Qualio

*Complete guide to the **Quality Management Maturity** program*

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The FDA's Quality Management Maturity (QMM) program is a welcome addition to the pharmaceutical industry.

For the first time since the ICH Q guidelines, a new model of pharmaceutical quality management that moves beyond the bare-minimum baseline of cGMP is taking root.

It's still early days, with further details to come. But this guide summarizes and breaks down everything you need to know about the QMM program to date - from what it'll measure, to the problems it aims to address and what full quality maturity really looks like to regulators.

We hope you find it useful, and welcome your comments and questions!

Meg Sinclair
Quality Operations Manager

Chapter 1

The background

It all began in the USA with a 2019 drug shortage report from the FDA.

The previous year, the Drug Shortage Task Force had launched an investigative analysis of historic drug shortages. 31 senators and 104 representatives asked for help after a steady growth in drug shortages nationwide, with some shortages lasting 8 years or more.

The FDA summarized the DSTF's findings, with some recommendations, in their report.

They found that 62% of shortages between 2013 and 2017 were triggered by suboptimal product or manufacturing quality.

Worse still, the problems were systemic.

"Many pharmaceutical manufacturing firms have focused their efforts on compliance with cGMPs, which include standards for material systems, equipment and facilities, production, laboratory, packaging and labeling, and a quality system.

These standards, however, are foundational and set a minimum threshold that companies must achieve in order to be allowed to supply the U.S. marketplace. They do not include more advanced levels of quality management..."

Three root causes were identified, with number 3 being the most significant:

1 — A 'race to the bottom' for cheap manufacturing led to limited investment in and modernization of drug manufacturing systems

2 — Logistical challenges within the physical supply chain brought knock-on disruptions which compounded the immaturity of manufacturers

3 — Manufacturers had no incentive to be better. They were rewarded for compliance with market access, but received no rewards or incentives for full operational maturity

These problems persist today.

After all, end customers and patients still have no visibility of drug manufacturers or their quality maturity.

Manufacturers don't get to demonstrate their quality in return for price premiums or competitive advantage, nor are they penalized for sticking with 20-year-old manufacturing lines.

Above all, it's easier to keep costs down by minimizing quality investment and keeping things at the bare minimum: compliance, and nothing more.

The QMM program is the industry answer to these systemic issues. Companies that understand it, embrace it and align with its expectations can expect significant rewards.

Chapter 2

The FDA's 3 suggestions

The 2019 report didn't just find the problem. It pitched 3 solutions:

1 — Cultivating a shared industry-wide understanding of the impact of drug shortages and the importance of guarding against them

2 — Promoting sustainable private contracts across the pharmaceutical industry to foster consistent supply of pharmaceutical product

3 — Establishing a quality management maturity 'rating' system that rewards companies reaching those 'more advanced levels of quality management'

Of the 3, it's the final point which has formed the heart of the QMM program and generated the most attention. Transparent ratings of operational quality maturity benefit everyone.

Patients

Enjoy more consistent access to drugs as the industry shifts to continuous improvement

Can choose medicines from higher-quality manufacturers and make more informed health decisions

Industry

Purchasers can choose to contract with more mature partners

Manufacturers are encouraged and empowered to continuously improve, tackle the regulatory flexibilities described in ICH Q12, and position themselves publicly as high-quality operations with the reputational and financial benefits that follow

Regulators

Can perform risk-based audits and inspections based on QMM ratings, homing in on weaker actors to more proactively protect against shortages

