When to adopt an eQMS

A timing guide to open the next chapter of your company's future

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4 options for managing quality

Paper

Spreadsheets

Adapted tools (SharePoint, email)

eQMS

What is an ‘e’QMS?

Typical analog quality management systems (QMS) that run on spreadsheets, paper and out-of-date legacy systems cost your business more than you think.

Unoptimized systems don’t only frustrate your staff and slow your route to market - they put your product quality and the safety of your patients at risk.

An *electronic* quality management system (eQMS) allows you to:

1. Proactively detect product quality and patient safety risks
2. Have confidence your quality records are secure and compliant
3. Ditch time-heavy manual tasks to focus on quality improvement
4. Digitally embed best practice across your business

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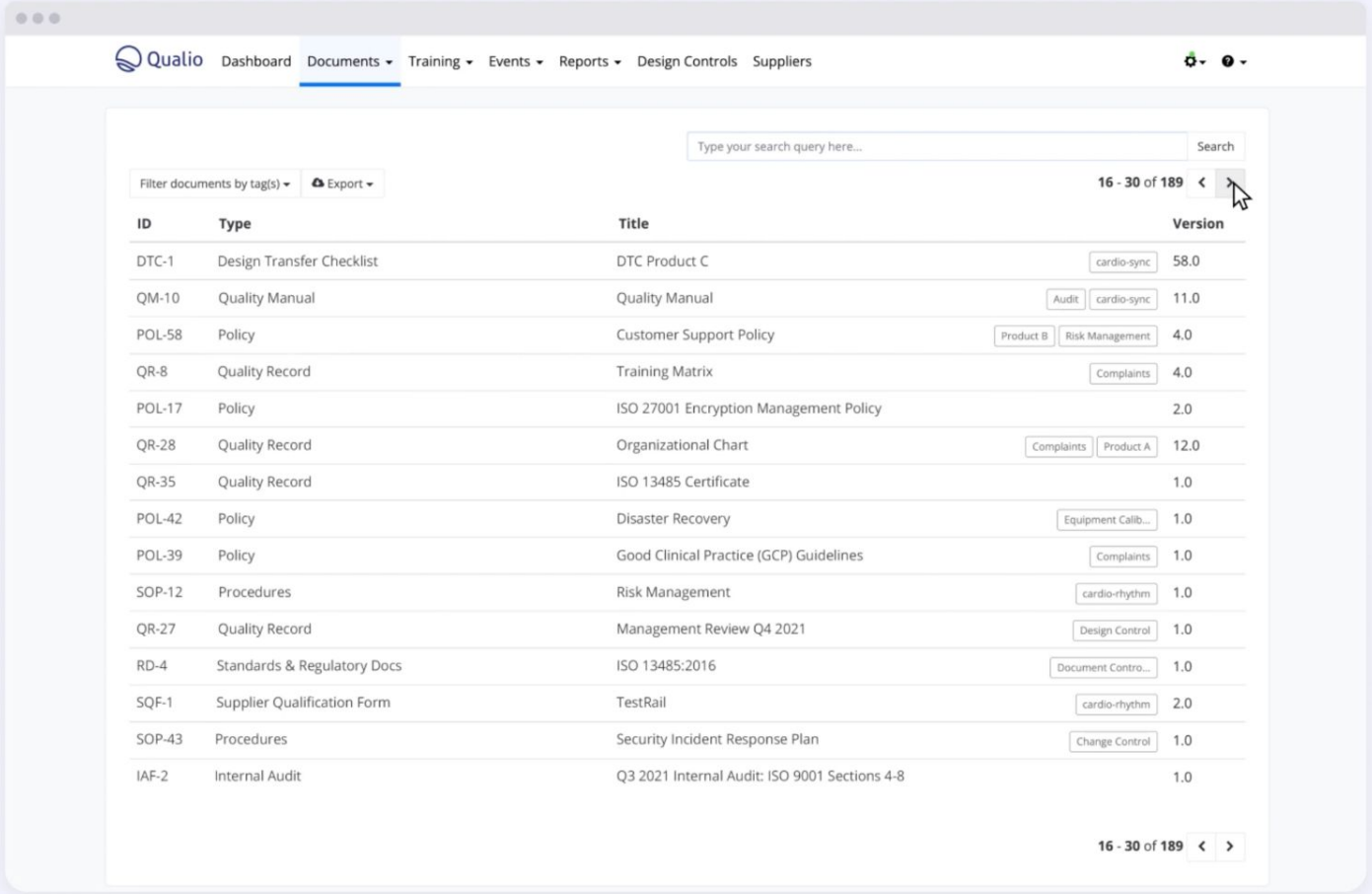
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Quality Record
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Supplier Qualification Form
TestRail
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SOP-43
Procedures
Security Incident Response Plan
Change Control
1.0
IAF-2
Internal Audit
Q3 2021 Internal Audit: ISO 9001 Sections 4-8
1.0
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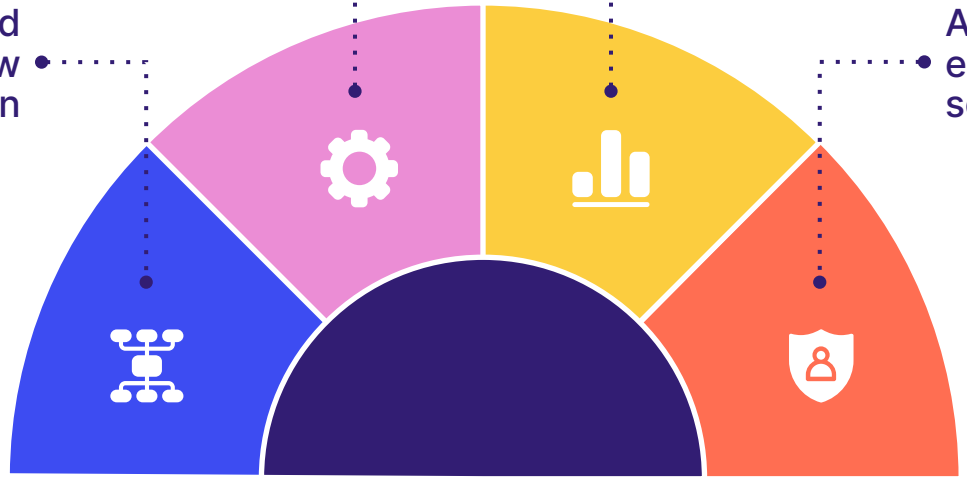
Modern eQMS functionality

