



"Management is, above all, a practice where art, science, and craft meet."

Henry Mintzberg

New product development success depends on efficient and effective project management.

It can be a challenge in smaller companies, because typically one person is handling multiple products and multiple teams.



GET THINGS DONE!

Track, Manage and organize your projects and your teams!

qmsWrapper was invented by medical device developers to meet the needs of medical device developers.

And that means project management that not only helps you stay in control, but also to help you stay FDA and ISO compliant.

It's an integrated software that includes six main modules:

- **Project Management,**
- **Document Management & Control,**
- **Quality Management,**
- **Risk Management,**
- **Traceability Matrix and**
- **Team Messaging.**



They are separate so you can work within each module as needs arise but, they are highly integrated and interconnected to maximize productivity and provide a seamless team based compliance experience.

The Project Management module:

- Has everything you need to organize, create and manage projects: plan it, track it, discuss it, act on it.
- Divide projects into manageable parts, subprojects, and tasks.
- Create Connected related and dependent tasks so teams can work independently but together.
- Create joint tasks, where many tasks need to be completed to move the project along.
- With **form editor**, you can create Issue templates (**Custom issue forms**) that can save your time and simplify data recording.



- Data collected using Custom Issue Forms can be easily converted into reports that you can export.
- You can easily find recorded events using the filters available in the projects.
- Clear accountability, **flexible workgroups** with **customizable roles** by project.
- **Versioning, Milestones, Roadmaps, and Gantt charts** to help you see the big picture and understand the project status.
- Organize **workflows, schedule releases** and track which issues relate to different releases of the product.
- Defined **QMS workflow processes** can jump-start your project - they make ISO 13485 and FDA QSR compliance easier.
- With the built-in qmsWrapper Workflow **Process Editor**, you have the freedom to build your own Workflow processes to suit your specific project or QMS needs.
- Documents are controlled and stored according to their respective projects, which makes it easier for the Team to find.
- Standards Documents can be placed in the common libraries, to make them available throughout your organization.
- The **Dashboard** provides a detailed, real-time visual overview of all the users tasks, reports, and assignments, to help them keep track of **milestones, QMS issues, deadlines, upcoming events, to-dos, and due dates** at a glance.
- For a real-time visual overview of all user tasks, there is a **“My Team”** function, that shows percentage done, reports and assignments. You can monitor who does what, with what efficiency. You can instantly identify any overlaps in the work and easily reassign tasks as needed, follow the over-all productivity and keep track of them.
- Projects in the Project Management Module are **mirrored** in both the Document Management Module and the Quality Management module where all QMS events for any project can be followed, monitored, and tracked by the QMS Manager. Also, with the QMS **approval workflows, automatic notifications** are sent to the QMS Manager for action.



- Built-in Team Messaging is **designed to support Team compliance**. Messages and files included in chats can be linked into particular projects or tasks -- the simplest way to document any issue. **For Compliance** purposes, you should save any Chat as a meeting to a particular project complete with follow-up actions. Remain one step closer to full compliance.
- The Project Management Module is directly connected to the **Risk Management** Module to ensure ISO and FDA compliance.

qmsWrapper is team collaboration and cooperation, FDA and ISO 13458 compliance and project productivity all wrapped into one.





Managing Through Quality (MTQ)

The new science of Managing for Compliance

QMS focuses on quality outcomes, but Managing Through Quality (MTQ) is about managing through the **QMS Workflow Processes** that lead to those quality outcomes.

In qmsWrapper, Quality Management is integrated with Project Management, Document Management, Risk management, and Team Messaging rather than implemented as a separate management layer – in other words, QMS is sewn into the very fabric of qmsWrapper.

This level of QMS integration means QMS Workflow Processes interact and interconnect with all parts of qmsWrapper, thereby making MTQ possible.

The integrated Team Messaging ensures everyone works together towards those quality outcomes fostering a culture of team-based compliance.

MTQ cultivates Good Management Practices (GMP) by encouraging good teamwork using quality outcomes to unite them in the innovative science of Managing for Compliance.