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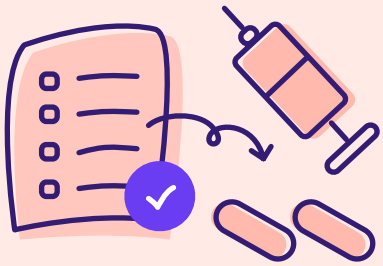

How to prepare for ICH Q10 compliance

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Qualio was founded in 2012 with a simple but important mission: to help life science organizations bring their vital products to market with a faster, stronger, more quality-centric approach.

Over 500 life science and healthcare businesses across the globe use Qualio to centralize, optimize and automate their quality management systems.

Qualio is a scalable and flexible cloud-based system that grows with your business and makes meeting your quality requirements truly simple, from ISO 13485 and ISO 17025 accreditation to FDA and GxP compliance.

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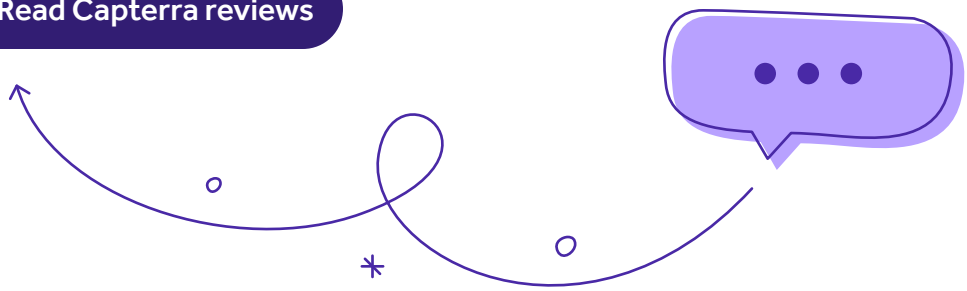

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Does your business manufacture pharmaceutical, therapeutic or biotech products? Current Good Manufacturing Practice (cGMP) guidelines should be a crucial backbone of your operation.

But GMP doesn't cover the entire pharmaceutical development lifecycle, or fully address the quality processes you need to bring your product to market and keep it there.

That's why ICH Q10 was developed.

ICH Q10 compliance marries GMP with the ISO 9001 structure of management responsibility and continuous QMS improvement, and is the best way to build a robust and holistic pharmaceutical quality system.

This guide, assembled by the Qualio quality team, breaks down the ICH Q10 guidelines and lays out the actionable steps your business should take for compliance. We hope you find it useful, and welcome your questions and queries!

Kelly Stanton
Director of Quality, Qualio

What is ICH Q10 compliance?

In **2001**, a PWC report uncovered shocking levels of inefficiency and waste in the pharmaceutical world, with scrap and rework rates touching 10% and costs of poor quality exceeding 20%.

In **2003**, FDA Commissioner Mark McClellan issued a damning assessment of drug manufacturing quality in the United States, labelling pharmaceutical quality management as less developed than that of potato chip and soap manufacturers.

And in **2005**, an IBM report found the average pharmaceutical process had an average sigma level of 4σ. Pushing processes closer to 6σ with a robust QMS driven by continuous improvement and quality by design (QbD), the report suggested, could unlock cost savings of over $10 billion a year.

Two decades later, the picture is better – but not dramatically so. Recalls, wastage and suboptimal quality continue to threaten pharmaceutical businesses and suppress the potential of start-ups and scale-ups in the sector. And the problem isn's just an American one: general lack of a cGMP- and training-driven QMS has now been the primary finding in UK MHRA pharmaceutical inspections for the past 5 years in a row.

ICH Q10 combines Good Manufacturing Practice (GMP) guidelines with the core QMS format of ISO 9001 to empower your business with a continually improving pharmaceutical quality system.

Complying with ICH Q10 lowers your costs, sharpens your processes, signals trust and strengthens your pharmaceutical business. Use this guide to take the first steps to compliance today.

