The business case for electronic GxP management

Automating quality control and compliance in GxP environments

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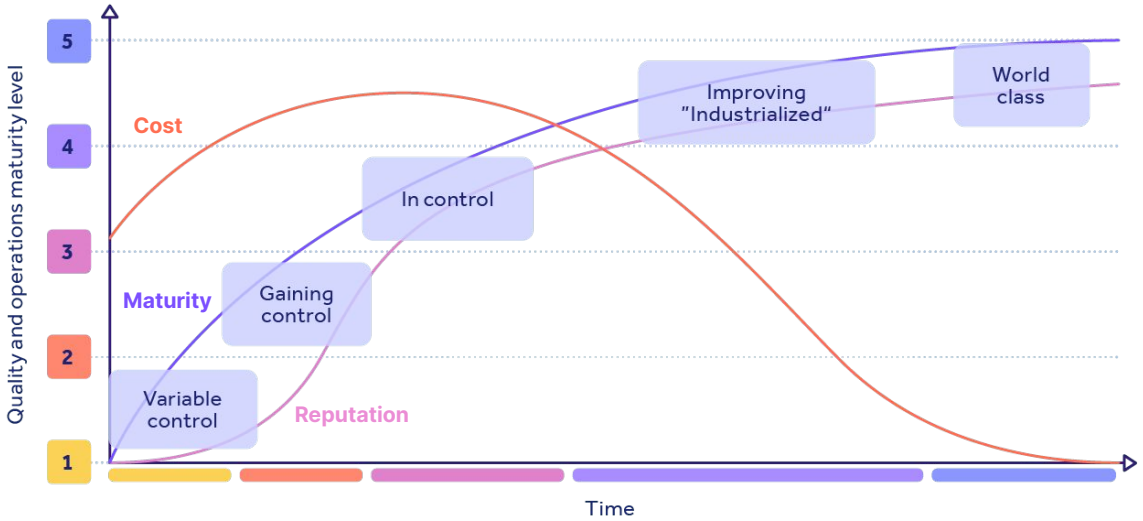
Quality and operations maturity level
5
4
3
2
1
Cost
Maturity
Variable control
Gaining control
In control
Improving "Industrialized"
World class
Reputation
Time


Quality improvement
Quality assurance
Quality control

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Why your GxP-regulated business needs an eQMS

Whether you need to comply with cGMP, GDP, GDocP, GLP, GCP, or a combination of several, your focus is always on patient safety.

But how can patient safety be assured and maximized without an integrated approach to product quality, data integrity, risk and training?

Being able to time- and cost-effectively manage and distribute information is critical if you are to demonstrate compliance in your regulatory submissions *and* enjoy complete confidence in your product.

> ***"85% of the reasons for failure are deficiencies in the systems and processes rather than the employee. The role of management is to change the process rather than badgering individuals to do better."***
>
> — W Edwards Deming

Electronic quality management software centralizes, automates and optimizes your core GxP quality and compliance activities, such as:

- Document, electronic signature and record control
- Training and competency management
- Quality event control, from CAPAs to complaints
- Reporting

Qualio is an integrated quality management software platform rated on G2 as the 'easiest to use' and 'easiest to set up' of all eQMS platforms.

We combine a powerful, centralized software system with expert support, speedy validation and best practice implementation to arm your business with everything you need for robust and automatic GxP compliance.

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*"The regulators are realizing there has been, historically, too much of a focus on compliance and manual quality control activities. Although this is important and essential, the real focus should be on quality **improvement**.*

*Where there aren't the tools and systems in place, there aren't enough resources or energy to put into quality improvement. 80% of the effort **should** be there, but currently it's where only 20% of time is spent.*

This means we're not focusing on the bigger picture, which is patient safety. Instead of line-by-line compliance, our focus should be on critical thinking and risk-based agile approaches to streamline assurance activity and evidence capture."

