Qualio

*How to build and measure a culture of **pharmaceutical quality***

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Every business talks about a quality culture. In a perfect world, all your employees would be aware of, engaged with, and fully supportive of, quality. Best practice quality would define a golden thread running from top to bottom of your organization, binding everyone together into a standardized, patient-centric and defect-free way of working.

The theory sounds nice. The reality is a little trickier. While 'quality' is easily defined with metrics, KPIs and indicators, 'culture' is harder to pin down.

What exactly is a culture of quality in practice? How can it be built and – more importantly – measured and defined?

This guide pulls together a few key areas you should consider, from guidance documents to case studies, to set you on the path to a real culture of pharmaceutical quality.

Meg Sinclair
Quality Operations Manager

Chapter 1

Defining a culture of pharma quality

The simplest definition of a quality culture is one where all employees, at all operational levels of your business, consciously prioritize quality as a way of working. The PDA offers 14 ingredients of the modern pharmaceutical quality culture:

1— Customer focus

Patients, not regulators, are your primary customer

2— Quality as the responsibility of everyone

Senior management, process owners, subject matter experts and all other employees 'own' and are responsible for quality

3— Quality before cost

Quality should make processes cost-effective with minimum waste – but should never be compromised to cut costs

4— Employee empowerment

All employees should be given responsibility and accountability for the quality of their work. Training should boost that quality

5— Continuous improvement

Processes should be continually reviewed and optimized with the objective of 95% right first time; critical processes should approach 100%. Six Sigma should be the long term goal

6— ISO 9000 system approach to management

The PQS should form a harmonized system of various interrelated processes – not discrete departments

7— Scientific approach

Decisions, specifications and limits based on data and modern scientific principles

8— Emphasis on prevention, not appraisal

Shift from quality by inspection to quality by design (QbD). More proactive, preventive events than corrective ones

9— Balance between short and long terms

Excellence requires years of consistent effort, driven by a long-term strategic improvement plan for the PQS

10—Teamwork

All areas of the business should work together, openly and honestly, to achieve common cross-functional objectives

11—Integrity

Management must hold themselves and their employees accountable for their actions

12—Drive out fear

Nobody should be scared to tell the truth or confront quality problems – business culture should reflect this

13—Risk management

Risk analysis and risk thinking permeates all processes and decision-making – everywhere

14—Give priority to learning

Benchmark and learn from other industries. Allocate 3–5% of available time for valuable training that improves the business

McKinsey, meanwhile, identifies 5 interacting elements that are critical for a quality culture to take hold:

Chapter 2

Communication: the 2 types of knowledge

Your quality culture will live or die on the strength of communication between all layers of your business, from shop floor to boardroom.

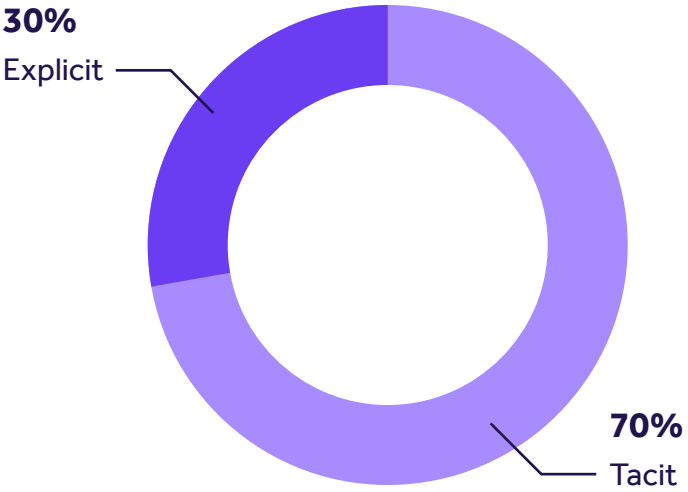
Clear information exchange, across your manufacturing plant, laboratory, pilot plant, analytical development lab and so on, allows your quality culture to take root and guides your organization towards patient-centric quality outcomes.

It's important that *both types of information* are understood and managed properly.

