OCTAVE

EBOOK

7 considerations for building your own QMS with AI

Everything it takes to build and own a quality management system with AI

Executive summary



You can use AI to create the first build of a quality management system, but AI won’t reduce all of the work that follows.



Governance, validation, security and maintenance are permanent commitments, not one-time costs, and these are the very things a commercial QMS vendor already handles for you today.



Building an enterprise-grade, multi-process QMS means becoming a software company internally, with the security, compliance and engineering functions that it requires.



The better use of AI for a QMS, for most organizations, is building differentiated capability on top of an established foundation and not recreating the foundation itself.

The real question you should ask before building a QMS

If you want to create a QMS using AI, you can. In fact, AI is making it easier to build software solutions faster than you could even a few years ago. **But should you?** We'd argue no. AI can't ensure you've built something that will work across sites and regions. It can help you keep pace with constantly changing regulations by summarizing what's new, but someone still has to interpret and implement every change. And even if it can help you integrate with different systems, it still needs someone to maintain, secure and defend it in front of an auditor.

This guide will focus on the tradeoffs in building your own QMS with AI or an LLM. It won't be about whether AI can create a QMS. We know it can. Instead, it will be about what you can and should do with AI, plus what it takes to own the entire QMS software ecosystem.

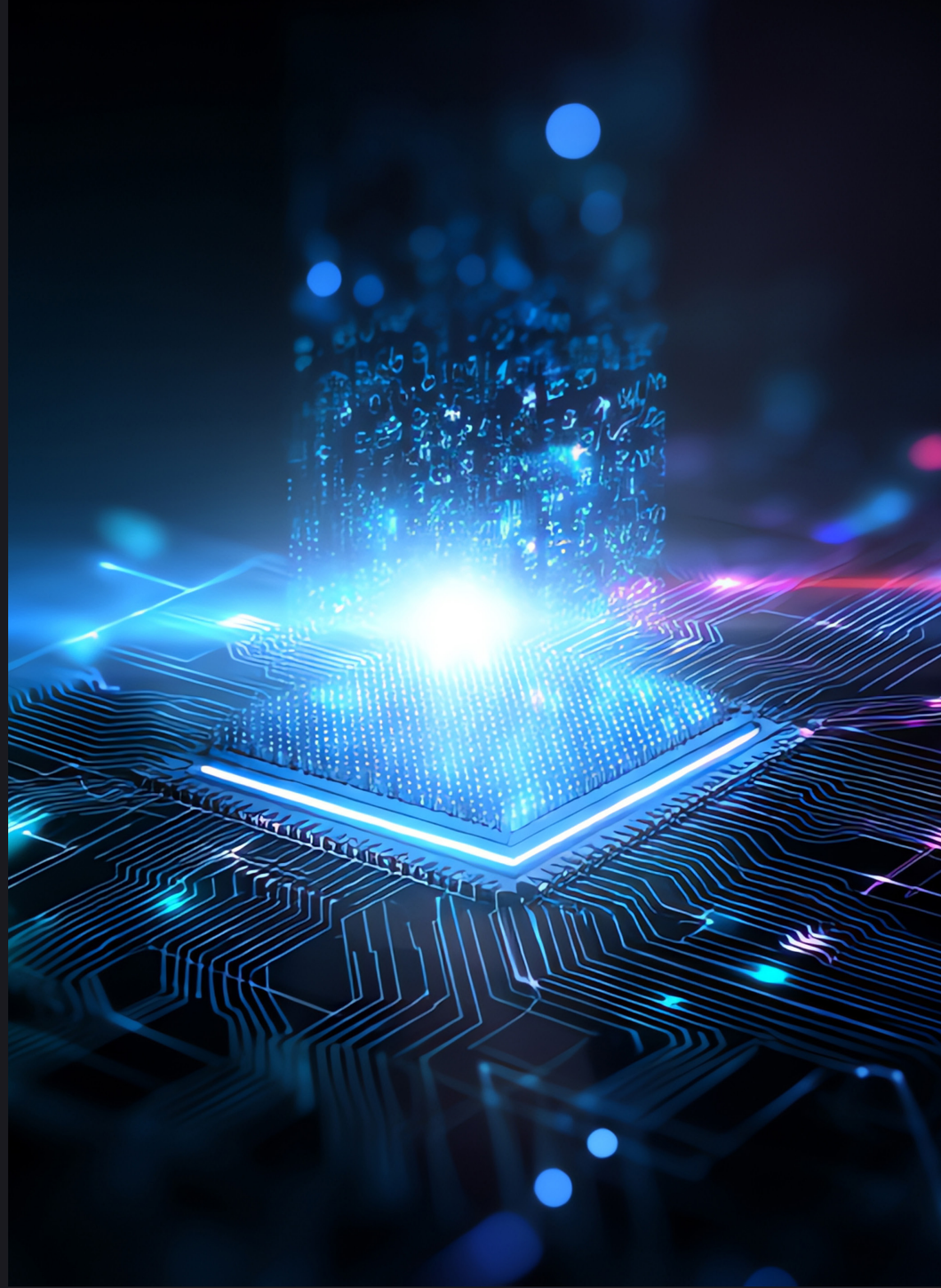


01

Consideration 1
Governance & the source of truth

Every quality record you produce will eventually be evidence someone else needs, whether that's an auditor, regulator or your own legal team. What makes a QMS trustworthy is how dependable that evidence is. For this, you need it to be immutable, timestamped and standards-compliant by default. That way, anyone viewing the information knows which record and version to use or refer to.

That dependability isn't a feature you configure once within a QMS. It has to survive the record's entire lifecycle, which includes corrections and migrations. When AI enters the picture, that bar moves higher, not lower. Automated validation and audit trails have to sit at every entry point, because any record you skipped or subtly altered without a log is a liability.



01

Consideration 1
Governance & the source of truth