Configurations and integrations with other systems

Interactive dashboards and reports for quality metrics

Process and workflow automation

Audit trails, e-signatures and security controls



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Why do businesses buy an eQMS?

Eliminate time-consuming, manual, paper-based admin

Scale and get new products to market more quickly with faster, more automated processes

Centralize control and visibility for continuous improvement and airtight compliance

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And why do they not?

"There are no live procedures to train people on yet."

"We're still in very early design and development."

"We don't need to manage quality events yet. We aren't marketized."

"Let's stick to paper for now.

It's cheaper. And we can start using paper right now!"

"Validating an eQMS takes ages!

That's for when we outgrow paper."

"Let's just focus on complying with our standards first.

They don't mandate an eQMS."

- Limited quality knowledge
- Limited software knowledge
- Low capital
- ‘One thing at a time’
- No processes to digitize
- Compliance focus
- Want something quickly

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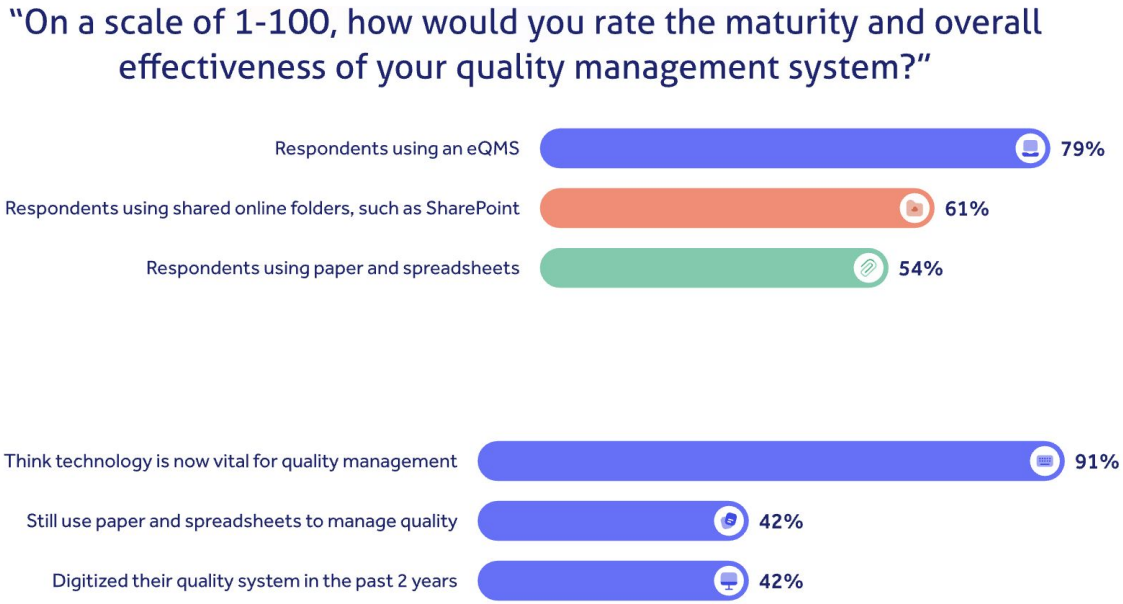
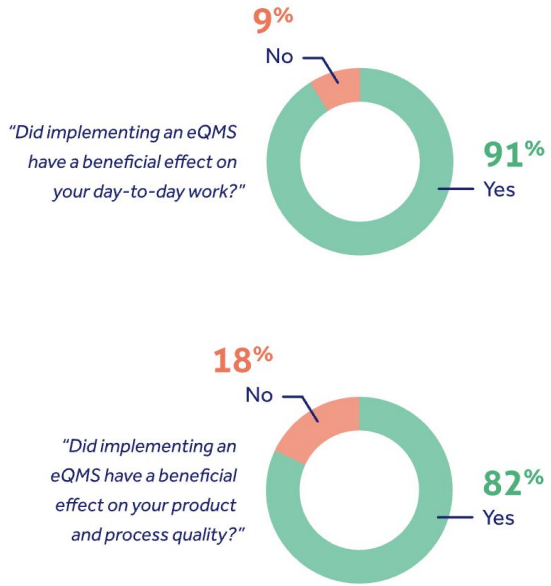
eQMS adoption





Source: [Qualio life science quality trends report 2024]

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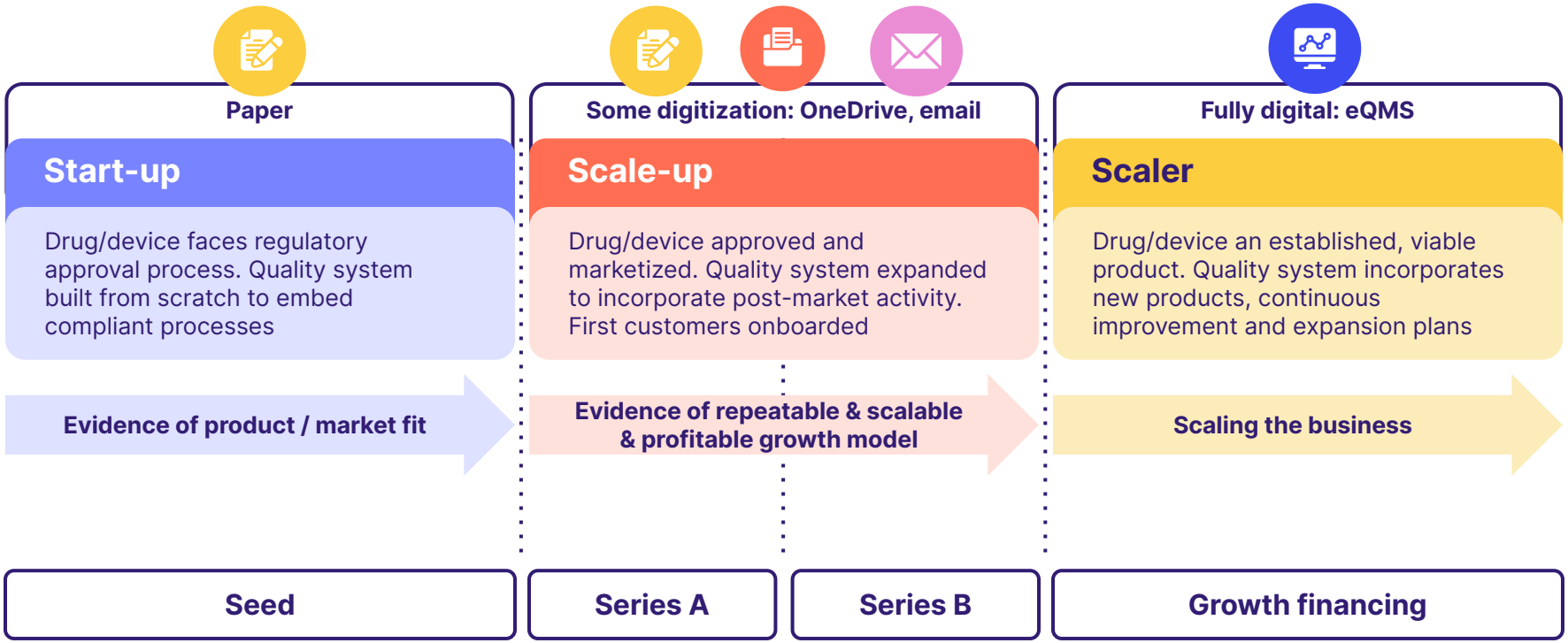
A typical journey: ‘paper now, eQMS later’