Explicit knowledge
documented SOPs, policies, records

Tacit knowledge
institutional know-how that's applied as situations arise

The modern pharmaceutical or biotech business operates in a knowledge industry. But tacit knowledge is often overlooked and ignored, despite McKinsey estimating the split between explicit information and tacit knowledge to be as follows:



Explicit knowledge

Scattershot, tick-in-the-box roll-outs of vast amounts of complex documents like SOPs and work instructions are common for pharmaceutical businesses, particularly for new hires. But this approach is guaranteed to block a quality culture.

When aiming to make quality a business-wide initiative understood and supported by everyone, it's important to ensure that your communication methods and styles don't get too insular.

Remember: most people in your company aren't quality people. The modern learner is saturated with data, systems, devices and information – they absorb explicit knowledge quickly, but not deeply. Attention spans are short, reward-oriented and often visually focused. And:

Average reading age

9

Dyslexia population coverage

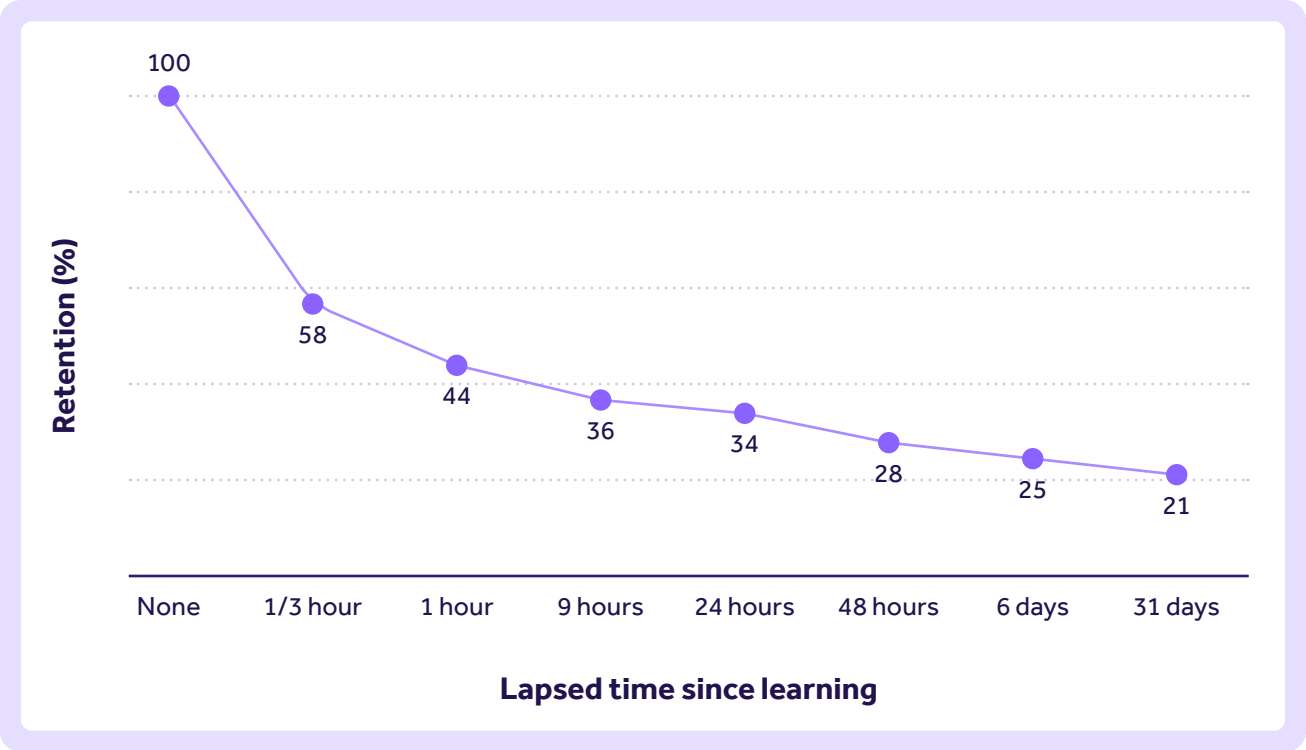
20%

Harvard Business Review found dissemination of explicit knowledge, and training people on it, is scuppered by 4 common problems:

- Wrong timing
- Wrong reasons for teaching
- Wrong focus of teaching
- Ignoring the 'forgetting curve'

The forgetting curve

If new information isn't applied, we'll forget about 75% of it after just six days.



