



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. qmsWrapper is adjusted to ISO 9001, too. Check [here](#).

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:

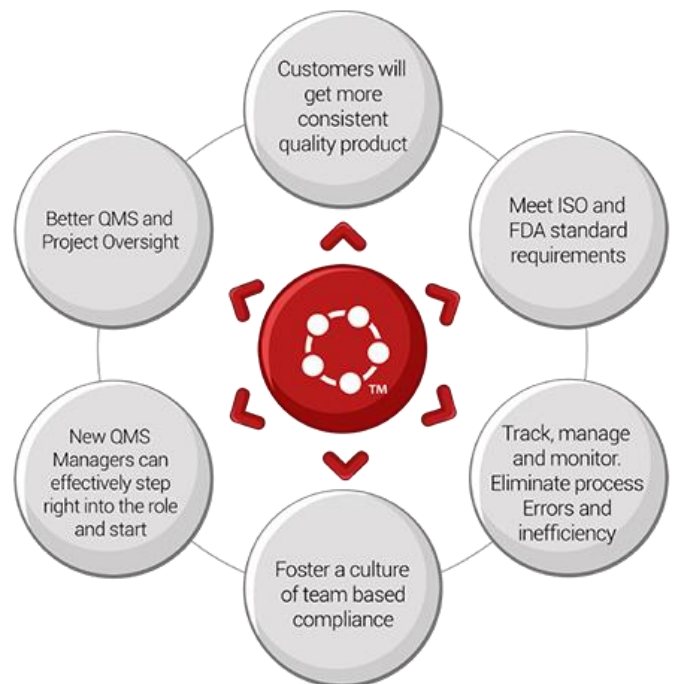
- **Quality Management Module (QM)**
- **Project Management Module (PM)**
- **Document Management & Control Module (DMC)**
- **Risk Management Module (RM)**
- **Team Communication Module (TC)**
- **Forms and Form Editor**
- **Quality Manual Creator and GAP Report tool**
- **Traceability Matrix (TM)**

...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.

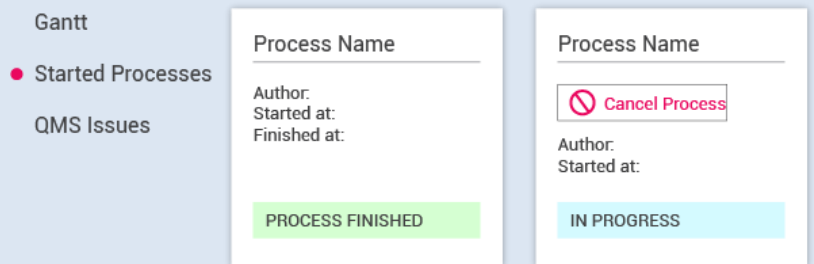
QMSWRAPPER PROVIDES A **STEP-BY-STEP** SEQUENCE OF TASKS WITH APPROPRIATE EXPLANATIONS, AND CAUTIONS, TO HELP QMS MANAGERS CORRECTLY PERFORM THEIR JOB.

➤ Workflows Processes define the many steps needed to complete a set of Quality requirement tasks – without missing a step.

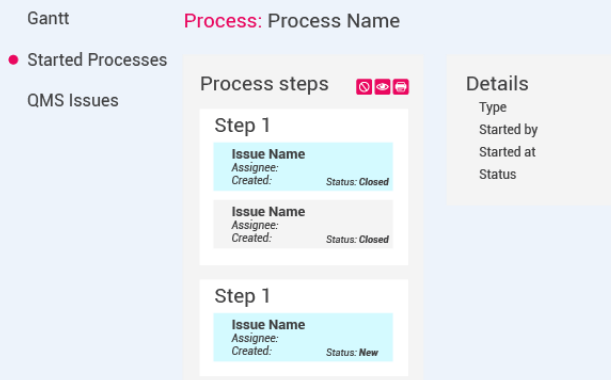
The QMS Workflow Processes help reduce errors, forgotten paperwork and missed QMS reports.