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The medical device world still feels backwards in many ways, entrenched in paper and with resistance to adopting new tools.

It feels like banking 20 years ago, when everyone was allergic to cloud SaaS products because of fear and bureaucracy.

Daniel Aragao
Chief Technology Officer
InVivo Bionics

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When’s the right time to get an eQMS?

As soon as possible.

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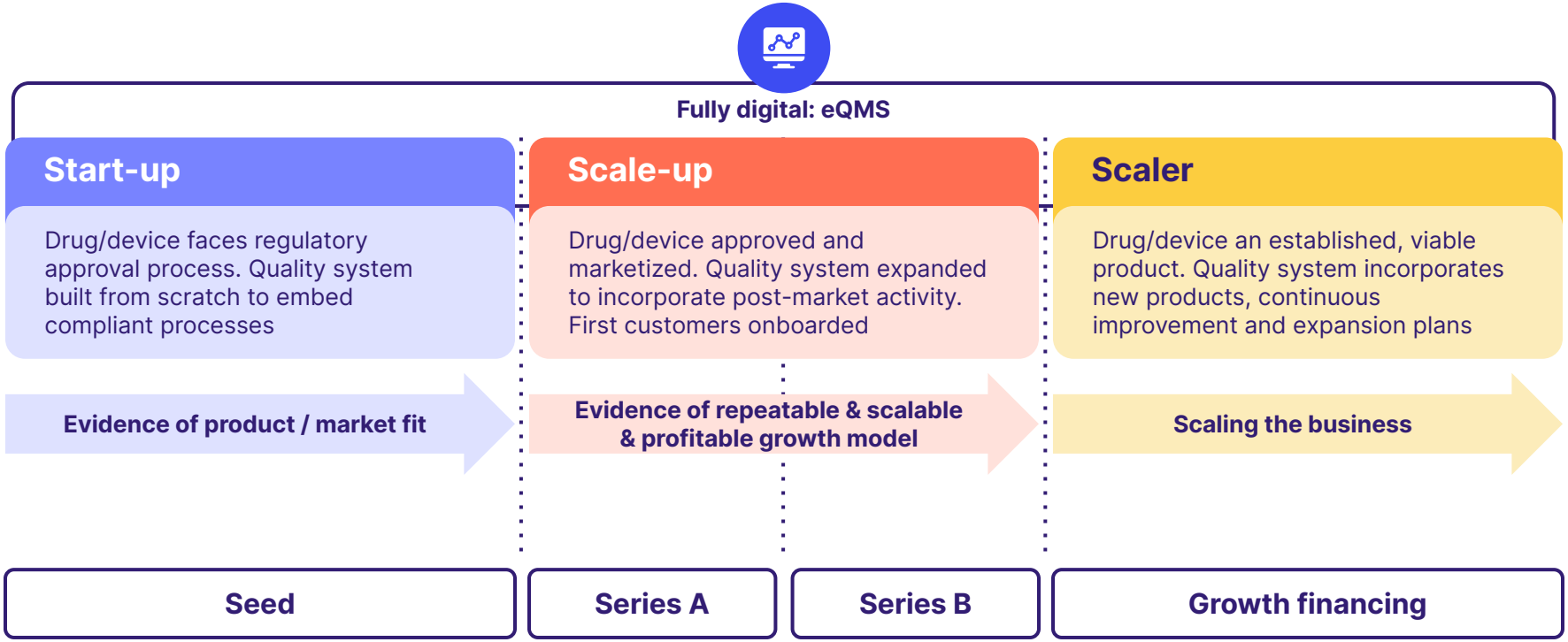
‘eQMS now, eQMS later’