Source: Hermann Ebbinghaus

Building an effective quality culture, understood and supported by everyone, is impossible without recognizing and dodging these explicit knowledge diffusion mistakes as follows:

Blocks quality culture	Builds quality culture
Difficult-to-trace paper documentation	Easily accessible, remotely organized, cloud-based documentation
Large amounts of infrequent, broad SOP/WI training	Small amounts of contextual, just-in-time SOP/WI training guided by SMEs
Textual information	Textual information supported by images, presentations, videos
One-time 'read and signs'	Documents easily available at point of use for repeat reference
No context	Broader operational context and quality 'whys' integrated into content
1:1 role-based training	1:many operation-based training

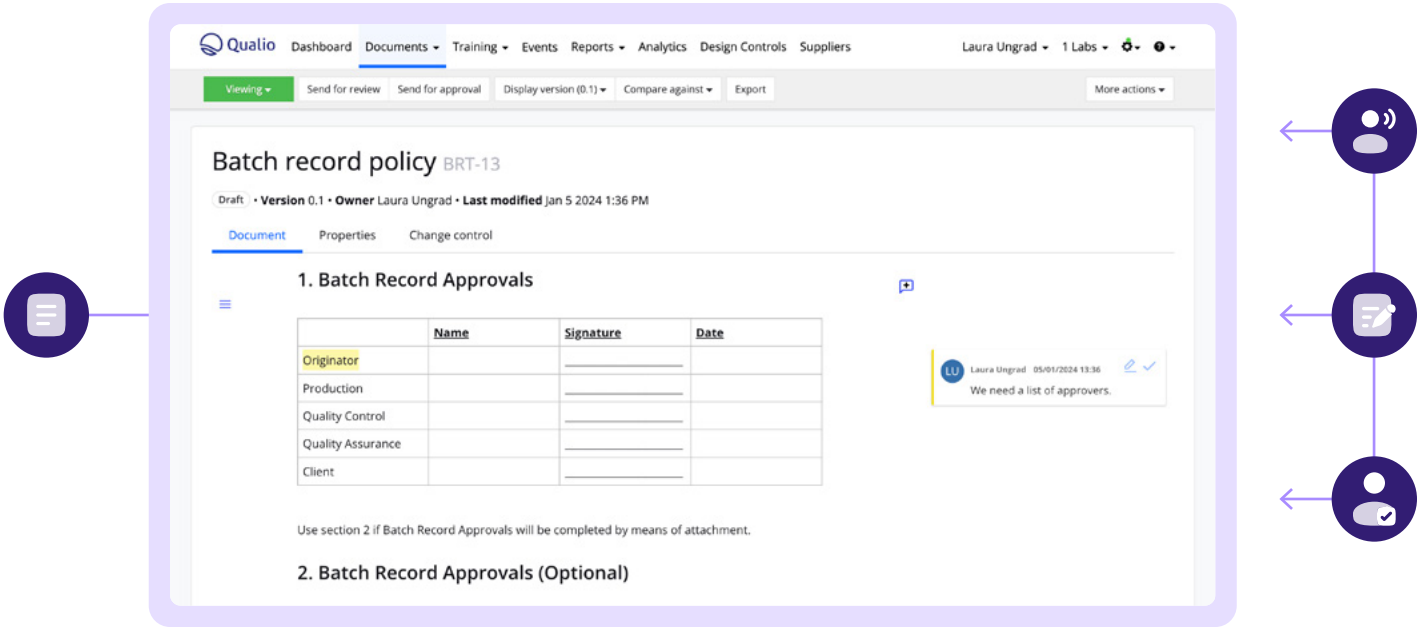
Don't simply train individuals on large amounts of documents based on their roles. Instead, map your processes, then train people with *different* roles who are involved in the *same* overarching processes on the same documents to encourage:

1— Deeper, specialized knowledge of that business area, such as the granulator stage of the line for example

2— Cross-functional perspectives on the same explicit knowledge

Consider an electronic quality management system, too, to offer an easily accessible repository of information for workers to view in seconds from the shop floor.

