service Leader

- Design Review Team

- Auditor
- Lead Auditor
- Inspector
- RCA Team

For example, in Start-ups and Small Companies, the CEO, CTO and Reporting Manager, can be the same person. E.g. one of the founders.

For more insight on assigning roles see:

https://www.qmswrapper.com/blog/understanding-roles-processes-in-iso-134852016

However, a few notes here. First, bite the bullet and get a QMS Manager. One person only for this role. Compliance is a big challenge; this role screams for single-minded purpose – compliance… will "… not be ignored, Dan[4]".

Risk Manager, this QMS role should NOT be piggy-back assigned to the QMS Manager. What does the QMS Manager know of the risks associated with the product and how to mitigate them. Rather this role is best assigned to either a Product Manager, a Manager or even a senior developer (project level) who would all know more about the product in question.

Other roles are more straight forward and easier to understand how to combine, especially when warm and available bodies within a company are rather scarce.

---

[4] Reference to the 1987 thriller movie, Fatal Attraction. You cannot cheat on compliance.

The initial Admin Start-up Wizard, helps admins define QMS Roles and assign users to them. Note: QMS Roles are defined to groups, so being part of the group, give the user that role.
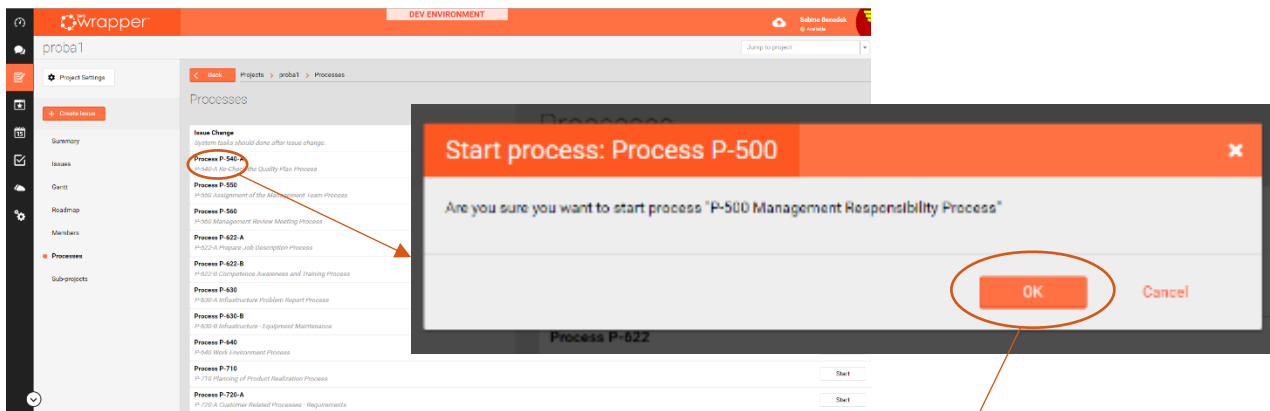
Example of ISO process in qmsWrapper:

Start process: Process P-500

Are you sure you want to start process "P-500 Management Responsibility Process"

OK   Cancel

These are the steps what the user sees
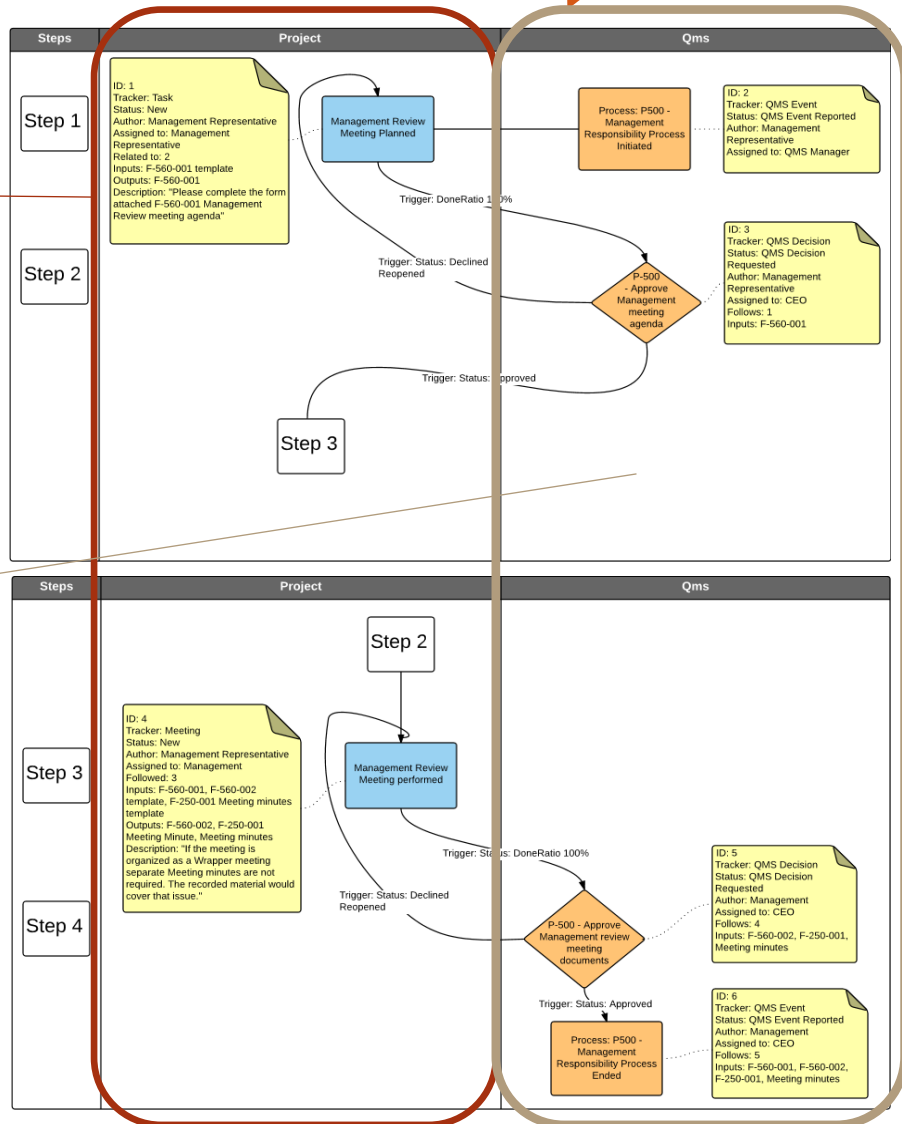
Steps that only the QMS manager sees and here he/she can decline or approve a document

