

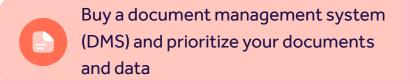
DMS vs. eQMS: which is right for you?

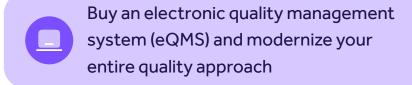


DMS vs. eQMS

You know you want to improve your quality and compliance processes by digitizing them.

You face 2 options:





Which is right for you?

That depends on the context of your business and your operational needs. This guide weighs up the pros and cons of each approach to help you decide.

DMS or eQMS?

Chapter 1

Option 1: DMS

OPTION 1: DMS 4

Why do regulated businesses opt for dedicated document management systems?

There are a few reasons:

- It's cheaper: DMS platforms do less, and therefore cost less, than a full-fledged eQMS
- > It's simpler: less functionality = less set-up and overhead time
- It's better for smaller, less mature companies: your company may not have many other processes or operational elements in place which demand a more holistic platform

There's no doubt that moving from a paper-based document system, or one built on adapted tools like SharePoint or OneDrive, to a dedicated DMS is beneficial for any regulated company.

All the <u>perks of digital document management</u> should come with any reputable DMS. That means you should expect functionality like version and change control, cloud-based storage and retrieval, audit trails, e-signatures, and even step-by-step workflows for tasks like review, approval, distribution and archiving.

For regulated companies who need to work to document standards like GDocP, ALCOA+ or FDA 21 CFR Part 11, a DMS can be a fantastic way to accelerate towards compliance – and to simply give yourself complete control and visibility of your document stack.

The tight focus of a DMS has a knock-on benefit when it comes to validation. Because document software is fairly rigid, and without layers and layers of complex, configurable functionality, it can be validated and launched into a regulated environment almost instantly. This can be a considerable benefit if you need to upgrade your document management system ASAP.

It's worth noting, too, that the question of whether to digitize your document stack or your entire quality system really comes down to the operational maturity of your business. If you're a start-up in the earliest days of your operation, you might not have processes in place yet for



OPTION 1: DMS 5

things like staff training, quality events, medical device design controls or supplier management. If you only have documents, it's easy to make the case for only requiring a DMS and nothing more.

Cost

The more focused, stripped-down functionality of a DMS is reflected in its pricing.

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Ballpark figures naturally vary by vendor and the territory your company operates in, but a good rule of thumb is that a DMS SaaS subscription typically represents a *four-figure annual investment*.

Buy a DMS if you:



Are a small company with fewer than 10 heads



Don't have (or require in future) more mature quality and compliance processes



Only have a minimal (4-figure) budget



Need to move away from your legacy document system almost instantly



Chapter 2

Option 2: eQMS

OPTION 2: EQMS

On the other hand, companies choose to invest in an electronic quality management system (eQMS) because:

- They're more powerful: eQMS platforms offer far more functionality than a DMS, giving you the opportunity to upgrade your entire quality system at a stroke
- They're futureproof: eQMS platforms offer a more comprehensive digital framework for all the quality/compliance processes you'll need to execute, both now and in the future
- They're better for established companies with existing processes (or plans) which warrant digitization

If a DMS is a targeted, dedicated solution for a single business need, an eQMS is a more heavy-duty addition to your company's tech stack.

Any reputable eQMS, including Qualio, will contain all the functionality of a modern DMS, plus lots more on top. That means as well as document control, you can expect to manage suppliers, training, CAPAs, deviations, design controls, change controls and more within a single system – usually with much more flexibility and configuration than a DMS can provide.

You should consider what you want to achieve with your DMS vs. eQMS system investment. If you're a growing regulated company planning for the future, perhaps for a product launch and entry into a new market, there's no way around it: you'll need to establish processes for these key areas at some point anyway.

If you opt for *only* a DMS, the time will eventually come when you need to move to an eQMS regardless. This could either leave you with multiple systems and sources of truth, or force you to ditch your DMS and to move your documents into the new eQMS. Aligning your system choice with your medium- to long-term company plans is the best way to avoid this unnecessary effort and cost further down the line.

You should also reflect on the quality management system that your company will need to operate in its regulated environment. Documents are the baseline and cornerstone of any QMS, but in themselves are



only markers or indicators of processes existing elsewhere in your company. If you have documented processes, there's a good chance those processes will benefit from being housed and executed in a dedicated electronic quality management system.

In a similar vein, an eQMS can provide key functionality your DMS can't. Although many DMS platforms offer basic analytics for things like document status and engagement, an eQMS sheds light on the performance of your entire quality system – from suppliers to CAPAs and deviations. And although some DMS systems naturally offer integration with document tools like Office or Google Workspace, some eQMS platforms go further, connecting to your CRM, product development and ticketing tools as well.

These insights and integrations can offer critical support and guidance as your company grows and matures, often making an eQMS a more helpful investment than a DMS.

These benefits should be weighed up against the higher complexity levels of an eQMS. Major eQMS platforms, like <u>Veeva</u> or <u>MasterControl</u>, can take many months to implement because of their validation and onboarding demands. eQMS platforms also demand more training than a DMS, meaning you probably can't roll one out at the same speed.

On the other hand, eQMS platforms designed for small to medium companies, like Qualio, tend to offer faster implementation, validation and roll-out than competitors, with their greater focus on ease of use resulting in lower training barriers. Choose a suitable eQMS, and you could therefore be up and running in a timeframe more like a DMS.

And if you choose the <u>pre-built document templates and workflows</u> that some eQMS providers offer to accelerate your operational maturity, an eQMS could even deliver organizational impact for you in a *shorter* timeframe than if you chose a DMS and had to build your document stack manually.



OPTION 2: EQMS

Cost

eQMS platforms usually cost more than a DMS, but offer greater value in return.

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If a DMS SaaS subscription typically represents a four-figure annual investment, an eQMS subscription usually falls into a five-figure one. Enterprise eQMS platforms for major companies can even run into six figures.

Buy an eQMS if you:



Are an established company with 11 heads or more



Want to upgrade your entire quality system – not just documents



Have a 5-figure budget



Want a more heavy-duty system for the long term

Chapter 3

DMS vs. eQMS comparison

DMS VS. EQMS COMPARISON 11

DMS Targeted solution Typically available as cloud-based SaaS

subscription

Short-term

Four-figure investment

Fixed

For accelerated compliance with document/ data integrity standards only

Upgrades your document management

Generally rapid set-up and validation

Could require additional system investments in future

Some document system integrations (varies by system)

Document analytics

Generally industry-agnostic

Manually build and add documents

eQMS

Comprehensive solution

Typically available as cloud-based SaaS subscription

Long-term

Five-figure investment

Configurable

For accelerated compliance with all quality/regulatory standards required for market access

Upgrades your entire quality system: document, training, process, supplier and design control management

Set-up and validation speed varies by system

Self-contained, future proof quality platform

More comprehensive integration suite (varies by system)

Holistic quality system analytics

Often tailored for specific regulated industries with appropriate benefits: niche compliance functionality, pre-built templates/workflows, etc.

Often supplied with pre-built, industry-specific documents and templates





Want to see an awardwinning eQMS in action?

Book your demo