11 benefits of ICH Q10 compliance

01. Integration with ICH Q8 (pharmaceutical development) and Q9 (risk management)

02. Splice GMP into a holistic QMS structure

03. Embed continuous improvement and quality by design (QbD)

04. Transfer and apply internal knowledge from the development and manufacturing lifecycle

05. Familiar ISO structure and terminology

06. Manage change and risk consistently and with diligence

07. Secure management commitment

08. Prove compliance to regulatory authorities

09. Reduce your cost of poor quality (COPQ)

10. Get to market and stay there

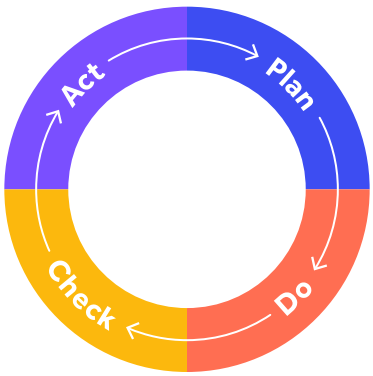
11. Build stronger, more consistent pharma manufacturing processes with less waste

Some key components of ICH Q10 compliance

The PQS

Adoption of a pharmaceutical quality management system to:

1. Consistently provide pharmaceuticals that meet patient needs and applicable statutory and regulatory requirements
2. Embed monitoring and control systems to assess and maintain process performance and product quality
3. Facilitate management commitment and continuous improvement
4. Allow 'enablers' of knowledge and risk management to be executed appropriately
5. Drive holistic CAPA and change management



4 lifecycle stages

Appropriate quality management across the 4 stages of the pharmaceutical lifecycle, as follows:

1. Pharmaceutical development

Designing a product and its manufacturing process to consistently deliver the intended performance and meet the needs of patients and healthcare professionals, regulatory authorities and internal customers' requirements.

2. Technology transfer

Transferring product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realization.

3. Commercial manufacturing

Achieving product realization, establishing and maintaining a state of control, facilitating continual improvement, assuring that the desired product quality is routinely met, suitable process performance is achieved, the set of controls are appropriate, improvement opportunities are identified and evaluated, and the body of knowledge is continually expanded.

4. Product discontinuation

Managing the terminal stage of the product lifecycle effectively, including activities such as retention of documentation and samples, continued product assessment (e.g., complaint handling and stability) and reporting in accordance with regulatory requirements.

Knowledge & risk management

Build a culture of shared knowledge and proactive risk management, with both feedback and feedforward underscored by frequent management reviews.

Design and manufacturing focus

Clearly documented manufacturing quality control processes, including key documentation like the quality manual, management responsibilities and identification of key processes, linkages and interdependencies.

Analysis and improvement

Leverage of data evaluation, statistical process control and process capability measurements to interrogate and continually sharpen manufacturing processes.

Learn more:

- What is cGMP in the pharmaceutical industry? An expert round-up
- 8 essential elements of pharmaceutical quality systems

Clause-by-clause breakdown

1. PQS

Lays out the broad requirements of a pharmaceutical quality system comprising 4 key components:

- Process performance and product quality monitoring
- CAPA
- Change management
- Management review

2. Management responsibility

Breaks down the areas that management should demonstrate commitment to and active involvement with the quality agenda, including:

- Allocation of resources
- PQS participation and oversight
- Communication
- Policies, planning and frequent review

3. Continual improvement of process performance and product quality

Lays out the core mechanisms and requirements to embed control and continual quality improvement of products and their adjoining processes, including:

- A CAPA system
- A control strategy
- Feedback capture
- Change management

4. Continual improvement of the PQS

Mandates a formal structure for reviewing and continuously improving the operation of the PQS, including:

