QMS wrapper™

Project & Quality Management System

for achieving and maintaining:

- **ISO 13485:2016,**
- **CE Mark,**
- **FDA QSR's (21 CFR 820)**

The backbone of a successful FDA or CE Mark submission is the QMS it is built on. Increasingly, the emphasis is on managing quality as ISO 13485:2016 certification is pathway to a successful medical device submission.

qmsWrapper helps you both organize and manage the development of your product and also to keep your commitment to quality.

qmsWrapper does this by integrating and ***combining Project and Quality management*** together as one, easy to use and understand system, software.

Built to help you manage your medical device development and get it to market faster. It helps you organize, manage, track and cooperate your team to help you get you through product certification faster.

FYI. Easily adaptable/customizable to ISO 9001.

QMS wrapper™

QUALITY BECOMES NOT JUST A BUZZWORD BUT A MEANS **TO GET THINGS DONE.**

IT TRANSFORMS COMPLIANCE FROM CONCEPT INTO A TRUE COMPETITIVE ADVANTAGE.

Companies that embrace quality, succeed!

qmsWrapper™ meets essential needs of **MedTech companies.**

It is particularly well suited for:

- **Start-ups and Smaller companies**

Developing Class I, Class II, and DeNovo (seeking Class II) devices and seeking 510(k) or De Novo clearance

- **MedTech companies**

Developing CE Class I, Class IIa and Class IIb and seeking CE Mark

- **Managing projects with the following compliance needs:**

FDA QSR 21 CFM 820,
ISO 13485:2016
ISO 14971:20xx
IEC 62304:20xx

qmsWrapper™: an all-inclusive integrated software that includes:

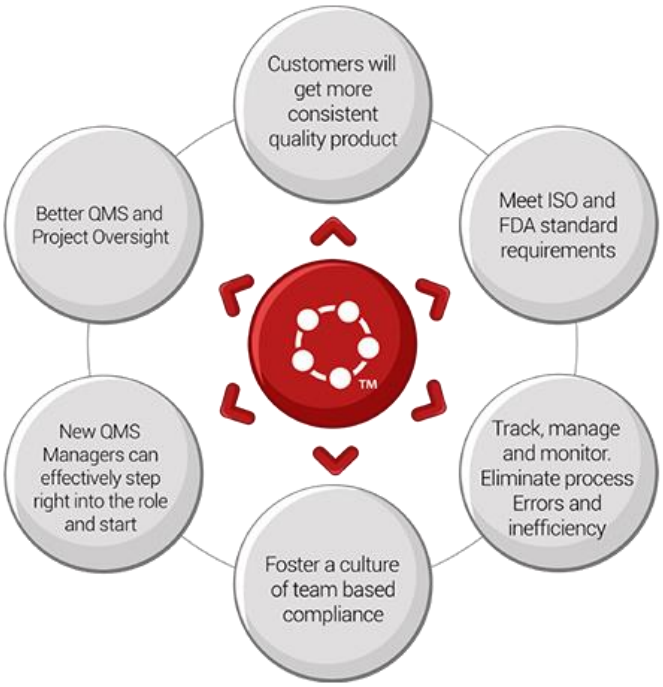
- **Quality Management Module (QM)**
- **Project Management Module (PM)**
- **Document Management & Control Module (DMC)**
- **Risk Management Module (RM)**
- **Team Communication Module (TC)**
- **Forms and Form Editor**
- **Quality Manual Creator and GAP Report tool**
- **Traceability Matrix (TM)**

...**it effectively eliminates the need for multiple software applications** and separate, "bolt-on", quality system add-ons.

- Each module exists both as a separate module so you can work within each as needs arise, but also, they exist as highly integrated and interconnected to maximize productivity and provide a seamless team based compliance experience.

- The advantages of such an integrated PM+QM system is that FDA or ISO compliance is not limited to "reporting" or to the tracking of reports, but rather they are integrated right into your workflow processes directly, **so quality becomes everyone's business.**

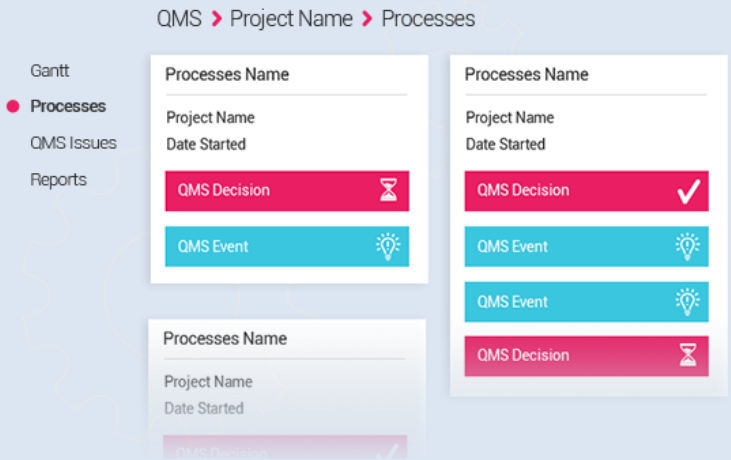
That's Managing Through Quality (MTQ).

