QMS for Beginners

A quick guide on where to start, and what to do first

QMS wrapper™

Whether you are freshly minted into the QMS position or the founder of a Medical Device Startup, you're reading this because your strategy requires **QMS** oversight and your first question is likely **"where to start"!**

This white paper will cover the aspects of:

Compliance with

ISO 13485:2016 for CE Mark and

FDA QSR (21CFR 820) for 510(K)

- Step by step guide – explained in 13 points

Checklist summary

- Steps for Implementing ISO a Quality Management System

- Checklist for implementing ISO 13485-2016

1. Figure out what QMS you need

FDA QSR, ISO 13485: 2003, ISO 13485: 2016, or ISO 9001: 2015.

- Secure a copy of the Standard you intend to be compliant with.
- Get somewhat familiar with its about, you need a general idea of what is expected before you can understand why.
- Get a feel for the technical language they use.

For example; both FDA QSR or ISO 13485: 2016, are based on principals of Risk Management, so you also need to also secure a copy of ISO 14971 Risk Management.

Then find the TR 24971 Risk management examples, yup, got ya twice they did.

2. Designate a QMS Manager (that's you in the mirror)

Designate the QMS Manager.

But if you want them to be effective, find someone who enjoys administration and documentation - yes, they do exist! They even think its fun!

As the founder, you're going to have to stay involved, especially in the initial phases to ensure QMS is "seen" as a priority, you need to keep it front and center as an important priority – which it is for all MD companies.

So, plan ahead now, when it's easier, don't wait 'til later, when it's so much harder.

3. You will need a QMS manual (a.k.a your Quality Bible)

The first thing auditors want to see is the **Quality Manual**.

In the QMS manual, you will **outline the various policies and procedures** your company and teams will follow to produce quality outcomes.

This will include:

- How you will measure quality
- How will you define risk
- How to correct mistakes and prevent them with what actions (CAPA or Corrective Actions, Preventative Actions)
- etc...

The QMS manual will also **define the various roles** that are needed within the company which connect to various responsibilities related to QMS. Basically, who is responsible for what and how.

The QMS manual then becomes your "go-to" book on what to do, you're quality bible.

The GAP Analysis – The difference between what you said you would do, and what you did do... (or not!)

You should realize that **the QMS Manual drives the GAP Analysis**.

It will point out the differences between what you said you would do to ensure Quality outcomes and the processes that you execute on and what you have done to ensure Quality outcomes.

The GAP is what you are missing!

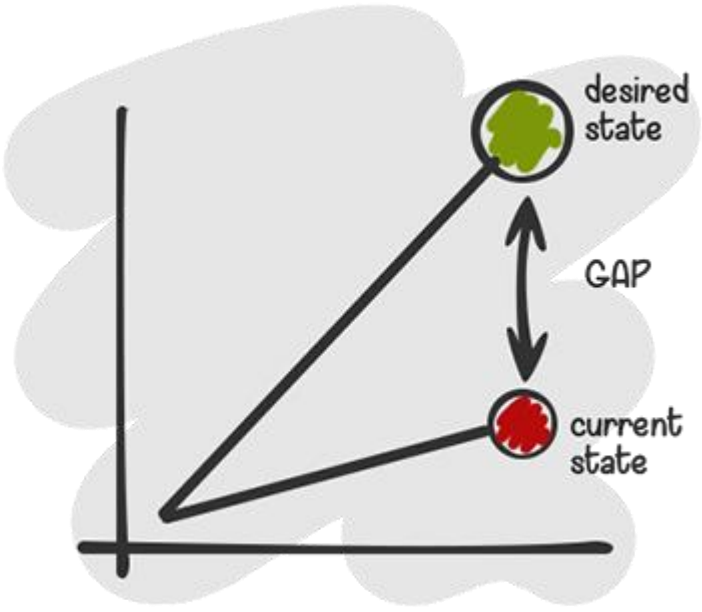
qmsWrapper GAP Analysis has 2 advantages :

1. When you subscribe for qmsWrapper you can choose optional add-ons, like the QMS Manual and the GAP Analysis Module (checklist)

   Not only does this represent a huge saving in costs, they can be very pricy to buy directly, the real cost, however, is in time – yours and your teams.