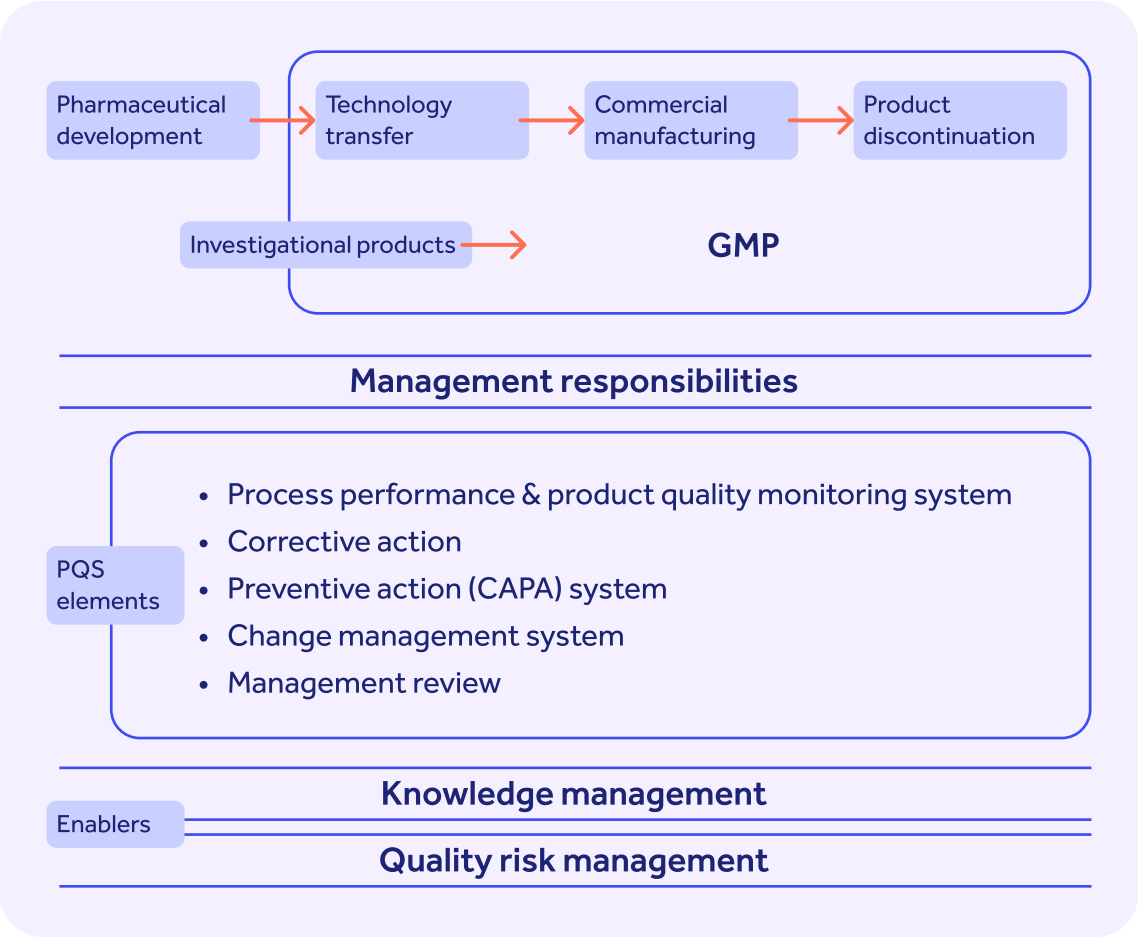
- Monitoring of internal and external impact factors
- KPI assessment
- Management review outcomes
- Monitoring of PQS objectives

5. Glossary

Definition of key terms and phrases, such as:

- Design space
- Enabler
- State of control

ICH Q10 PQS structure



9 ICH Q10 compliance tips from the Qualio quality team

01. Look to Pharmaceutical Inspection Cooperation Scheme (PIC/S) guidance for some of the broader and more ambigious areas of Q10, such as 'demonstrating the effectiveness' of your PQS

02. Use resources like Qualio's GxP toolkit to get to grips with cGMP requirements around data integrity and quality by design (QbD)

03. Keep the '4 pillars' and '4 lifecycle stages' front and center of your ICH Q10 quality planning and let them structure everything you do

04. Pharma just doesn't use core quality tools and techniques from other industries, like COPQ. Stand out from the competition by measuring things like that

05. Think of ICH Q8 and Q9 as supporting elements of your Q10 PQS

06. The content of Q10 which goes beyond GMP guidelines is technically optional – but embrace these areas as key competitive differentiators. A world class PQS will bring GMP automatically in its wake!