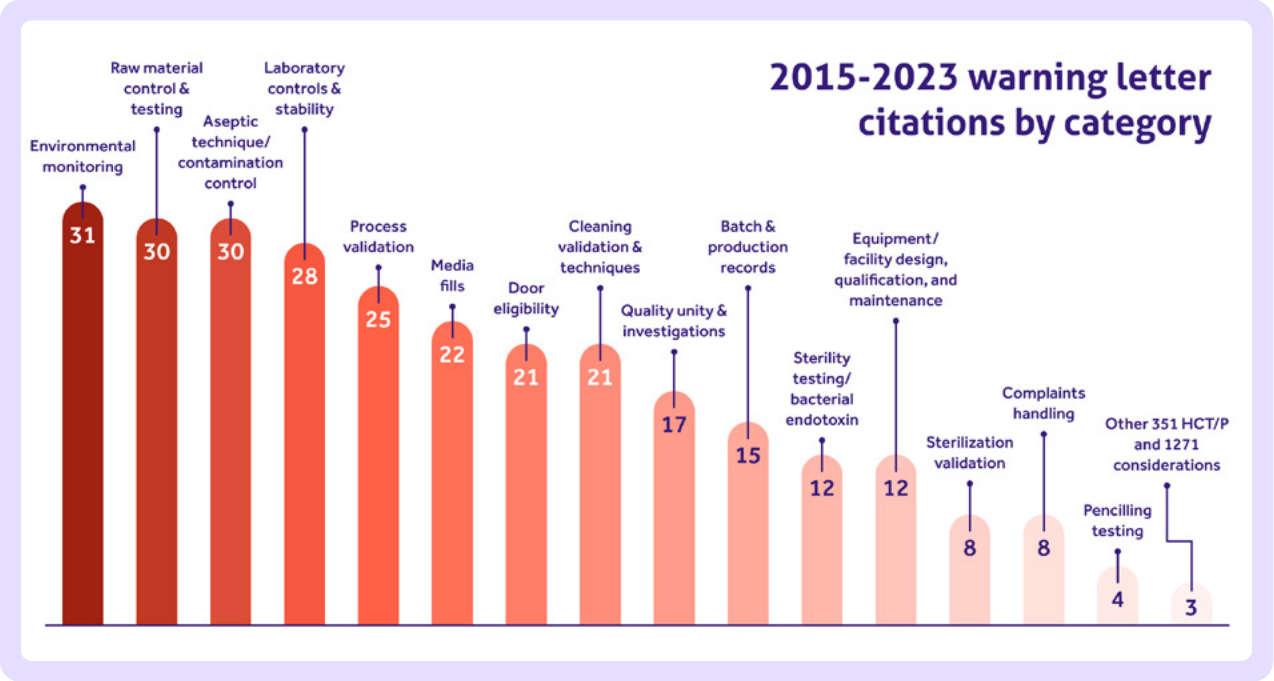
CDER Quality Management Maturity

Chapter 3

The new pharmaceutical quality system

All is not well with the modern pharmaceutical quality system.

FDA Form 483 and warning letter data shows basic operational ingredients like procedures either not existing or, even more worryingly, being in place but not being followed in active use.



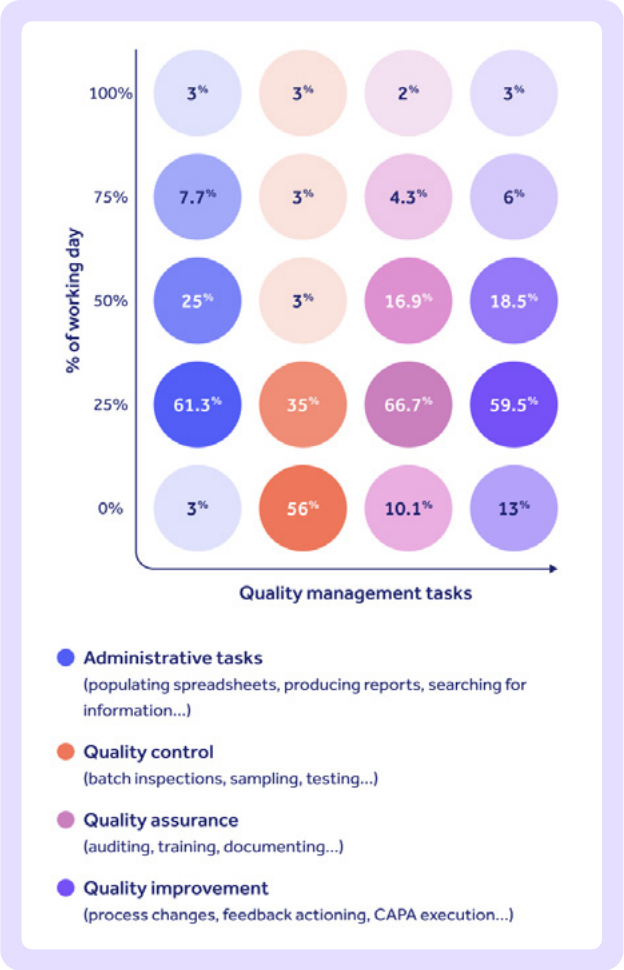
In the UK, quality systems and documentation have, since 2015, formed the most common deficiencies noted by the Medicines & Healthcare Products Regulatory Agency (MHRA).