Sion Wyn
GAMP SIG expert
Managing Director, Conformity

Sion assisted the FDA as a consultant with its re-examination of FDA 21 CFR Part 11, is an active member of GAMP and ISPE, and has extensive experience providing computerized system validation (CSV) consultancy for the drug, device and clinical sector

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Getting buy-in

Manual quality systems 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 integrated electronic quality management system (eQMS) allows you to:

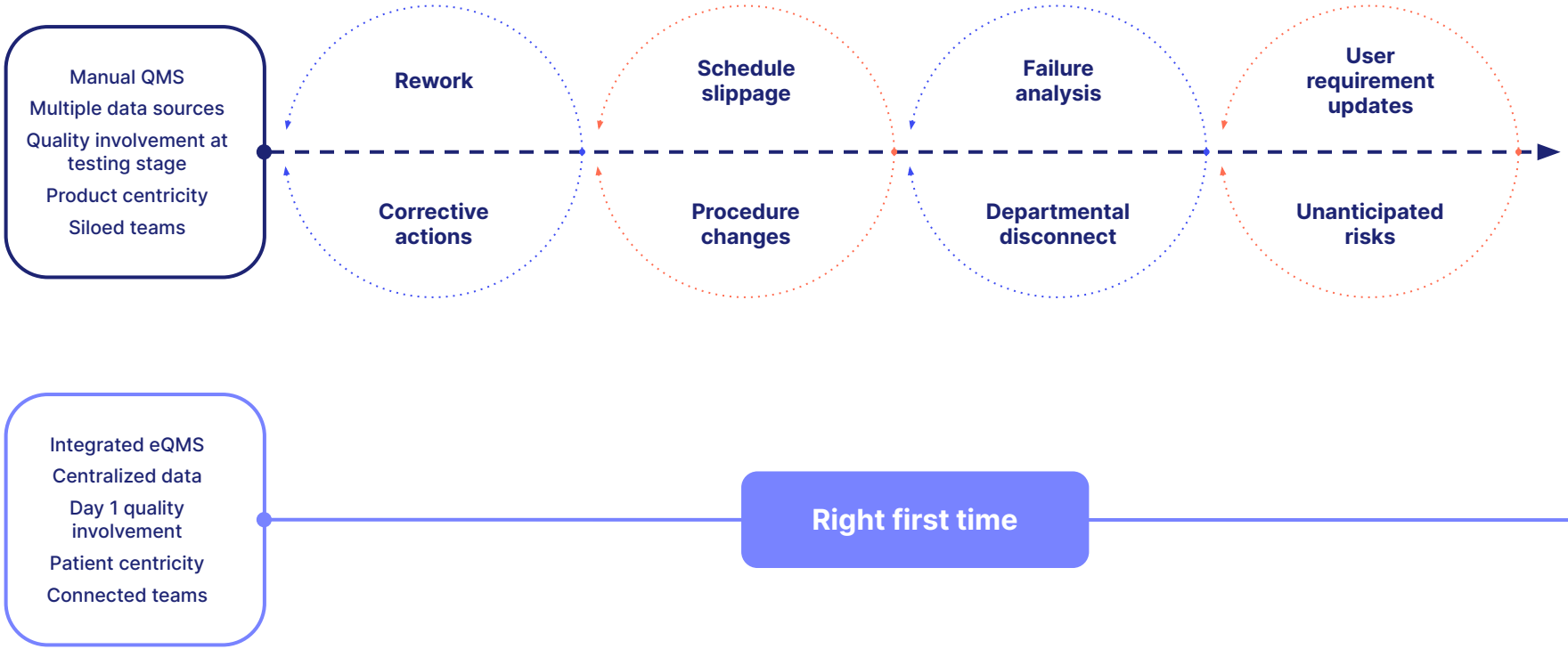
1. Proactively detect product quality and patient safety risks
2. Have confidence your electronic records are secure and compliant
3. Ditch time-heavy manual tasks to focus on quality improvement
4. Embed ALCOA+ best practices across your business

Qualio is designed for, and in partnership with, GxP-regulated companies and quality professionals and is trusted and supported by GAMP 5 industry experts.

Why GxP businesses are embracing eQMS platforms

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 GxP-regulated businesses than any other. Qualio users enjoy considerable operational time savings compared to a manual system, and by extension dramatically faster routes to market. One of our customers 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 2020-21. 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 CSV 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."	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).