07. The 'desired state' referred to by the FDA's Dr Woodcock gives you a flavor of what you need to do to comply: 'A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drug products without extensive regulatory oversight'

08. Continual quality improvement is at the core of Q10 – consider how to dedicate as much of your time to this as possible by digitizing and automating admin and quality control/assurance work

09. ICH Q10 heavily emphasizes management participation and leadership – that means your CEOs and directors, not quality managers and batch release overseers. Use Qualio's culture of quality toolkit for actionable tips to drive this internal dynamic

Busting ICH Q10 myths

Myth #1: You can get certified to ICH Q10.

Truth: Just like ISO 14971 for medical devices, ICH Q10 is sometimes misinterpreted as a certifiable quality standard like ISO 9001. In fact it's an optional guideline that gives your business the ingredients for a functional pharmaceutical QMS and makes you far more likely to satisfy FDA, MHRA and EU auditors and get your products to market.

Myth #2: Pharma businesses with outsourced operations don't need a full ICH Q10 PQS.

Truth: ICH Q10 places emphasis on site-by-site compliance. Even if the sites don't belong to your business, the responsibility nevertheless rests on you as the sponsor to monitor, assess and guarantee quality. Clause 2.7 focuses specifically on management of outsourced activities and purchased materials for this reason.

Myth #3: Paper-based quality systems are suitable for long-term ICH Q10 compliance.

Truth: You can get by with a paper-based system in the short term if your company is very small. But if you have any growth ambitions, long-term go-to-market plans, or desire to maintain a baseline of compliance without undue effort, a paper-based system is unsuitable. More and more pharma and therapeutic companies are turning to electronic quality software as a way to ease the burden of compliance and make their way to the optimized Six Sigma processes called for by the industry.

Myth #4: You need ICH Q8 and Q9 before you can work to Q10.

Truth: It's best to have all three elements supporting and feeding into each other, and the ICH explicitly refers to the 'tripartite' approach. But ICH Q8, 9 and 10 aren't strictly integrated and there's no set order for your PQS pathway. For instance, you can still start building and applying the core elements of ICH Q10, like CAPAs and knowledge management, even if you don't have a complete quality by design (QbD) or risk management approach yet. Start with the elements you already have in your business, refine and strengthen them, then bring in the additional elements you need.

Myth #5: ICH Q10 is only for pharmaceutical companies, not biotech companies.

Truth: Pharmaceutical and biotech businesses are technically different: pharmaceutical companies produce synthetic small-molecule drugs which require a New Drug Application (NDA) with the FDA, while biotech businesses make cellular and biomolecular products using living biological samples, which require a Biologic License Application (BLA). But although ICH Q10 pertains to a 'pharmaceutical quality system', its requirements and demands are just as applicable to a biotech company as a pharmaceutical one. We therefore recommend pursuing ICH Q10 compliance whether your company works with synthetic or biological products – your company will be regulated and audited in the same way.

Top ICH Q10 mistakes to avoid

01. Not bothering to pursue compliance because it isn't mandatory

02. Trying to build a PQS from scratch: instead, take stock of your existing processes and how they interlink

03. Weak supplier qualification and verification processes

04. Lack of GMP training, or training records, to demonstrate to auditors

05. Paper-based and manual CAPA processes with low traceability

06. Weak document processes and general lack of GDocP to drive a uniform, documented PQS

07. Not conducting management reviews frequently enough, or closing out subsequent review actions

08. Inordinate focus on reaching the market without proper attention given to post-market surveillance and discontinuation phases of the lifecycle

8 steps to a functional and compliant PQS

ICH Q10 compliance is a powerful addition to your pharmaceutical quality approach. Follow these 8 key steps to kickstart your compliance journey today.

1. Familiarize yourself with the guidelines

Take time to read the guidelines thoroughly and make sure you understand what's required of you, your colleagues and your business leaders. View the ICH Q10 guidelines here.

2. Meet CAPA standards

Refer to the FDA's inspection guidelines, ISO 9001 8.5.3 (prevention), and ISO 9001 8.5.2 (correction) to ensure your company meets the CAPA standards prescribed by ICH Q10.