And Qualio's 2023 global life science quality trends report found quality professionals losing huge amounts of time to manual administrative upkeep tasks ('negative work') like populating spreadsheets, collecting training signatures and searching for quality data.

Almost three-quarters of respondents could allocate no more than 25% of their working day to continuous quality improvement tasks. 13% had no time at all to do so.

At the heart of the QMM program is a new understanding of what the pharmaceutical quality system (PQS) is and should do.

Instead of an independent, discrete departmental function designed to embed compliance, the mature PQS should be seen as a business-wide operation synchronizing all elements of your organization to move them beyond compliance, and to make continuously improving quality and consistent drug output part of how you do business.



cGMP	ICH Q10	QMM
Bare-minimum manufacturing compliance	cGMP + ISO 9001 (PQS)	ICH Q10 PQS + continuous improvement

" Quality management maturity is the state attained when drug manufacturers have consistent, reliable and robust business processes to achieve quality objectives and promote continual improvement."

" Quality systems shape culture." — FDA

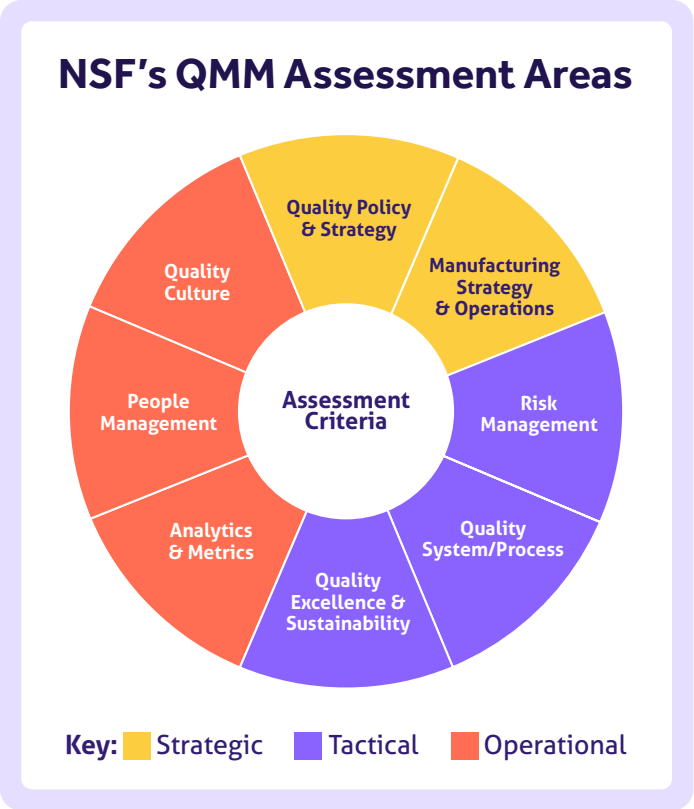
Chapter 4

Measuring quality management maturity

It's all easy to say. But how should businesses actually assess and act on their own operational quality maturity?

The traditional quality system approach rests on establishing a QMS, then measuring and altering performance with Plan Do Check Act underpinned by internal audits and quantitative metrics.

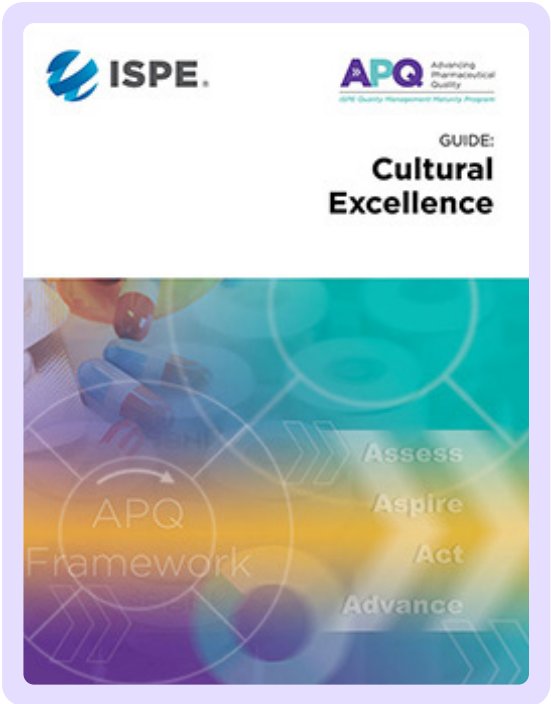
The QMM program pushes for a more holistic approach, with the PQS the driver of a cohesive combination of corporate governance, technical processes, and a collaborative culture of quality that incentivizes everyone towards quality outputs and deliverables.