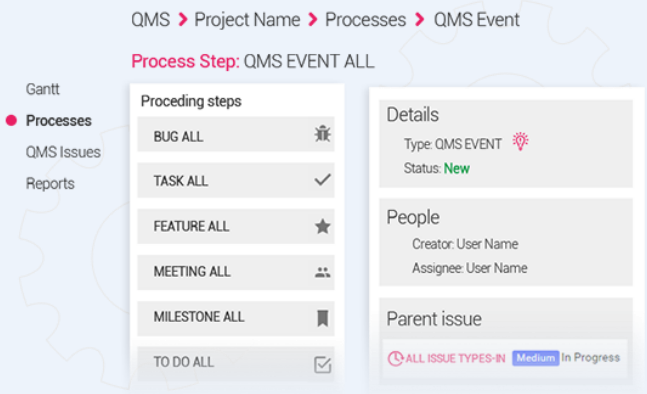


Quality managers with little experience or knowledge of the supported Standards, can easily step into the role and effectively start.

QMSWRAPPER PROVIDES A **STEP-BY-STEP** SEQUENCE OF TASKS WITH APPROPRIATE EXPLANATIONS, AND CAUTIONS, TO HELP QMS MANAGERS CORRECTLY PERFORM THEIR JOB.

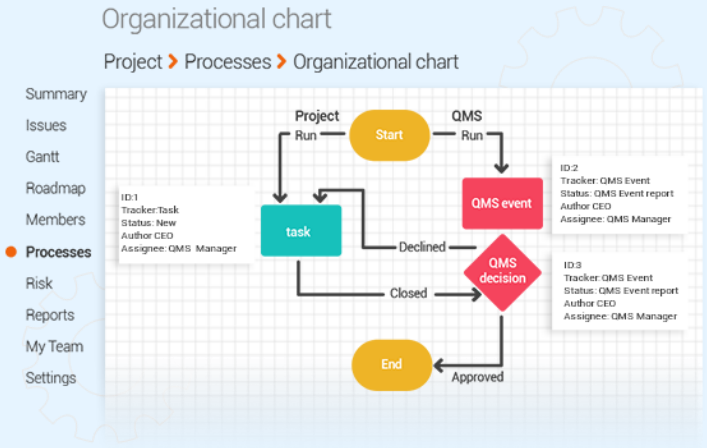
➢ Workflows Processes define the many steps needed to complete a set of Quality requirement tasks – without missing a step.
The QMS Workflow Processes help reduce errors, forgotten paperwork, missed QMS reports.
Users know exactly what to do when to do it, and how to complete a compliance requirement within their assigned set of project tasks, that are monitored and managed by management automatically.