A functional CAPA system is one of the 4 'pillars' of the ICH Q10 PQS model and cannot be neglected.

3. Monitor, monitor, monitor

Establish a mechanism for process performance and product quality monitoring. Without it, the rest of ICH Q10 - from management oversight to continual improvement - is impossible.

4. Establish robust supplier management

21st-century pharma businesses are strongly interconnected and complementary, and outsourcing to CROs and CMOs is part and parcel of modern drug development.

Create written procedures and policies that establish a supplier management framework. Give yourself the ability to mandate documents like SLAs from suppliers and interested parties, assess and record risk levels, and establish audit frequencies to continuously monitor supplier performance.

5. Culture is king

ICH Q10 follows the lead of ISO 9001 and Annex SL in mandating strong management commitment, then goes even further.

Consider how to drive a real culture of quality and strong lines of communication from the boardroom to the manufacturing line, and back again, so that quality initatives, objectives and action steps are quickly shared and understood by all.

6. Weave GxP into your business operation

Roughly speaking, an ICH Q10 pharmaceutical quality system combines the requirements of cGMP with the traditional QMS structure of ISO 9001.

Following cGMP guidelines within an integrated QMS is the backbone of your ICH Q10 compliance - but don't stop there.

Embed as many GxP processes as are applicable and appropriate for your business. Alongside GMP, consider GLP if you have a laboratory, GDocP for your document stack, GVP for your post-market surveillance activities, GDP for your product distribution, and so on.

The more GxP benchmarks you can realistically apply and maintain, the stronger your compliance will be.

7. Focus on quality by design (QbD) to earn trust

Quality by design doesn't only facilitate lean, right first time manufacturing. Minimized batch failures and rework, better consistency of product and demonstrable control of your product lifecycle will in turn mean less burdensome regulatory oversight for your business.

Pharmaceutical regulators will generally apply scrutiny appropriate to an organization's perceived risk level. Earn trust, ease your burden of compliance.

8. Build a digital quality management system

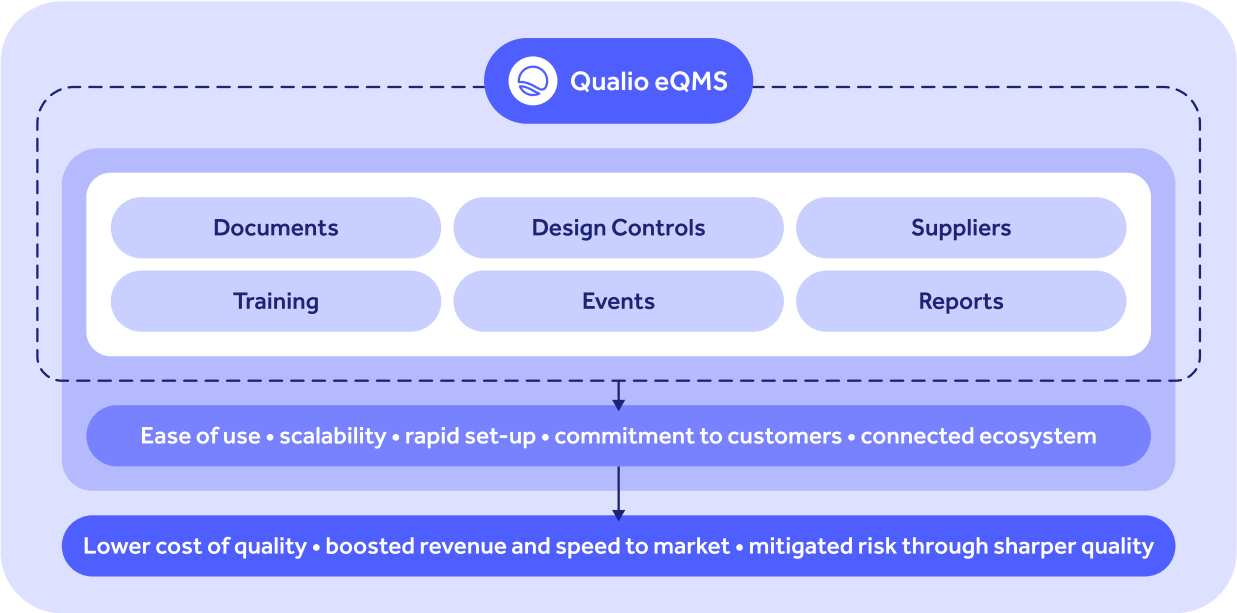
Manual paper-based quality systems bog down pharmaceutical quality managers in time-intensive admin tasks and block the continual improvement, knowledge management and 20/20 visibility demanded by ICH Q10.