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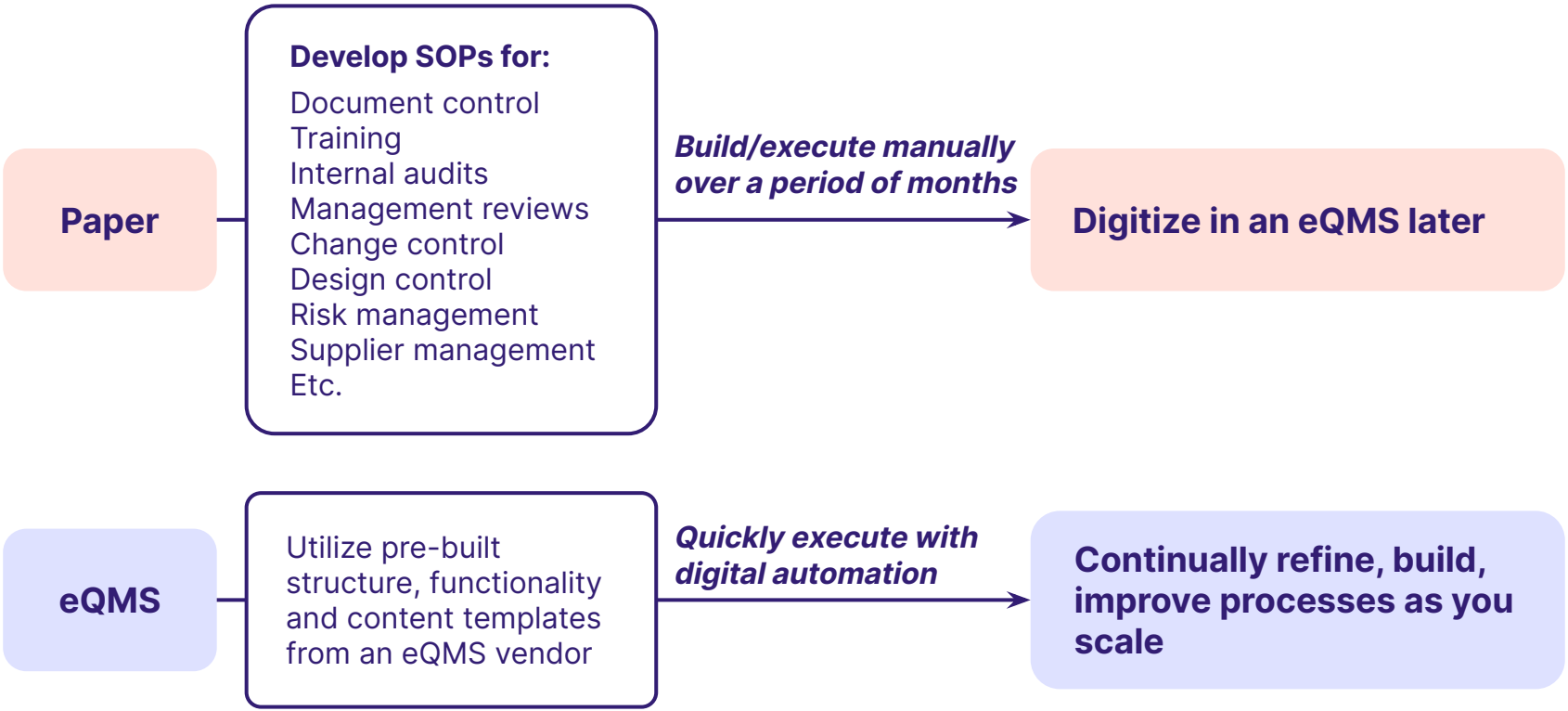
Reason for not getting an eQMS	Very good reason why you should
"We're getting by with our manual paper-based processes. We're ok."	Time is more precious for life science businesses than any other. eQMS users enjoy considerable operational time savings compared to a manual system, and by extension dramatically faster routes to market. One Qualio customer sliced their FDA submission process time by 90%!
"We've never had a recall!"	Drug and device recalls are rising. Almost 200 drugs were recalled by the FDA in 2022. Almost a fifth of recalls are triggered by specification failures, with mislabelling, contamination, adverse reactions and product defects also contributing. An electronic quality system allows you to bake product quality and data integrity into your processes from the beginning, insulating your business from the risk of a costly recall.
"Data integrity is the quality team's responsibility. We just need better quality people."	True GxP compliance and data integrity requires a holistic business-wide approach which connects and empowers your teams. Qualio allows best practice to become automatically ingrained into your daily routine while providing a single source of truth.
"Validating one of these systems is a nightmare and costs twice as much as the system itself!"	Qualio provides an end-to-end GAMP 5 CSA service as part of an industry-leading implementation timeframe. With a combination of documentation, templates, training and expert support, we can validate and set up your system in 60 days or less — *without* the excessive cost and time demands of other systems.
"We can't afford to invest in software right now. Paper is cheaper."	The costs of an eQMS are dwarfed by the costs of non-compliance which come with a manual GxP system. Product quality issues, rework, recalls and time-to-market delays can all amount to double or triple the costs of an eQMS investment (and often more).