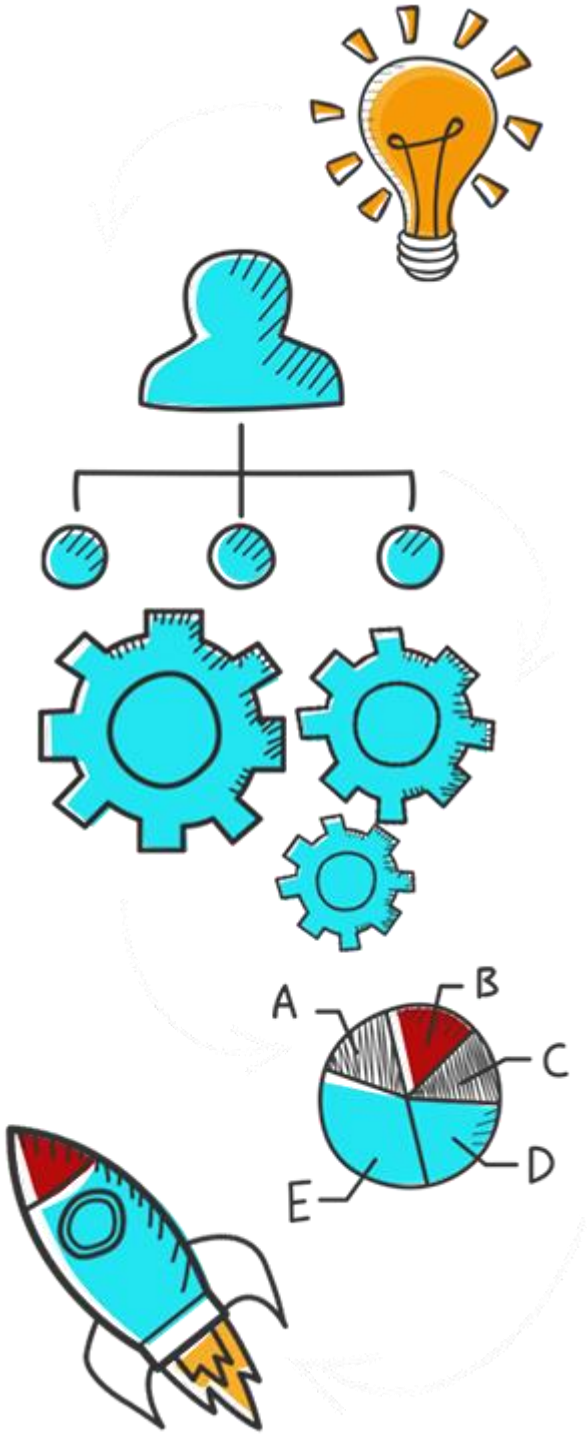
2. The second big benefit of using the QMS Manual from qmsWrapper, is that ***it is integrated into and throughout the qmsWrapper software***. What you document in the QMS Manual is reflected in the qmsWrapper application, in particular through the QMS Workflow processes. So, what's in the manual is executed in the Workflow processes.

Both the Manual and QMS Workflow processes, are integrated into the GAP analysis Module.



4. QMS Workflows Processes that Organize the work

Next, you will need to **define the flow of how work gets done within your organization**, i.e. the **workflows**.



A workflow process is a series of predefined tasks organized in steps, automatically initiated, and to be sequentially followed. Such workflows processes help reduce work-related errors and provide documented trails or records of what was done, by whom and when – ideal for compliance.

What is important for you is that **Workflows and processes can include QMS rules and requirements** defined as QMS events or issues or tasks.

In qmsWrapper, they are specifically called QMS Workflow-Processes and represent the easiest way of achieving Compliance.

In qmsWrapper, Workflow Processes for ISO 13485: 2016 and FDA QSR, are included.