Users know exactly what to do when to do it and how to complete a compliance requirement within their assigned set of project tasks, which are monitored and managed by management automatically.

QMS > Project Name > Processes



QMS > Project Name > Processes > Process Name

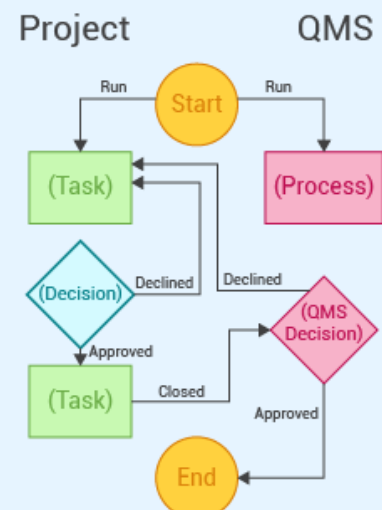


➤ In qmsWrapper, the QM module virtually mirrors the PM and the DMC modules, tracking all the QMS events for each of the projects as they are defined in the PM module. This mirrored approach means a QMS Manager does not need to chase the project members for compliance issues – rather the issues come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

Process CHART



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.

Settings > Processes

(Process templates)

Name

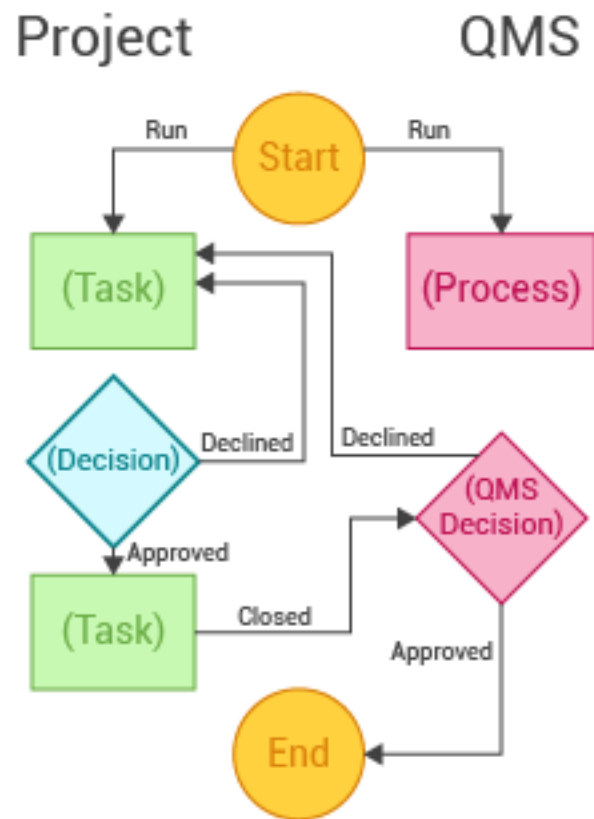
P-340 14971
Process description

P-412
Process description

P-416
Process description

P-423
Process description

...



➤ To improve flexibility, we developed 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.

More about the **eQMS for MedDev**, find out [here](#).

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.
- The **Wrapper File App** is developed to make file/document editing easier and safer.
- 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.

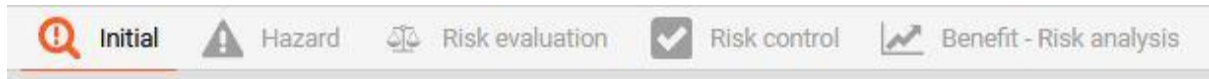
This tool simplifies the process of establishing the quality manual that correlates directly with qmsWrapper and the Processes used.



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

Risk Management - ISO 14971

qmsWrappers Risk Module is encouraging you to focus on the relationship between requirements and design, with emphasis on risk-based design.



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!