1. Processes

“We have no processes so we don’t need an eQMS”

Read a real case study ›

- An eQMS can provide a ‘shortcut’ to mature, established processes for early-stage companies
- System structures, workflows and templates provide QMS ingredients at a stroke in a way which paper and spreadsheets cannot
- Less time manually building QMS processes from scratch means more time focusing on product actualization and your route to market
- Limited internal quality expertise can be a powerful reason to implement an eQMS, not a reason to avoid one


Paper
Develop SOPs for:
Document control
Training
Internal audits
Management reviews
Change control
Design control
Risk management
Supplier management
Etc.
Build/execute manually over a period of months
Digitize in an eQMS later
eQMS
Utilize pre-built structure, functionality and content templates from an eQMS vendor
Quickly execute with digital automation
Continually refine, build, improve processes as you scale

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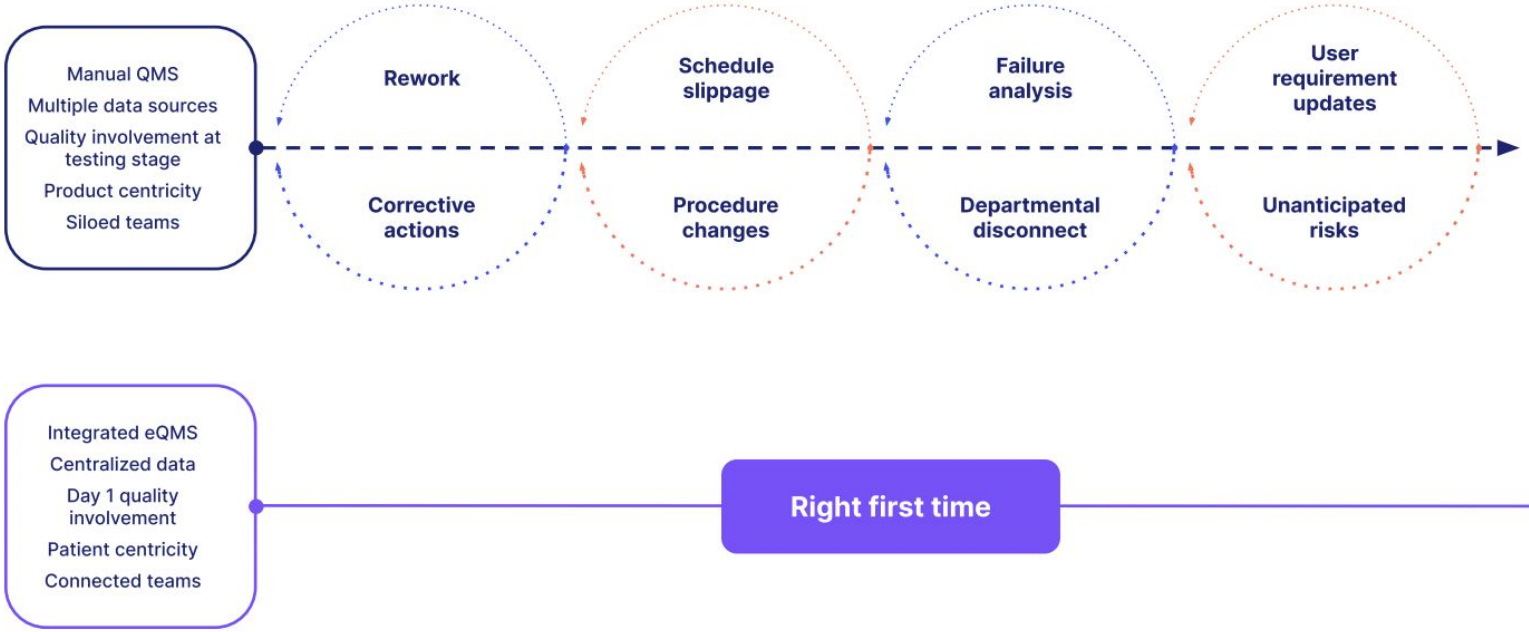
Getting it right first time