Steps	Project	Qms
Step 1	ID: 1 Tracker: Task Status: New Author: Management Representative Assigned to: Management Representative Related to: 2 Inputs: F-560-001 template Outputs: F-560-001 Description: "Please complete the form attached F-560-001 Management Review meeting agenda"	ID: 2 Tracker: QMS Event Status: QMS Event Reported Author: Management Representative Assigned to: QMS Manager
Step 2	Management Review Meeting Planned	ID: 3 Tracker: QMS Decision Status: QMS Decision Requested Author: Management Representative Assigned to: CEO Follows: 1 Inputs: F-560-001

Process: P500 - Management Responsibility Process Initiated

Trigger: DoneRatio 100%

Trigger: Status: Declined Reopened

P-500 - Approve Management meeting agenda

Trigger: Status: Approved

Step 3

Steps	Project	Qms
Step 3	ID: 4 Tracker: Meeting Status: New Author: Management Representative Assigned to: Management Followed: 3 Inputs: F-560-001, F-560-002 template, F-250-001 Meeting minutes template Outputs: F-560-002, F-250-001 Meeting Minute, Meeting minutes Description: "If the meeting is organized as a Wrapper meeting separate Meeting minutes are not required. The recorded material would cover that issue."	ID: 5 Tracker: QMS Decision Status: QMS Decision Requested Author: Management Assigned to: CEO Follows: 4 Inputs: F-560-002, F-250-001, Meeting minutes
Step 4	Management Review Meeting performed	ID: 6 Tracker: QMS Event Status: QMS Event Reported Author: Management Assigned to: CEO Follows: 5 Inputs: F-560-001, F-560-002, F-250-001, Meeting minutes

Step 2

Trigger: Status: DoneRatio 100%

Trigger: Status: Declined Reopened

P-500 - Approve Management review meeting documents

Trigger: Status: Approved

Process: P500 - Management Responsibility Process Ended

If a process is <u>approved</u> by the QMS manager, it looks like this:

If a process is <u>declined</u> by the QMS manger, it looks like this:

When a <u>QMS event</u> is created and <u>needs to be checked by the QMS manager</u> (it cannot be approved or declined):

Management Responsibility Process Initiated

Details

Type	QMS Event
Status	New

If a process is waiting for <u>approval/decline from CEO/QMS Manager</u>, it looks like this:

P-622-A Approval - Approve Job Description

Details

Type	QMS Decision
Status	New

Why qmsWrapper?

It's simple, it simplifies compliance. It makes compliance a team based responsibility without adding another later of management.

By combining the best of what's essential is Project Mangement, Document Management, Quality Management and Team communications, it transforms simple to use software into a real productivity booster. No longer is compliance simply someone elses responsibility, it's a team responsibility shared by all members, not the punished.

Managing Through Quality unburdens Management and allows them to blend compliance into product development. Objectives become more achievable. Compliance, no longer an after-thought.

Every correctly finished QMS Process, brings the company a step closer to ISO 13485/FDA compliance and the final product.

After all, compliance is not the main objective, but if you don't get it right, it's would be like driving your Bugatti Veyron into a cement wall at 200mph on the road to success. Compliance will "…not be ignored, Dan!".

qmsWrapper, making MTQ, a formula for success.