Also, the Wrapper Workflow **Process Editor** allows you to create your own or edit/modify the existing ones.

This gives you the flexibility and power of an enterprise level system, ideally packaged for any small to the medium-sized company including Startups.

5. Software or paper-based Quality Management System

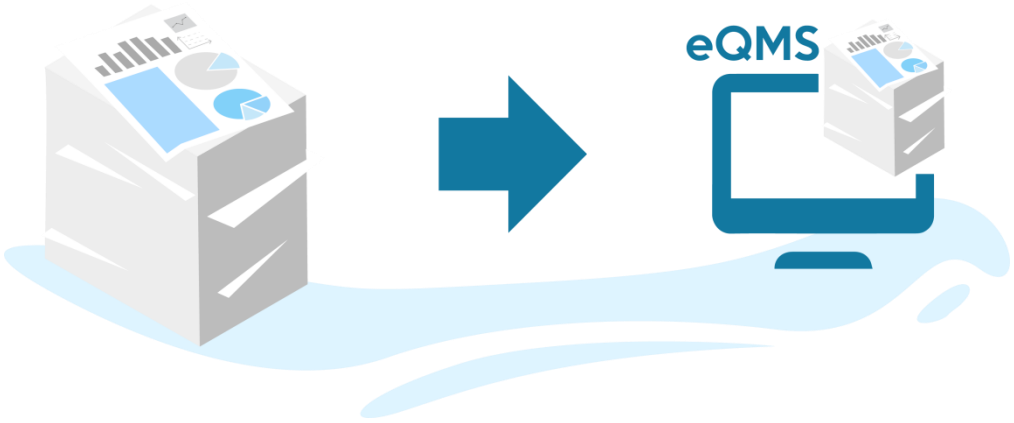
The main reason for companies to migrate from paper-based to a computerized system is usually related to either the increasing cost of personnel or lack of trained personnel.

Startups and small companies understand the HR problem clearly.

The reality of today is that you should start with an appropriate QMS software, it's easier than a paper-based system.

qmsWrapper has built-in all the rules and procedures for Compliance.
Just add your own tasks.

With qmsWrapper you don't have to be a highly qualified QMS expert, you don't need to know all the exact details of FDA QSR or ISO Standards for medical devices to stay compliant – they are already included.



6. The basis of FDA's QSR and ISO 13485 (2016) - Risk Management (RM) and Risk Analysis (RA)

FDA's QSR and ISO 13485 (2016) specifically, refer to ISO 14971 for how to determine what is RM and how to do it.

Whatever you select, it still has to include RM as part of the solution.

A Stand-Alone system can work as it helps you address the problems. But when RM is integrated into Project Management, then it can create a history of RM issue for a project or sub-project that is Traceable and Trackable.

You seriously need to factor that into the plans.

7. Document Management & Control (DMC)

Many medical device startups initially make the mistake of thinking a Document Management (DMC) and control system is all they need to start with. (or some big medical device QMS software company convinced them that if they cannot afford the real enterprise system as a startup, you can somehow settle for DMC, yeah right!)

There is far more to Compliance than a signed document and version control.

DMC is necessary but it is not enough for achieving compliance:

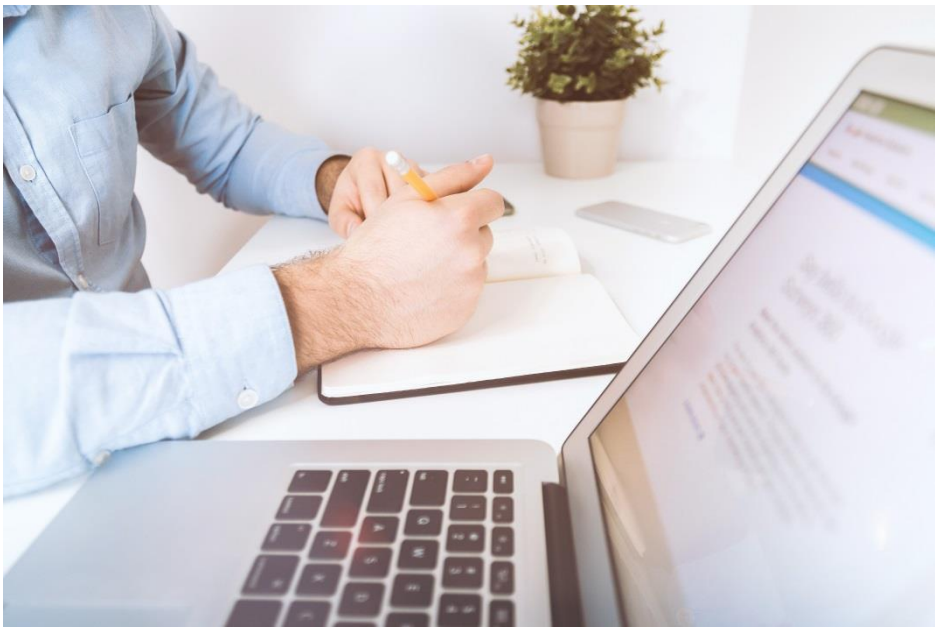
- Many enterprise QMS system vendors want you to believe that DMC is all a small company needs.

  They are trying to protect their high end and high priced systems.

  Document Management only systems are just that - Document management, they are not a QMS.

  The simple DMC does not support the workflows.

- The second problem for DMC only solutions is knowledge. Although you read the ISO standard 100 times, you don't know all the details required for Compliance. Your priority, after all, is the product and sales.



You need help not just with DMC
but also with all the other details
that lead to Compliance.

Another type of DMC is the **Forms-only based system based on PDF's**.
These types of Compliance systems can initiate a "basic workflow"
where a PDF form is circulated, usually by email,
to designated assignees.
These Assignee Users have to know what to do with it and,
here's the hard part, know exactly when to initiate it.

Not being integrated into the real workflows,
these types of add-on systems depend heavily
on outside triggers and user knowledge.
Although they do handle documents well,
initiating and getting the work and tasks that lead
to the completed forms is lacking.

Forms must be supported by completed tasks that show who did what, when, how and approved by whom.

8. Selecting the right Quality Management System to support your Compliance

Compliance Solutions are essentially QMS based solutions.

They come in all shapes and sizes.

Some solutions are nothing more than forms tacked on to a project management workflow.

They are missing many of the Compliance elements of a complete QMS system.

Most QMS systems are big enterprise level systems.

Sometimes they provide scaled-down versions but the usual suspects usually remain expensive and just as difficult to manage as the enterprise systems they are based on.

A Startup has to include various QMS functionalities to properly support Compliance but to do it in a way they can handle.

Rarely are there more than only 1 x QMS manager in a startup or even a medium-sized company.

What to do?

Don't be fooled by scaled down systems.

They rarely inherit the good genes of their original systems, they are designed not to be too good, so vendors can protect the pricing of the Enterprise Systems.

Focus on solutions designed for Startups and Small and Medium Sized Company's.

9. Go with the web-based QMS Solution!

The next issue is whether you have the human resources to support an in-house network. Stop thinking this is even a possibility. Nowadays, web-based options move network management to the web application provider.

The reality is that you simply don't have the manpower or technical expertise to set up and manage an internal network.

The web-based solution **keeps your team focused on their essential tasks**.

10. Team communications – how will you communicate with each other?

Team messaging is the best and easiest way for teams to communicate, and although there are many Team messaging apps on the market, none are purpose-built to help your team support Compliance - except one.

The problem with the "only" Team Messaging apps is that chat messages, and files shared via chat, are lost to compliance. Sure, some of them have a Bot function you can program and hope it catches everything, but that's time-consuming and more work.

The real culprit is that most of those apps are really meant to include Social in the workplace. These apps want users to have their social and work contacts together.

Can you say, not working on priorities? Can you say, Security Back-door?

Keep the team focused - on work!

Email? Not for internal communications!

Chat is faster and far more efficient.

Users get to the point immediately.