Prioritize systems with intuitive editing and collaboration features, so that accessible image-based documents can be built instead of text-heavy and quickly forgettable SOPs.



Why your life science business needs electronic document management

Tacit knowledge

If tacit knowledge really is tacit, how can we define it and integrate it into our quality cultures? Here are some examples of what tacit knowledge typically covers:

Experience

- Details of order/importance of operations
- Unusual operation of items of equipment
- Interventions, workarounds
- 'What good looks like' (e.g., clues of appearance, sound, etc. which indicate something is working normally)
- Tips, tricks, techniques
- Risks/failure modes/what could go wrong
- Rules of thumb (what to do, when)
- Lessons learned

History

- Past problems and their resolutions
- Decision rationale/history
- What has been tried in the past

Expertise

- Proven and best practice
- Mental models
- Insights, ideas, continuous improvement opportunities
- Ability to see patterns/trends/responses
- Understanding 'why'

Context

- Assumptions
- Changes since last run, other situationally specific details

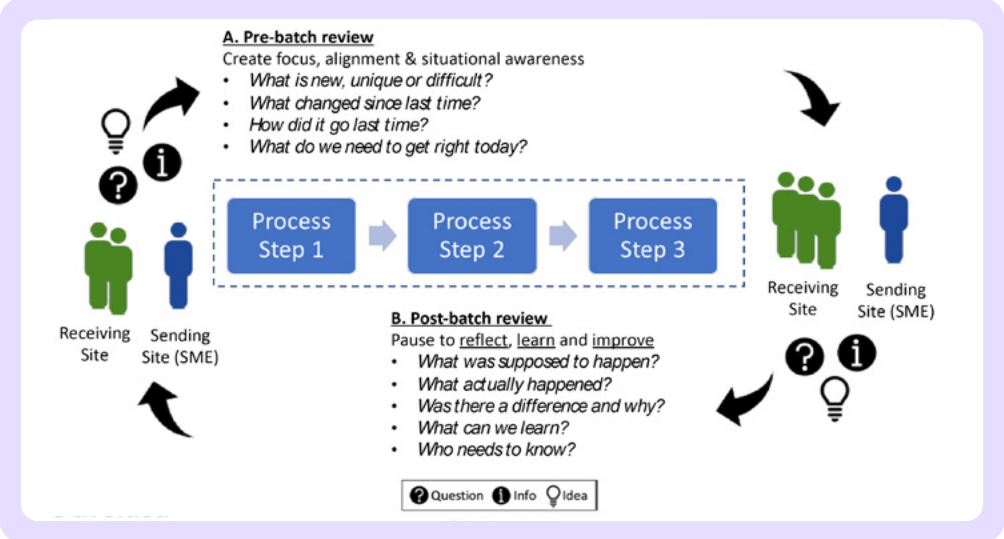
Resources and processes used to solve problems or get help

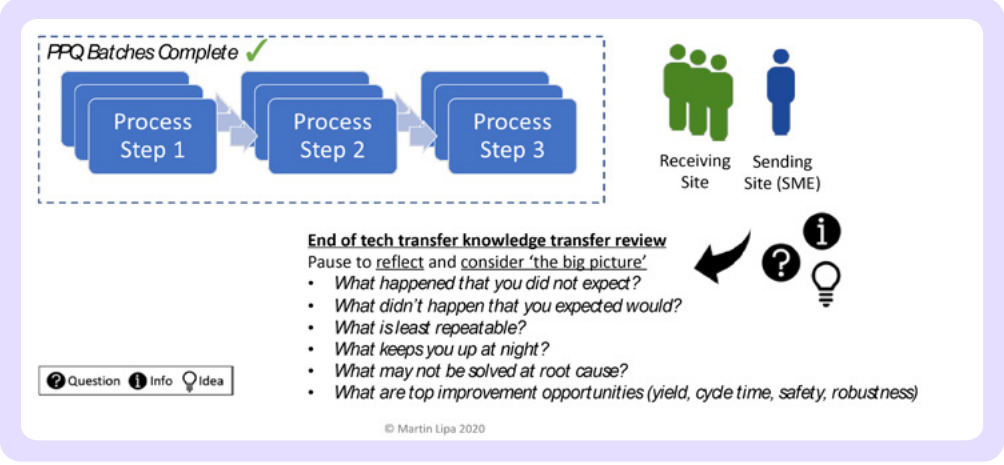
- Who SMEs are

Aligning the two

A robust quality culture depends on a strong combination of explicit knowledge with the far more common tacit knowledge throughout your product lifecycle. Designing processes so that learning before, during and after is baked in is a great way to ensure your culture encourages quality adherence *and* continuous improvement.