NSF's QMM assessment model of both quantitative and qualitative elements holds some helpful clues of the areas that should be investigated and worked on.

The three 'pillars' of the operational, tactical and strategic are covered by their respective elements, all of which are quantitatively assessed on a sliding scale from Undefined through Defined, Managed, Improved and Optimized, before a 'qualitative narrative' and improvement roadmap are generated and worked on.

The ISPE also has some helpful measurement guidance here. Since QMM hinges on 'softer' elements like quality culture, take a look at their Cultural Excellence guide for some insights into how to begin measuring your cultural and climatic quality environment.

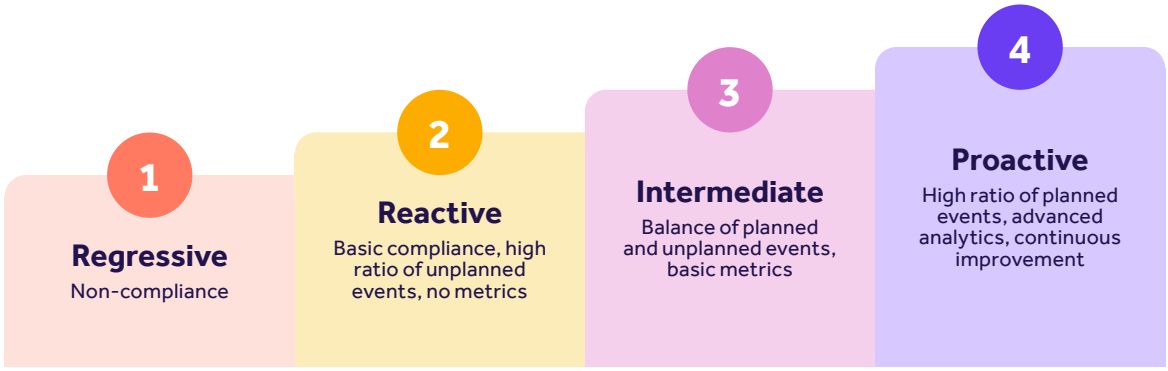


Chapter 5

Quality management maturity signals

What does the program suggest as the signals and characteristics of functional quality maturity for a pharmaceutical operation?

Low maturity	High maturity
Out-of-date procedures with low operational adherence	Modern, appropriate procedures with complete adherence
Low levels of proactive improvement work, high levels of 'negative' admin and upkeep tasks	Quality admin automated and digitized, freeing time and effort for continuous improvement
Lagging indicators, basic metrics	Leading indicators, advanced predictive metrics
Reactive: high number of unplanned events, deviations, excursions and 'firefighting'	Proactive: low levels of rework and unplanned events, primary focus on voluntary improvement initiatives
Fragmented culture	'Golden thread' culture of trust and openness
Low morale, high turnover	Positive ethos and environment with happy, loyal employees
GxP compliance focus and effort	Quality best practice and automation focus with natural compliance as byproduct
Decisions made by small number of managers	Decisions made by empowered, engaged staff



Four stages of maturity

Chapter 6

What now?

Both domestic and international pilots of the QMM program have been run by the FDA, followed by an industry stakeholder discussion.

As of late 2023, the FDA is actively consulting with industry experts across the globe for input and recommendations – and appears to be taking the QMM program very seriously as a medium-term initiative.

Though limited to the US for now, the chances of a broader international roll-out of similar programs and initiatives are high. The EU is worrying about drug shortages just as much as the US, as evidenced by the content of its proposed Human Medicines Regulation and of Regulation 2022/123, which goes live in 2025 and includes the set-up of a European Shortages Monitoring Platform overseen by the EMA.

In all, the QMM represents a watershed moment in how pharmaceutical businesses think about and work towards quality deliverables and outcomes.