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“We need to focus on marketization, not digitization!”

Read a real case study ›

- Medical device manufacturer NeuFit realized their paper system was holding their products *back* from market
- After digitizing, event resolution speed tripled and regulatory audits were cut by 5.5 days each
- Director of Operations & Quality Management Ami Anderson estimates 3 years have been shaved from their next product launch timeframe

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“Digital quality is for businesses actually in the market”

Read a real case study ›

- Regulated companies hold off on eQMS upgrades because of the belief that certain functionality, like event management, isn’t necessary for pre-market businesses

- But quality events can be critical from Day 1 of your business: suppliers, NCRs, CAPAs, product issues and process issues should be given maximum control and priority early

- An eQMS gives your business a mechanism for capturing event data, learning from it, and making quick proactive changes

2. Costs

Which is cheaper?

or

Typical eQMS time/cost savings

Root cause analysis

2 colleagues, 1 hour per week	=	12 days/year	$2400	-45% with eQMS

Planning CAPAs and deviation responses

2 colleagues, 1 hour per week	=	12 days/year	$2400	-20% with eQMS

Managing resolution/implementation tasks

2 colleagues, 1 hour per week	=	12 days/year	$2400	-30% with eQMS

Tracking and trending quality event data (CAPAs, complaints, etc.)

2 colleagues, 1 hour per week	=	12 days/year	$2400	-15% with eQMS

Documenting event activities and tasks

2 colleagues, 1 hour per week	=	12 days/year	$2400	-10% with eQMS

Assigning and organizing QMS document training

1 colleague, 0.5 hour per week	=	3 days/year	$600	-20% with eQMS

Completing training: accessing, reading, signing off on documents

25 colleagues, 0.5 hour per week	=	78 days/year	$15,500	-20% with eQMS

Tracking and reporting on training status

1 colleague, 0.5 hour per week	=	3 days/year	$600	-50% with eQMS

Managing document lifecycles

1 colleague, 0.5 hour per week	=	3 days/year	$600	-60% with eQMS

Retrieving event management documentation

2 colleagues, 1 hour per week	=	12 days/year	$2400	-20% with eQMS

35 days/year saved › **$7000**

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The longer you use paper, the more money and time you waste

90%

of corporate memory exists on paper or in computer files that are not indexed or easily searchable

of all paper documents in the average office are merely shuffled and moved from place to place

7.5%

of paper documents get lost and **3%** misfiled

The average company spends:

- **$20** on labour to file a document
- **$120** in labour to find a misfiled document
- **$220** in labour to reproduce a lost document

The average document is copied

19x

Professionals spend up to

50%

of their time looking for information, but only 5-15% of their time using the information they retrieve

AIIM estimates small paper-based businesses spend $25,000 a year on production, usage and storage costs for hard documents