A case study of a major multinational biopharmaceutical organization, assembled by Technological University Dublin, throws light on a good way to get this done.





Consciously drawing on the tacit knowledge of SMEs connected to the process yielded a whopping 82 improvement actions – 52 of which were implemented, avoiding 43 potential deviations and creating 39 proactive process improvements.

This conscious interrogation and improvement of processes through 'after action review' (AAR) will be key for adherence with the FDA's approaching Quality Management Maturity program.

Harvard Business Review found a 20% productivity boost for companies that do it. Merck saved $50m in 5 years when they started doing it.

AAR question examples
1. What was supposed to happen?
2. What actually happened?
3. Was there a difference and why – went well or did not go well?
4. What can we learn?
5. Who needs to know and how do we share with them?

Ensure that the learnings you glean from tapping the tacit knowledge of your teams are then fed back into the explicit knowledge of your SOPs and work instructions – making them more appropriate, evidence-based and 'real-life' than theoretical documents built in a vacuum. Places to foster this communication include:

- Deviation management / investigations / recalls
- Production
- Technology transfer
- Risk management
- Change management
- Process & analytical development
- Talent management (onboarding, offboarding, succession planning)

Culture and behavior

"A culture of excellence is one which fosters cross-functional ownership of quality and treats quality not as a hindrance for success, but as a necessity that allows the company to make decisions that best benefit patients."

— ISPE Advancing Pharmaceutical Quality Cultural Excellence Guide

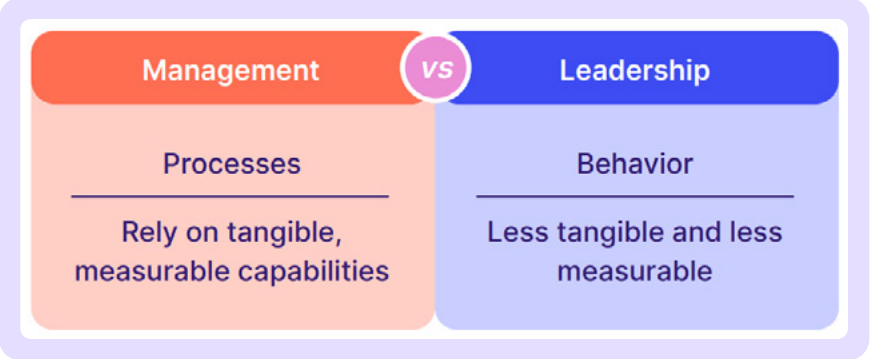
As you look to build a culture of quality in your pharma or biotech business, it's important to remember:

You don't change culture – you change behavior.

Culture is the aggregate of your entire organization's daily behaviors and can't be changed all at once. Only by working on individual strands of behavior can the broader picture begin to change. For this, employee engagement and cultural champions are critical.

Managers are formally responsible for human resources and performance management by providing direction for day-to-day work.

Leaders, on the other hand, take responsibility for the situation, team or objective, and help others to achieve their goals.



Engaged employees – champions – form a vital cog in your culture of quality by acting as *leaders*. They do this by:

- Proactively identifying risks and opportunities for improvement
- Speaking up openly
- Motivating peers to do what's right
- Demonstrating desired behaviors through their actions

It's crucial that both management and individual leaders purposefully direct the influence these champions have within your organization to ensure positive cultural outcomes.

By interacting day-to-day with your other employees, on the same hierarchical level as them, your champions can both monitor and shape 'hearts and minds', encouraging positive attitudes that build over time into the desired behavior of your quality culture.

