

WHITEPAPER

# Why an eQMS Should be the Central Brain of Your Organization



## What is a QMS?

A Quality Management System (QMS) is a formalized system that documents policies, procedures, processes, and responsibilities.

It is a general system that instructs individuals on best practices for an organization's core functionalities. This allows an organization to run seamlessly — everyone immediately knows the best practices and has documentation to support their decision-making. While each QMS is different (some organizations incorporate everything into their QMS while others limit it to only specific processes and procedures, either required by regulation or international standards). The key behind an effective QMS is designing to fit your company's operations; to drive key activities that lead to key quality decisions, improved customer satisfaction, and improved products.



## How the COVID-19 Pandemic Accelerated QMS Development

Surprisingly a lot of QMS systems are paper-based (or a hybrid of paper and electronic). Because of this, organizations discovered very early in the COVID-19 pandemic that it was challenging to maintain consistent operations and day-to-day business functions, with limited essential employees allowed on-site. Those employees were attempting to locate appropriate documents or records from the QMS for offsite people, leading to confusing and disorganized situations. As a result, companies recognized the need for a more streamlined system to access essential documents or records from anywhere. To get by, organizations implemented electronic Quality Management Systems, which hosted all elements of a QMS in one place and created interconnectivity between the various parts and subparts of operations or processes.

It may seem like a “no-brainer” to have an eQMS in place if it creates greater efficiencies, protects you from regulatory scrutiny, and reduces errors. However, these systems were initially expensive and time-consuming to implement. Fortunately, implementing an eQMS has become streamlined and less costly to maintain, which leads to a beneficial investment.

## How an eQMS Can Help Your Organization

In the past, a QMS could have been perceived as a policing unit rather than a tool to help individuals do their jobs better. However, a thorough QMS allows things to run efficiently and results in a higher quality product. The key is to ensure that the QMS is set up correctly from the beginning and that your team views the QMS as helpful rather than hindering. If a quality system is poorly set up, it might indeed create some roadblocks and interfere with operations or productivity. However, if it is well thought out, well-engineered, well-developed, and well-integrated, it can help your organization deliver better outcomes. A standardized approach allows consistent training, resulting in more individuals working in the same, efficient way. However, disjointed QMS systems can create bottlenecks. Couple that with several processes that are tied together, and it is clear how issues can arise.

Another element to consider with a QMS is regulations. While regulatory bodies may not enforce the use of an eQMS, it can be an instrumental tool to ensure that complex requirements, standards, and regulations are all documented and managed in the system.

As platforms and software systems become more agnostic, electronic Quality Management Systems are more robust than ever. For example, an organization can link its non-conformance report (NCR) system within the QMS to document final acceptance activity testing for a manufacturing process. Suppose something is out of tolerance or specification from the manufacturing perspective, in that case, it could put that lot or batch of product on hold and immediately flag the NCR to notify a Quality Engineer. Then, the individual can complete their investigation and document that information in the material review board. The Quality Engineer will receive that notification electronically, review it, and approve it. Finally, the products will be taken out of the hold and made available for customer orders. Without an eQMS, one step of the process could be missed, or a report could be lost, leading to an observation or finding.

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Because of the accessibility and affordability of an eQMS, the risk of not having one is greater than the cost of developing one. For example, consider that you are creating a product in the US and do not have evidence to show you used a quality unit to develop a product. You have no material review board (MRB) process or procedure. You could receive a citation and face regulatory enforcement. Depending on the severity of the violation, you could be forced to stop operations or recall your product entirely. With an eQMS, that risk is reduced, as your organization should document how it conforms to regulations in the system. An eQMS allows for very agile, efficient, and effective ways to show inspectors and auditors how you handle your operations, control your environment, and comply and conform to your requirements and those of external regulators and notified bodies.





## What are the Primary Differences Between a QMS and an eQMS?

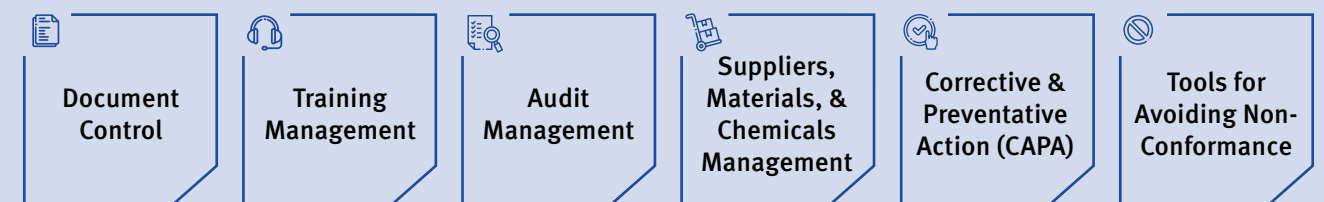
The main difference between a Quality Management System and an electronic Quality Management System is in the name – electronic. While a traditional QMS is typically paper-based or a hybrid version of software, files, and tools, an eQMS is completely electronic – and all parts of the QMS are connected and interact in an electronic fashion.