Build a QMS yourself, and every part of that process becomes your responsibility. At the start, you're defining the record lifecycle and who owns correction and retention decisions. As you maintain it, you're the one proving to both internal and external individuals and teams that the record someone's looking at is actually the authoritative one. As you expand, each new system or AI feature that touches your data is another place context and traceability can degrade.

The real cost of building your own QMS

- Dedicated data governance ownership
- Ongoing records and QA oversight
- Rising audit exposure as more systems draw on your data



Ask yourself

If your AI-assisted system and your official record ever disagree, which one do you trust and, more importantly, can you prove which one's the right one to trust?

02

Consideration 2
Validation, testing & audit readiness

A working application is not the same thing as a validated one. Functioning software simply proves it ran. A validated system proves the application does what it's supposed to do and, more importantly, keeps proving it every time something changes. In a regulated environment, that's the difference between a tool and a system of record.

This is where building a QMS with AI-assisted development starts to crack a bit. The hard part of building a QMS isn't speed, but amassing enough evidence, release after release, that the system remains dependable. Even if your development time shortens, your evidence trail doesn't. If anything, it adds to the validation load. Every AI-supported function is one more thing that needs its own testing strategy, not an exemption from one.



02

Consideration 2
Validation, testing & audit readiness

If you build a QMS yourself, validation, testing and audit readiness become a permanent workstream that you have to maintain. Starting out, you need a testing and assurance strategy plus a way to document outcomes and manage defects. Maintaining all of that plus every workflow change, integration or AI update triggers a fresh impact assessment and fresh regression testing. The responsibility doesn't end once you go live with your QMS. Instead, it restarts with every release. If you expand, each new process or site adds another surface that has to be independently validated before you can trust it.

The real cost of building your own QMS

- QA and compliance expertise, not just developers
- Recurring regression testing with every release
- Potential remediation costs if evidence doesn't hold up



Ask yourself

If an auditor asked for the full history of a record built before you had formal validation practices in place, could you produce it?

03

Consideration 3
Security & data protection

Sensitive quality data needs to stay protected even after you configure permissions, and that requires someone actively watching, testing and responding to threats against it for as long as you continue using your QMS, which is all the way through development, monitoring, incident response and every subsequent update.