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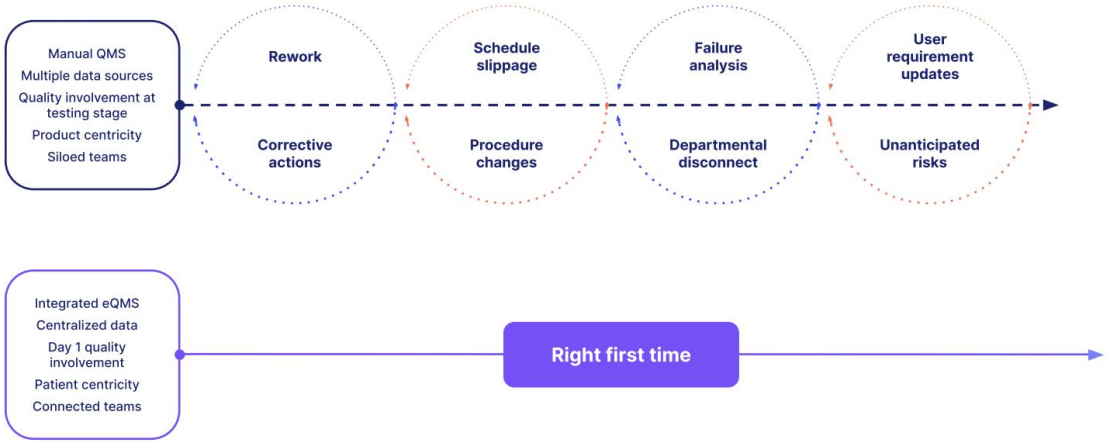
Right first time: even more important!



A McKinsey study found that poor quality event management costs between **6.8%** and **9.4%** of the average medical device company's annual sales revenue

The total median cost to implement a substantial protocol amendment for a Phase II clinical trial is **$141,000**.

For Phase III, it's **$535,000**.

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An eQMS saves you money by...

- Accelerating your processes and your route to market
- Mitigating headcount spend
- Insulating against financial risks like defects, recalls, trial termination
- Freeing up non-value-add time for continuous improvement and optimization work

Calculate your return on investment in less than 19 seconds!

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3. Quality culture

Accelerated culture-building from Day 1

Read a real case study ›

- An eQMS offers a trusted single source of truth to help a quality culture coalesce in your start-up and scale–up phases
- New hires understand the role and significance of quality immediately
- Everyone knows where to go to access information and complete actions
- Set the right tone while you’re still small, so it stays embedded as you scale

Keeping up with industry changes

- The FDA's Quality Management Maturity program was teased at the PDA/FDA Joint Regulatory Conference in September 2022

- Pharmaceutical companies can receive FDA-backed 'scores' of their QMS activity, so high-quality operations are rewarded with more business

- Continuous quality improvement is to be pushed as a key business initiative, with businesses scored against themselves over time

- Parallel initiatives like **new CSA guidelines** and the **GAMP 5 Second Edition** show that regulators *want* life science companies to digitize to achieve these aims

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eQMS adoption to scale the quality maturity curve

Strong

- Full digitization
- Thoughtful metrics selection
- Predictive analytics
- Strong quality culture
- Senior management and general staff commitment to quality
- Continual improvement of product, process and quality system

Evolving maturity

- Some digitization
- Evolution of metrics selection
- Promotion of quality culture
- Senior management commitment to quality
- Use of metrics and statistics in decision making

Weak

- Paper-based
- General, unspecific metrics
- Minimal product review program
- React to existing problems

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Pick the right eQMS for you

Qualio is a GAMP 5 Category 4 software tool.

Features include:

- Document, SOP and policy control
- FDA Part 11- and EU Annex 11-compliant e-signatures
- Staff training record management
- Event, incident, CAPA and change management
- Supply chain management
- Quality reporting
- Complete audit trailing
- Flexible user permissions
- Design control management with ISO 14971 and FMEA risk control
- API integrations

Our customers see results like:

- Faster time to market (savings of years and months)
- ROI in 8 weeks
- 35% reduction in cost of poor quality (COPQ)
- 20% time savings vs. manual processes
- 90% reduction in FDA submission process time
- Minimal or zero audit non-conformances
- Natural and automatic GxP
- Increased access to quality and compliance data

"The cost of our Qualio licenses is insignificant compared to what we've saved by just improving our processes."

— Peter B., Director of QA, Watchmaker Genomics

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12 questions to ask before buying an eQMS

Make the right choice for the next chapter of your business

Download free guide ›

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Boosting your competitive advantage with an eQMS

How a digital quality framework wins and keeps customers, clients and partners

Download free guide ›

See our eQMS in action

Request a demo

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