The GxP route to market: manual vs. eQMS



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Intelligent GxP quality management software

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
- Deep 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
- 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

"Qualio is a great eQMS to achieve GxP compliance: easy to set up and use!"

— Muriel C., Chief Quality Officer, Pharnext

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Compliance-as-a-service approach to GAMP 5 CSV

The perceived burden of computerized system validation (CSV) is often the main reason GxP-regulated organizations shy away from electronic quality systems.

Qualio offers an integrated methodology that makes your validation process quick and truly painless, by providing a complete validation pack certifying your eQMS as compliant and appropriate for operation within a GxP environment.

From defining user requirements to producing a summary report and trace matrix, the Qualio implementation team do the legwork for you, eliminating the headache of validation and letting you focus on getting to grips with your new eQMS.

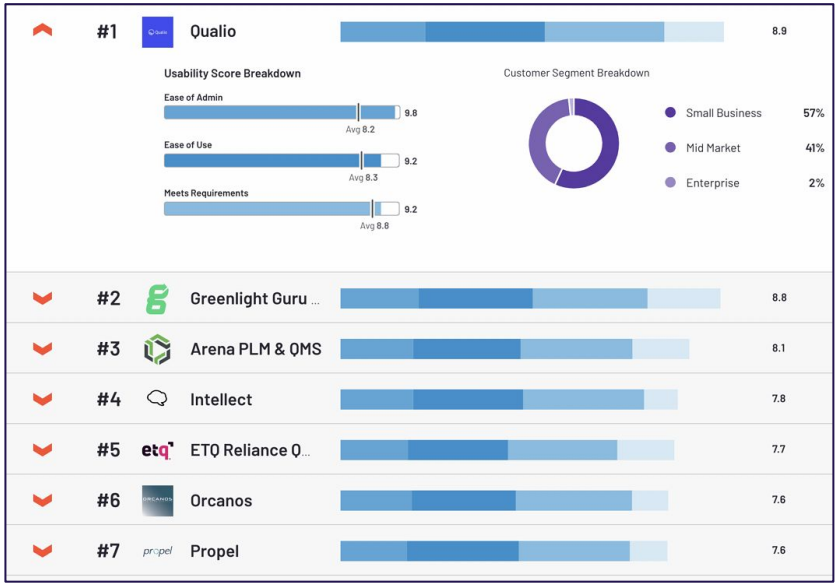
GxP-regulated businesses using Qualio

When you choose a GxP management software tool, you want complete confidence you're investing in a tool that delivers real results.

We don't just provide software then leave you to it. Our customer success team builds a lasting partnership with you to ensure you hit your quality and growth objectives long into the future, evolving your QMS as you go.

We routinely rank highest on G2 against our competitors in key areas such as:

- Implementation speed and ease
- Usability
- Results seen
- Return on investment



Read our real customer reviews ›

Qualio

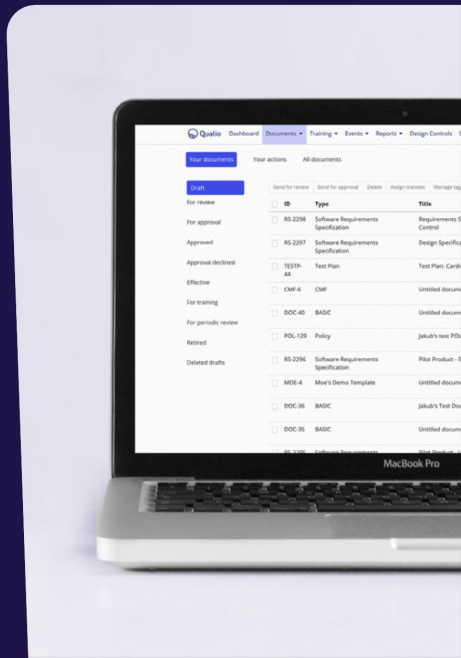
“Qualio is a great tool. Once you understand how it works it's really easy to plan out processes and put them into place within the quality management system.”

“The user friendliness of the tool is fantastic - having used traditional, heavy and complex eQMS, Qualio is a breath of fresh air.”

“Qualio is extremely user-friendly and provides a clear and concise quality management system.”

See our GxP quality management software in action

qualio.com/demo



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