THINGS TO KNOW BEFORE YOU BUY

QMS Owrapper™

Quality is our business

DO IT RIGHT THE FIRST TIME

A good quality management system is a must. It defines what a company does and what it expects its employees to do.

It directs the activities of the organization, monitor work progress and how the products and services are being delivered. It also supports change management and gives room for improvement.

Today, the paper-based quality management system is seen as being ancient and hard to sustain because a lot of time is usually wasted in the search for papers and data stuck within the different sections of the company.

It can make difficult to carry out duties efficiently.

IT'S ALL ABOUT MAKING THE RIGHT CHOICE

So, there is no doubt the electronic quality management systems gained popularity amongst companies that are now embracing it due to its huge benefits to it, its products, clients, and employees over the paper-based QMS.

But how do you know which eQMS is the best for your organization?

The selection of the proper quality management system software is critical to the success of any company. Picking the wrong one, the company may experience a long implementation.

We'll help you to understand why qmsWrapper is the best choice for your company.

QMS wrapper™

TO FIT TO WHAT YOU NEED

01 INCLUDE AND SCALE YOUR TEAM

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Before anything else, preparation is the key to success

INCLUDE AND SCALE YOUR TEAM

> *"...the main reason for companies to migrate to a computerized system is usually related to either the increasing cost of personnel or lack of trained personnel."*

The best way to evaluate a software based on company size is according to the number of employees. Also, the software should help growing companies build scalable and compliant processes.
Adopting a software which the company can grow up is a risk.

qmsWrapper is for small medical devices compranies and startups, but we scale with your growth. Maximum number of members that we support is 250 per company. Please note, we're fully tested for 100 members in a company.

TRANSITION FROM PAPER-BASED SYSTEM

Transitioning from paper can seem overwhelming, but right help, the company should be able for a painless transition into electronic quality management.
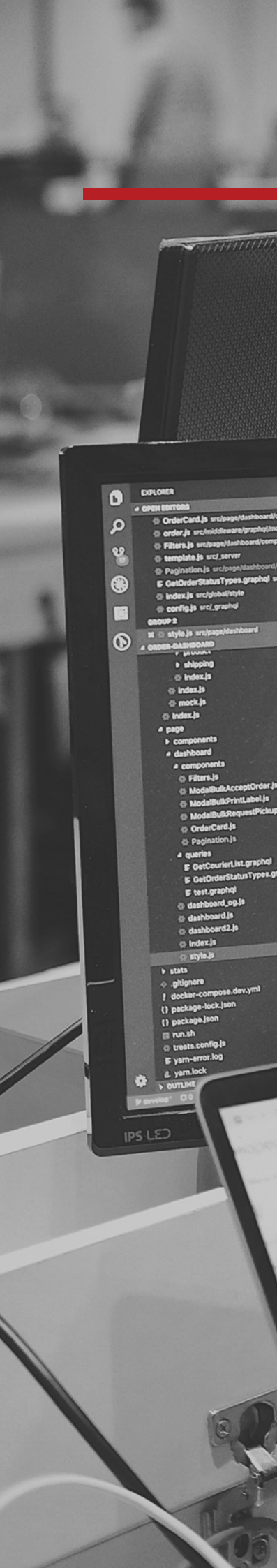
qmsWrapper helps organizations transition from paper to electronic QMS. The service can be provided on customer's site or remotely.

Please note, providing this service will require access to your data.

QMS**wrapper**™

INTUITIVE SOFTWARE

qmsWrapper is very intuitive software
that can be simple adopted by end-users.
But, as we're aware an onboarding
services are valuable,
we provide very comprehensive
"How to" documentation available
on our web-site.

Also, our Customer Support Team would
be happy to help you whether with
software or QMS related questions.

CUSTOMIZATION AND FLEXIBILITY

A system should be customizable enough to fit companies existing processes and scale as the company grows. Customization is a must, since the system should be modified to fit company's current processes and requirements.

qmsWrapper has flexibility to easy adapt company's current processes and can rapidly react when new opportunities for quality improvement are discovered.

COST VS. VALUE

Let's be honest, the cost is the most important consideration.
Affordability is important, but it's critical to evaluate both the pricing and value of software options. Also, to determine whether there are any hidden cost.

qmsWrapper offers a lot for very affordable pricing that includes all Modules: Project -, Quality -, Document - and Risk Management Module, Traceability Matrix and Team Messaging.

qmsWrapper allows companies and its members to communicate, collaborate and remain productive.

"Management through quality compliance is different because the focus is not on quality as the end game, but rather on quality as the process to achieve compliance."

STREAMLINE YOUR COMPLIANCE

qmsWrapper is built to help companies manage their medical device development and get it to market faster. It help can help to organize, manage, track and cooperate team and to get the company through product certification faster.

Compliance is complex, but complying with regulatory requirements won't be difficult using qmsWrapper.
The system is built to conform FDA 21 CFR Part 820 and 21 CFR Part 11 requirements and with ISO 13485:2016 and ISO 14971.
Since the system is very flexible, it can be adaptable to implementation of other Standards (i. e. ISO 9001, etc.).

Organizations in the MedDev industry expect their data to be secure, confidential, and highly available.
qmsWrapper believes in <u>security</u>, that's why we use AWS back up.

We are applying Risk Assessment as well, preventing losing any data and, putting it on a minimum.

YOUR DATA

ARE SAFE

Also, qmsWrapper is giving the option to download any folder, for any purpose that
is needed with a single click.

There are many worries while developing a Medical Device, but now one less. qmsWrapper wants you to feel safe while working.

QMSWRAPPER
IS VALIDATED FOR USE

MedDevs must carefully consider the impact of introducing the software applications, particularly where the company needs to demonstrate compliance with regulations and standards.

The quality management software must be validated when a computer system is used in a good practice process, to revise the quality of a product or to generate information for regulatory bodies.
Validating the software helps reduce risk and legal liability, as well as providing evidence that the computer system is fit for purpose.

qmsWrapper is validated per ISO/TR 80002-2:2017 Medical device software — Part 2: Validation of software for medical device quality systems and we provide Validation Documentation Set to subscribed users.

AN EQMS CANNOT BE IGNORED BY ANY COMPANY THAT WANTS TO IMPROVE CONSTANTLY AND TO ADAPT TO CHANGES.

IF YOUR COMPANY IS LOOKING FOR A QUALITY MANAGEMENT SYSTEM THAT CAN BE CUSTOMIZED TO MEET ITS NEEDS AT A BUDGET-FRIENDLY PRICE,

THEN QMSWRAPPER IS THE BEST SOLUTION!