Every AI capability, new integration, data source, location or AI service you add is a new potential entry point, and each one needs its own review before it goes live. That’s true no matter what you’re protecting, whether customer data or the intellectual property embedded in how you manufacture.



03

Consideration 3
Security & data protection

When you build a QMS yourself, you need to find a way to ensure security is handled from the start, which usually involves hiring an employee or, at the very least, a freelancer or agency. Additionally, you need to comply with any InfoSec policies your organization already has in place. You need to define requirements and establish access controls from the beginning. You also need to review every third-party service in your processes. Someone needs to be responsible for managing vulnerabilities and monitoring incidents. As you expand, every new change you make to your QMS means reviewing the code for security issues.

The real cost of building your own QMS

- Dedicated cybersecurity and privacy expertise
- Continuous monitoring and incident response
- Financial exposure if a breach happens on your watch



Ask yourself

If a security incident happened today, do you know who detects it, who responds and how fast you're required to notify anyone affected?

04

Consideration 4
Scale, architecture & integrations

One of the challenges of building a QMS is ensuring it can work for all the workflows across your organization. AI can help you do this, sure, but AI is only as good as the information it's trained on. Odds are good you'll run into gaps. Even if you account for all the gaps, you'll need to ensure your QMS works reliably with every system and service you already use or may add later.

Decisions that work fine for a single-team pilot (including how identity, data, backups and performance are handled) often need to be substantially rebuilt before they can support a second process or connected system. Scaling is about more than increasing the volume your QMS handles. After all, it's one thing to support a single site or a handful of quality experts, and another to support hundreds of locations and thousands of users worldwide. A custom-built QMS that doesn't have the capabilities you require may hurt you when you need it most.

Then there are integrations, which make building a QMS harder. Many integrations aren't fully in your control. A QMS almost always operates in a system where it needs to reliably exchange data with CRM, HR, operational and reporting systems that other teams own and change on their schedules. When sales swaps CRMs or HR onboards a new HCM platform, every connection you've built from your QMS to their old system needs to be reconfigured for the new one.



04

Consideration 4
Scale, architecture & integrations

With a self-built QMS, you own these changes indefinitely. Sure, when you first start out, you're building for an environment you already understand. But environments change, and they take time to configure later, even with APIs and documentation. You'll need a dedicated owner to maintain every integration. Expansion can mean moving into real reengineering work, too, not just configuration. A merger or acquisition can mean reconciling two entirely different systems at once.

The real cost of building your own QMS

- Architecture and integration expertise
- Recurring maintenance for every connected system
- Reengineering costs as scope or regions expand



Ask yourself

If another team swapped a system you're integrated with tomorrow, who owns rebuilding that connection — and how fast could they?

05

Consideration 5
Maintenance, support & continuity

As long as you're using your self-built QMS, it needs continuous production support whether you're using AI to code it or not. If anything, AI-generated components need the same ongoing scrutiny as anything else. The last thing you want is to assume it got all the code correct. After all, you're still responsible for any mistakes or lack of traceability.

This is arguably the most consequential of all seven considerations. Yes, AI's biggest advantage in building a QMS is that you could probably get a working version up in two days. But speed is the last of your concerns once it's up and running.



05

Consideration 5
Maintenance, support & continuity

Patching, updates, defect resolution, user administration and monitoring all fall on you or your staff. It's an open-ended operating commitment with dedicated expertise needed to support users, fix defects, patch security issues, manage dependencies and adapt to changing regulations or AI models.

Worse, if the people who built your QMS move on, whoever takes over needs to understand, maintain and safely change what they inherited—possibly even without all the context the original builders had in their heads.

The real cost of building your own QMS

- Dedicated development and operations capacity
- An annual operating budget
- Key-person risk if institutional knowledge walks out the door



Ask yourself

If the person who built this left tomorrow, could someone else pick it up? How long would that handoff take and how much might it cost?

06

Consideration 6
Requirements & quality governance

Aligning all your processes in a QMS isn't easy work. Products, policies and regulations change. From approval structures to record requirements and regulatory obligations, your system has to accurately represent everything, or it stops being trustworthy.