Chapter 7

FAQs

When will the QMM program be going live?

Unfortunately, we just don't know yet. The program has been gathering momentum steadily since 2019 and continues to come into focus. But an actual launch date still appears at least a couple of years away.

What will the rating system look like?

This, too, isn't known yet. But we can make some educated guesses. The FDA already publishes certain inspection information publicly on its Inspection Classification Database. Publication of QMM ratings could follow a similar pattern and format.

The QMM program could even place manufacturers' quality maturity front and center of the public eye, with ratings on medicinal labels available for scrutiny in the same way a restaurant's hygiene rating is posted by its front door. We can only wait and see.

How will a 'good' QMM rating help a pharmaceutical business?

A business committing to the tenets of quality management maturity will be rewarded with a higher public-facing score than one still focusing on bare-minimum GMP compliance. A 2022 Qualio consumers & quality sentiment report found

the public taking unprecedented interest in the healthcare products and services they use, and this consciousness of drug quality should result in a natural preference and demand for drugs from more quality-mature manufacturers.

Highly-rated businesses can therefore expect higher competitiveness and commercial success, as both industry purchasers and the wider public prioritize products from these organizations.

It sounds like the program is a way off. I guess there's nothing to be done yet.

Wrong! The QMM program is a major initiative which will have a lasting impact on the pharmaceutical industry, in the United States and probably beyond.

The adage of the early bird catching the worm is particularly true here. Businesses that can take stock now and begin to move to a more mature state of operation will be better-placed than those moving from a standing start when the program launches.

The QMM program won't only provide businesses with the commercial incentivization noted above. Moving to a state of higher quality maturity in itself brings cost savings and boosted efficiency. There's therefore no need to wait. The benefits of higher quality maturity can be felt even before the program takes off!

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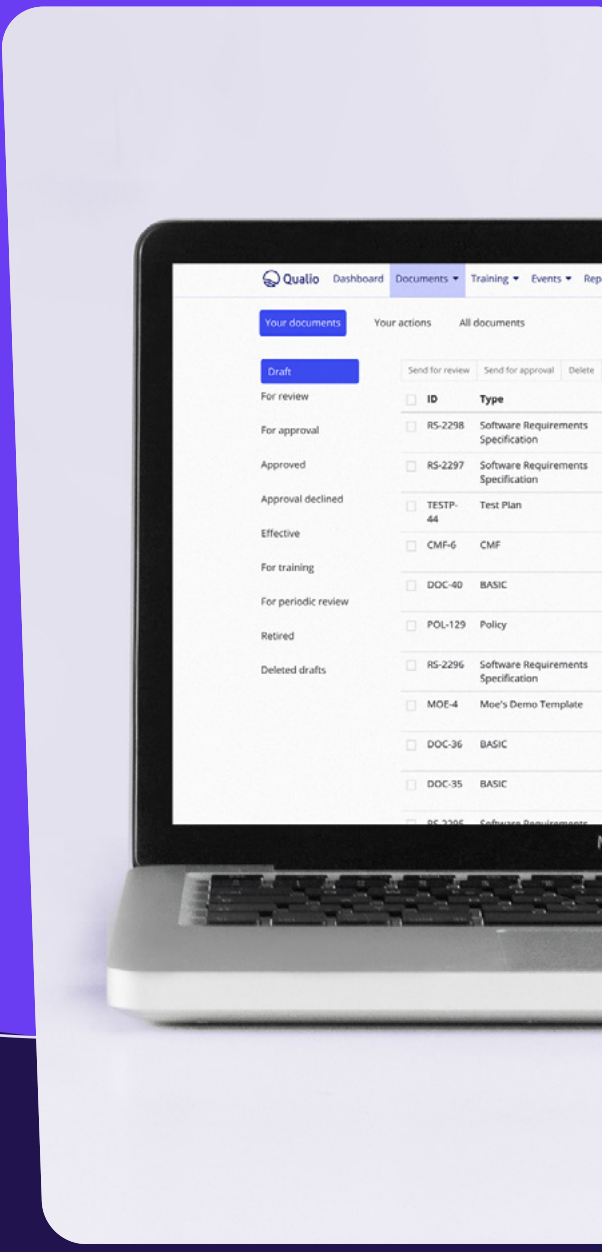
Explore the best pharmaceutical quality software options for 2024

Learn more



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