And much like any 3rd party chat app, compliance documents stored in emails are also lost to document management and compliance.

Email routing or sorting is not the same.

Use Email for communicating with the outside.

Use Chat for the Team inside.

qmsWrapper chat is **Team based compliance**:

- Purpose built to support compliance
- Files shared via chat can be connected directly to Projects
- There is no losing focus from external social media distractions
- No more time wasting on email ping-pong
- What more do you want!

11. Validate the QMS system before you use it

Before you can use a QMS system, **FDA requires that you validate your QMS system for "Intended Use" and ISO 13485 requires validation "For Use"**. Although they are similar, they differ in the level of testing.

What is critical for you, however, is that **your validation efforts must be documented**, even if the "off-the-shelf" application does not belong to you.

This means creating your own requirements, specifications, validation documentation, which will steal valuable time from your team, from your product development.

Validation Documentation is extensive and takes a serious amount of team time.

qmsWrapper can offer you an up to date and the full set of QMS compliance documentation so you can prove compliance for either FDA's Validation for Intended Use or ISO's Validation for Use.

This complete set of FDA and ISO compliance documentation represents an estimated 231 hours of your team's valuable time saved, and this for each software update so your compliance requirements are always current.

12. Customer Support and Life Cycle Management

Customer support is not the issue at this time. You need to develop and finish your product first, then get it cleared through FDA and CE Approved. You need a system that's focused on those issues.

Don't get confused by these future requirements.

Life Cycle management. Like customer support, **focus on FDA 510(k) or DeNovo approval first, then ISO 13485.**

Life Cycle management comes after and is really handled differently.

For now, focus on building success and don't be distracted by vendors saying that customer support and life cycle is needed now – they are NOT!

But in the same vein, they should NOT be forgotten!

Rather **what will help your organization now is an integrated QMS system** that combines Project Management, Document Management and Control, QMS, Risk Management and Team Messaging.

It's not that each individual function is some Editor's pick, it's that they are picked tor compliance.

13. Cost

Costs are always a factor.

If costs overrun budget, then the project fails before it cannot get to the finish line.

A fully integrated QMS app will make using and supporting it in-house much simpler and straightforward – i.e. less expensive.

Reducing the QMS paperchase is a huge plus and getting users to understand their workflows, which include QMS events based on the selected QMS Workflow Processes, will greatly reduce ongoing operating costs.

Compliance is a team issue, not one person's burden. It's a shared responsibility.

QMS For Beginners - Checklist Summary

- Get a copy of standard you need and get familiar with it
- Appoint a quality manager in your company
- Establish Quality Manual
- Run GAP analysis
- Define QMS workflow processes
- Include risk management into your QMS
- Determine your budget
- Chose smart, cloud-based QMS solution that is integrated with workflows and Quality Manual
- Validate your QMS system and document validation process
- Focus on getting FDA and CE approval

Understand your team and figure out what you can handle.

Factor in all the above points.

The conclusion is pretty straightforward:

For a startup and small to a medium-sized company, you need a web-based, fully integrated QMS software solution, to foster team-based compliance.

qmsWrapper is a Workflow process-driven system that integrates the 6 essential functionality that makes for a great compliance-oriented team.

qmsWrapper, QMS is in its DNA©.

qmsWrapper is focused on **ISO 13485** and **FDA QSR** to support **510(k)** and DE Novo applications for Medical Devices.

With the quality workflow process-based approach, the system fosters a team based compliance and introduces an innovative approach to managing QMS, called **Managing Through Quality** or MTQ.

MTQ is not purely a QMS; it's also a more effective and the efficient way to manage your QMS.

The **QMS Workflow Processes** reduce errors, forgotten paperwork, missed QMS reports by fostering a team-based approach to compliance.

Your team should not guess what to do next for compliance; it's defined for them, monitored and managed by management automatically.

MTQ helps to coordinate, control and direct your organization's tasks and activities, to help you not only meet your customer's quality requirements but also your regulatory and compliance requirements.

Everyone is involved!

The Innovation of compliance©