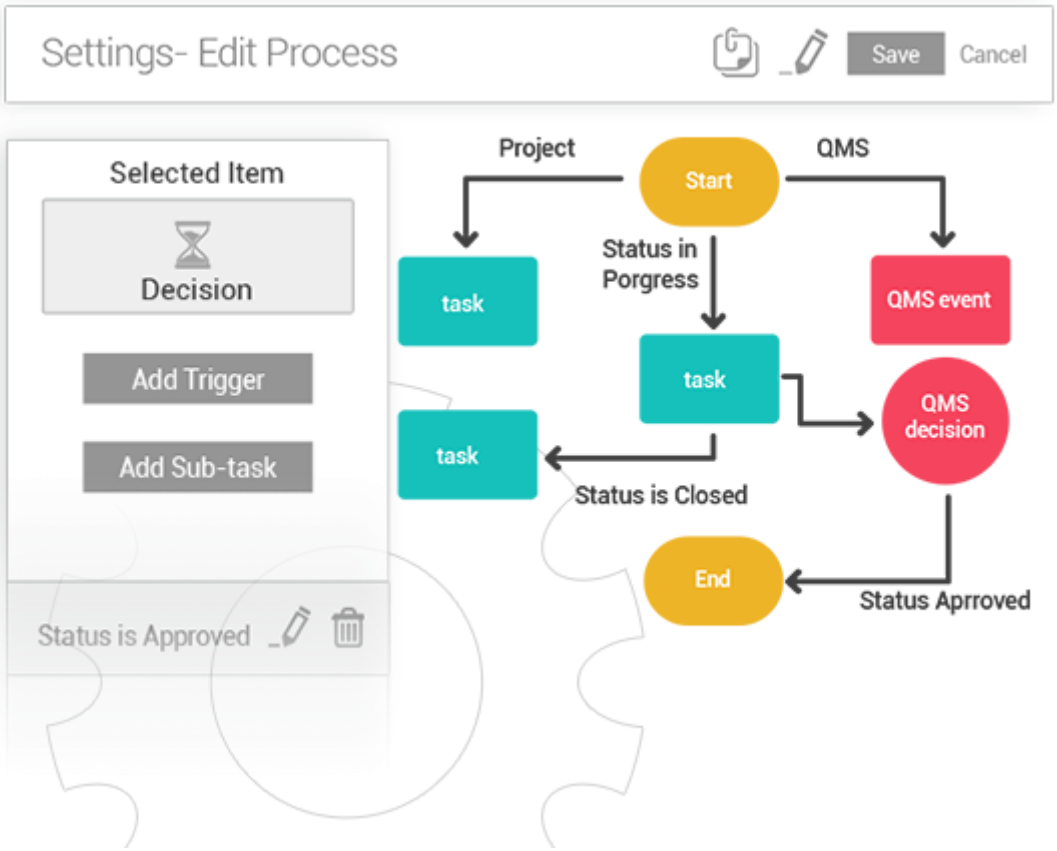


➢ In qmsWrapper, the QM module virtually mirrors the PM and the DMC modules, tracking all the QMS events for each of the projects as they are defined in the PM module.
This mirrored approach means a QMS Manager does not need to chase the project members for compliance issues – rather the issues come to them.

➢ There is no need for the QMS manager to shadow the Project Manager.
There is no QMS paper-chase.
➢ The flip side of this approach is that project members are automatically included in the compliance process, as the QMS workflow processes will automatically include them in whatever compliance issue is necessary and at what point it is necessary, including identifying what form to complete and what to do with it.



A **QMS Processes Driven Project Management** ensures that the projects are managed in a most efficient way. **qmsWrapper** includes ready-made process workflows that are defined according to the ISO and FDA standards.



➢ To further improve flexibility,
we built an ultimate Process Editor
that allows customers to customize
the default QMS Processes or SOPs
to fit their company's particular workflow needs,
or build new processes from scratch,
just by following a few easy and simple steps.

The QMS documentation – especially for a complex project – can be endless and daunting.

qmsWrapper is designed to find a needle in the haystack, any document can be listed and filtered only for the desired process, furthermore, all document searches are fast, and results are returned immediately.

- A comprehensive DMC includes file version control, detailed history, tracking, tagging, comments and authority control, full support for document search.

- Secure data management with **QMS Vault, ERES**, and **role-based permissions** access.

- Includes a built-in **Quality System Manual builder tool**.
The Quality Manual defines the qmsWrapper and the processes used.

Certification audits all start with the manual, now the manual is the start of qmsWrapper.

This tool simplifies the process of establishing the quality manual that correlates directly with qmsWrapper and the Processes used.

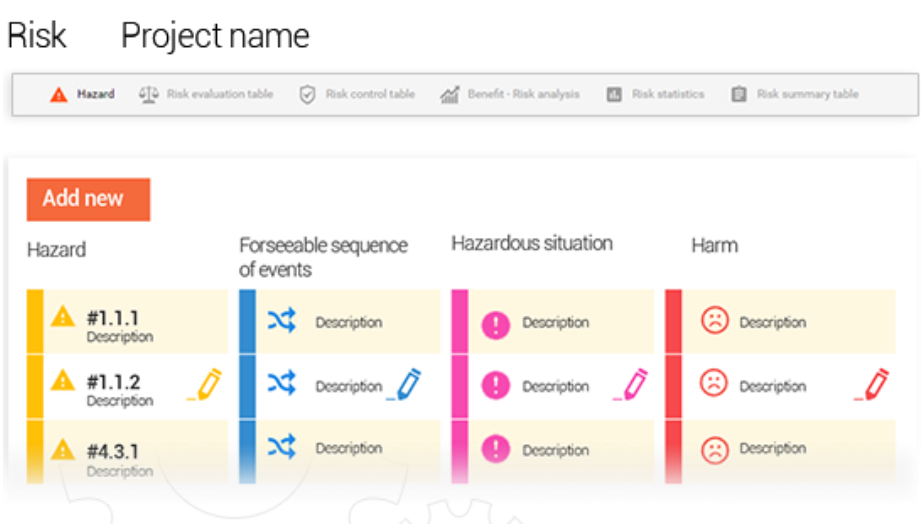
IT WILL SAVE HUNDREDS OF HOURS OF DOCUMENTATION WORK FOR YOUR TEAMS.

ISO 14971 based flexible Risk Management,

where you can **create your own Risk Analysis in any process**, and define your own risk varieties and action plans.

It was built with an integrated approach to manage risk across an organization.

It's flexible so it can be appropriate and proportionate to the complexity and type of organization involved.



The continuous improvement, Tracking and measuring of your operations inevitably leads to an increase In productivity and efficiency.

qmsWrapper, makes the process of achieving and maintaining ISO, CE Mark or FDA compliance as painless as possible, without the need for a 2nd bureaucracy to manage it.

If you're ready to get serious about your quality management and product development efforts, qmsWrapper is your solution

START MANAGING THROUGH QUALITY TODAY!

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