Attitude A settled way of thinking about something

Mindset An established set of attitudes held by someone

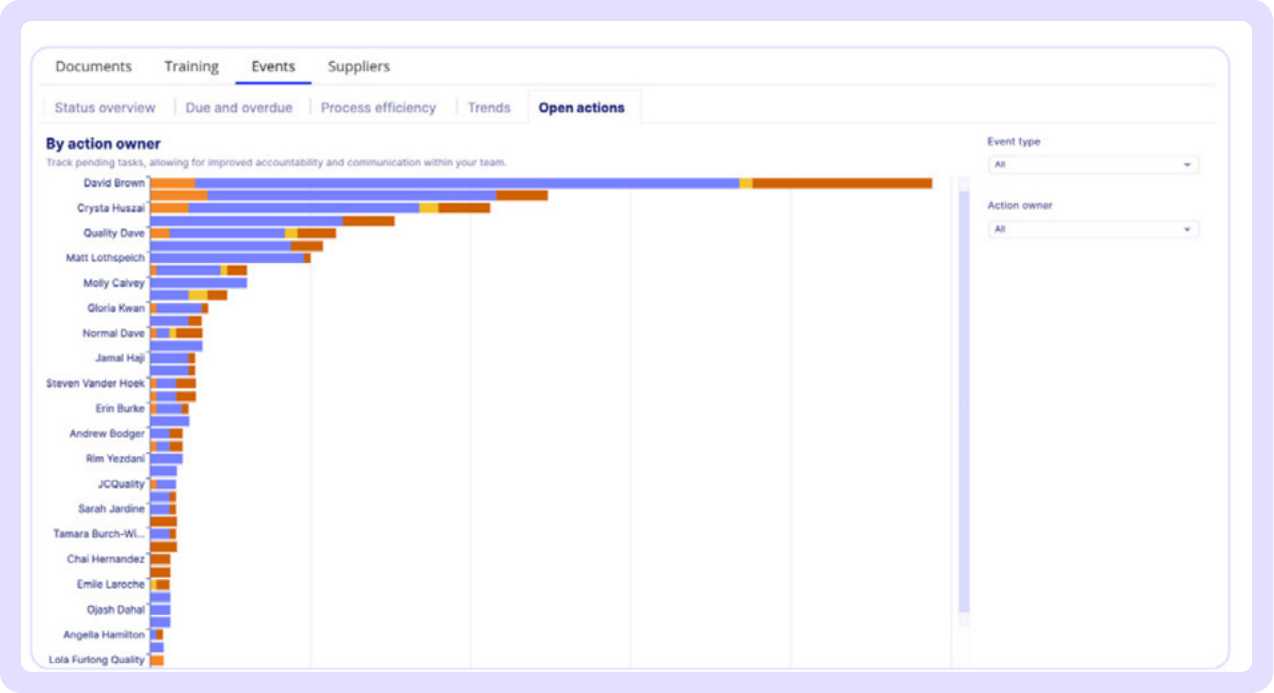
Behavior The way in which one acts or conducts oneself

Attitudes → **Mindsets** → **Behaviors** → **Actions** → **Results** → **Performance**

Consider other ways to shape and encourage 'good' behavior.

ThermoFisher Scientific, for instance, linked individual work to the broader 'why' with their 'I make hope' internal communication program:

Digitizing your PQS also allows easier surfacing of individual and group quality performance, allowing smart data-driven action to be taken. Qualio Analytics, for instance, unlocks visual insights of key information like overdue quality tasks and departmental training statuses.



These quality KPI dashboards offer a living picture of your organizational culture, allowing bottlenecks and weak areas to be spotted and fixed.

Chapter 3

Measuring a pharmaceutical quality culture

Taking everything together, then, how should your quality culture be measured day-to-day? The analytics and KPIs noted above are a great place to start, and there are other areas to consider, too. Since behavior is so critical for your quality culture, as we saw above, key behavioral indicators (KBIs) are another important metric you shouldn't ignore.

Prioritize leading indicators, rather than lagging indicators like the number of CAPAs closed in the past quarter or completed training this year. Leading indicators are behavior-based predictors of future outcomes, rather than historical measures of past results – they're therefore the weathervane of your quality culture and help you be more forward-looking in your quality approach.

Suitable leading indicators include:

Recurring deviation rate

Employee engagement rate

Cost of poor quality

Ratio of corrective to preventive actions (the more preventive, the better!)