In addition, automation plays a part in an eQMS system. For instance, if an organization wants to update an electronic message board to inform its employees of what products are running in a specific room, they can do so with an automated eQMS.

## How to Transition to an eQMS

Before you choose an eQMS software, you should outline what your organization wants to be in the future and how an eQMS fits into that long-term strategy. Consider the needs of your business, customers, and products. It's also worthwhile to engage stakeholders to ask about current functionality vs. future state. Pull together a stratified sample of stakeholders in the organization that represent all functions so you can build a robust QMS.

### Every QMS should include:



Several eQMS software choices are available, each with its strengths and weaknesses. The first step in transitioning to an eQMS is doing your research. Discuss your needs with other industry professionals to find out what they use and collect feedback. From there, choose three to five top providers that align with your needs and have them present to you.

While eQMS software solutions are often customizable, generally, it's advisable to stick to one that checks as many boxes for you out of the box, as customization can lead to more work, time, and costs. In most cases, there will be some level of customization, but it's best to avoid a fully customized solution.

Once you've chosen your preferred software, you should partner with a consulting company or preferred supplier to discuss requirements and the next steps. The implementation will work best if you partner with an experienced individual or organization to give you the best practices.

### Following these additional steps will help you achieve a successful implementation:

- ▶ Create a change management strategy
- ▶ Identify measurable priorities
- ▶ Engage and motivate your team
- ▶ Reinforce your training plans
- ▶ Leverage resources from your QMS partners

## What Systems Can be Incorporated into an eQMS?

Any day-to-day operations that are involved with making or shipping a product, or any process that has to do with improvement activities in operations can and should be incorporated into an eQMS. In the long term, this will make your operations more efficient, leading to sustainable compliance and continual operational excellence.

**To begin tying each system in to your eQMS, you'll need to take the following steps:**

1. Map out all processes that the organization would like to connect
2. Share the map with key stakeholders, your IT team, and any other individuals that might contribute
3. Evaluate requirements for specific systems to determine whether their IT interfaces can connect
4. Build your IT infrastructure map
5. Configure the eQMS and system you are trying to connect
6. Perform the necessary qualification and validation functions for everyday use

Follow this process for each system you'd like to integrate with your eQMS. While you can always add more processes later, it is time-consuming. That is why it's critical to maintain a list of systems on record, including information on the last time the system was verified from an IT perspective.

Adopting digitalization of systems and interacting with systems differently requires a change in mindset. Remind others in your business to keep an open mind to change and be willing to adjust methods slightly to work with these systems. Ultimately, the eQMS systems are in place to help companies and individuals efficiently achieve compliance, increase customer satisfaction, and create robust processes with better functionality.

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## Interoperability, Accessibility, and Remote Focus

With an eQMS, you can have connected interoperability and accessibility that you do not have with a traditional QMS. You can now connect processes, procedures, requirements and records, and make them work together and operate interchangeably. Instead of working on one system at a time and switching between paper and digital, an eQMS offers an opportunity to have accessibility and interoperability in a digital environment, which can be accessed remotely. As a result, time is saved, and efficiencies are created by seamlessly transitioning between various gates and subparts. When you have that seamless integration, you have better visibility into what your system is doing and how your processes are operating.

This interoperability also creates an opportunity to pull data and see where you can increase efficiencies even further. With paper systems, it can be difficult to get a bigger picture. This heightened visibility allows you to catch and address potential issues more quickly. With the creation of dashboards, you can see each connected system at a glance and create triggers to catch errors. All of this means that you will more easily maintain compliance.

An additional bonus of an eQMS is the potential for remote access. COVID-19 pushed the envelope, with organizations coming to the realization that remote access was truly the way of the future. Those that adopted an eQMS early on discovered the value of being able to complete work more efficiently and effectively. The potential opportunities of remote access are limited only by your vision. Whether you want the ability to remotely check an NCR, validate a new piece of equipment, check in on efficiencies, or review guidance documents, the possibilities are endless.

Of course, as with any electronic technology, there are some security risks that should be considered, and companies will need to review their risk thresholds. Ensuring all security features are in place, a robust risk profile has been established, and the eQMS is fully validated should mitigate security concerns. Diligent reviews should be completed regularly to ensure security is maintained.

While many organizations are still in transition, others have yet to begin. Experiencing the worst-case scenario of COVID-19 was a wakeup call for organizations that simply cannot have delays in their work.



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