And the governance burden grows as your organization grows. Every additional site or process you bring onto the system multiplies the number of stakeholders who need to align and the number of places a single regulatory change has to be traced through and accounted for.



06

Consideration 6
Requirements & quality governance

You need to consider how willing you are to own all that alignment work indefinitely. Maintaining the QMS along with every requested change has to be evaluated for its downstream effect on records, workflows, reporting and training. Expanding your QMS to a new site or new market comes with new regulations. The work adds up fast and it multiplies the governance load you already had.

The real cost of building your own QMS

- A clear, permanent owner for requirements and change governance
- Cross-functional review time for every material change
- Risk of delayed decisions as scope expands



Ask yourself

If a standard you comply with changed tomorrow, who's responsible for updating the system and proving the update was correct?

07

Consideration 7
AI governance & oversight

Using AI inside a quality system adds to your governance workload. Somebody has to decide where AI is appropriate to use, what data it's allowed to access, what output requires human review before it's trusted and how all of that is enforced as the system evolves. And you have to design and maintain it like everything else in this guide.

Then there's the AI service you use to build your QMS. Cloud-hosted models can raise prices as providers work toward profitability. They can also get acquired or, worse, deprecated in favor of a newer version. You can use a self-hosted model to sidestep some of that exposure, but even they can stop receiving support or updates. Nothing is certain right now in the world of AI, and if you build your QMS around a specific AI service, then you also inherit that service's business risk on top of its technical risk.

And none of this includes the more important challenge of protecting your intellectual property. The person or people in charge of your code need to make sure that sensitive information doesn't make it onto a public database.



07

Consideration 7
AI governance & oversight

When starting out, you'll be responsible for defining and reviewing acceptable uses and data boundaries for anything AI touches. As you maintain it, you're responsible for monitoring output, enforcing change controls and re-evaluating those boundaries every time the underlying model or vendor relationship shifts. When you expand, every new AI-supported feature is another place where unreviewed AI output could reach a consequential quality decision if you don't scale your oversight with it.

The real cost of building your own QMS

- A named owner for AI governance
- Ongoing human review of AI output
- Exposure if your AI vendor's business changes out from under you



Ask yourself

If your AI provider doubled its price or discontinued the model you built on, how would you continue updating your QMS and could you rebuild it without that support?

Where AI can safely add more value

Add up every consideration above, and it should be clear that the cost of building your own QMS compounds every year you keep operating it. Governance, validation, security, architecture, maintenance, requirements and AI oversight are each a recurring line, not a project expense that ends once the system goes live.

Sure, you may be able to go live with version one of your QMS faster and cheaper than if you onboarded a QMS from a trusted vendor. But the total cost of ownership—and any of the extra costs you would incur from quality issues, warranties, returns and fines/fees—will quickly outweigh the savings.

So far, every consideration in this guide has been about the cost of rebuilding the foundation of your QMS. But we would argue that the foundational quality infrastructure isn't the place to differentiate yourself. A trusted vendor already carries that governance burden, reducing both your risk and your cost. Building a QMS yourself means potentially paying more than full price for something you could have onboarded that was already governed.

Instead, AI can be used to build on top of that foundation. The advantage is in the workflows and insights specific to your business.

You should spend your resources on what makes you different instead of rebuilding what every competitor also has to have. Yes, a differentiated AI feature you build will effectively become infrastructure, but it shouldn't require as much time or as many resources.

AI brings many benefits to companies. Instead of using it to build an entire QMS, build a focused application when the problem is narrow, the risk is contained and someone clearly owns it going forward.

And if you'd like help implementing a foundation you can build on, we're always here to help. →

About Octave

Octave is a leader in enterprise software, turning data into decisive action and intelligence into your edge. Our software solves for and simplifies complexity, from the design and build to operations and protection of people, property and assets – for any scope, at any scale. For decades, we've partnered with customers to sharpen performance, elevate efficiency and amplify results. From factory floors to entire cities, our solutions are tuned to scale up what's possible from day one onward.

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