Electronic quality management systems designed for life sciences companies — like Qualio — are designed to embed the quality control, operational efficiency,

connected knowledge, regulatory compliance and robust manufacturing processes you need for an ICH Q10-compliant PQS.

The perfect eQMS should provide essential functions such as document control, training and CAPA management, while fostering collaboration and eliminating and automating quality management tasks.

When you implement a robust eQMS like Qualio for your pharmaceutical company, you're instantly one step closer to building – and maintaining – ICH Q10 compliance.



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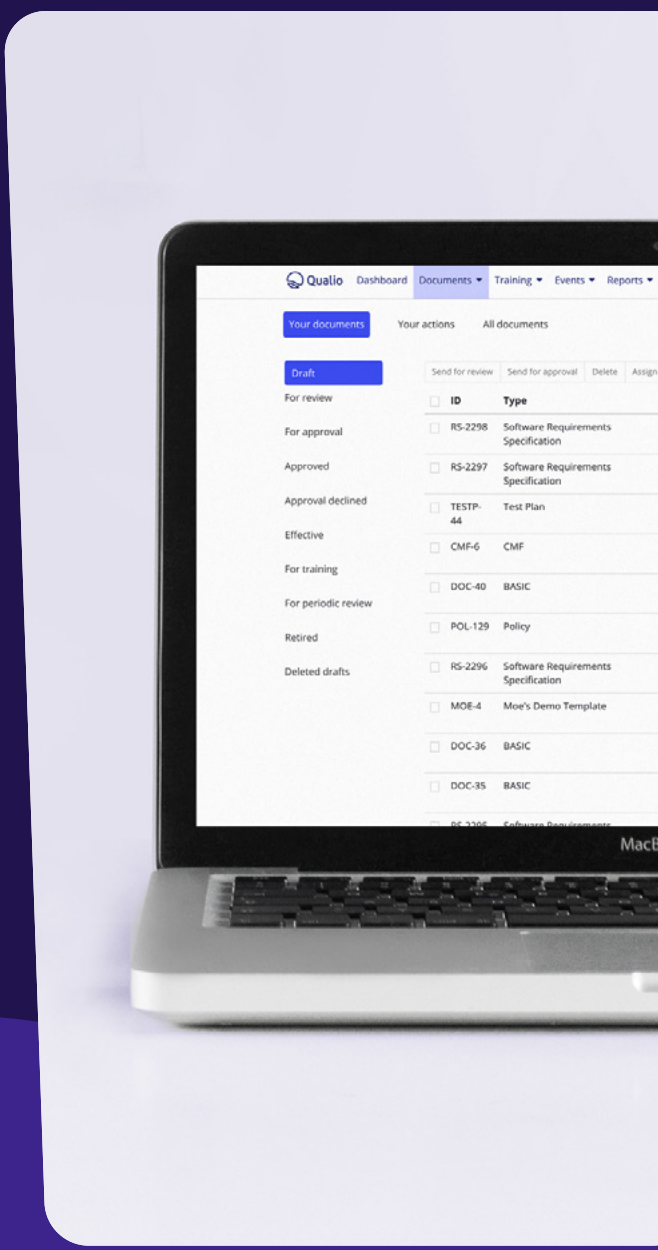
See our pharmaceutical quality management software in action

Learn why hundreds of pharmaceutical and therapeutic companies use Qualio to bring their products to market and embed GMP and ICH Q10 compliance.

Request a demo today



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