% of CAPAs triggered by human error

Other 'softer' cultural-behavioral markers to check up on could be:

How patient focus is encouraged and cascaded from senior management business-wide

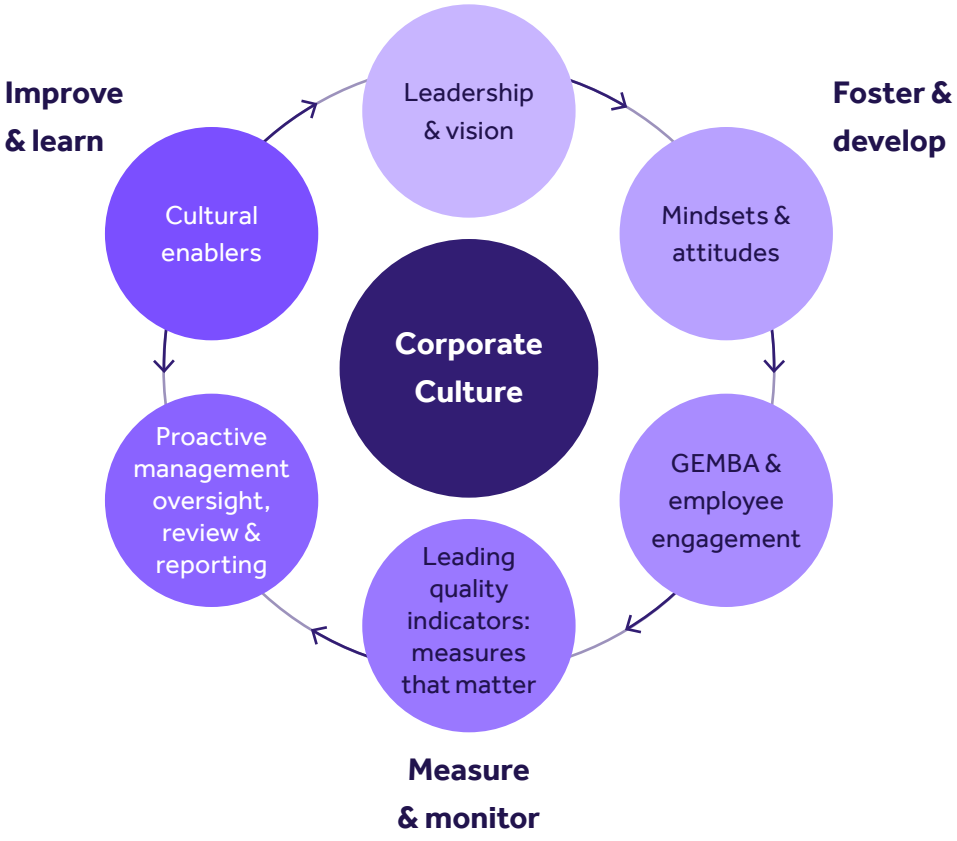
Number of quality issues raised by shop floor staff vs. spotted by quality

Planned risk reviews for the next quarter

The ISPE's Advancing Pharmaceutical Quality Cultural Excellence Guide is a great source of metrics and measurements to track your quality culture.

Level 1 **Undefined**	Compliance risk	Undefined	Uncontrolled	Not monitored	No evidence
Level 2 **Defined**	Partially meets ICH Q10 requirements	Partially defined	Not formally controlled	Not formally monitored	Person dependent
Level 3 **Managed**	Fully meets ICH Q10 requirements	Defined policy & processes	Meets req. for application	Process monitoring and controls in place	
Level 4 **Improved**	Demonstrates improved / optimized execution	Defined policy & processes	Routine application	Routine monitoring, advancing improvements	
Level 5 **Optimized**	World class / industry leader	Proactive	Continual improvement	Predictive	

APQ 5-Level Maturity Model



CE sub-element 1: Leadership & vision				
Level 3: Managed	Fully meets ICH Q10 reqs.	Defined policy & processes Meets requirements for application Process monitoring & controls in place	**Management Behaviors** › The organizational leadership has established a clear vision and set of organizational values, that include patient-focus, and have communicated this to the business › Manager and Leader behaviors are aligned with the organizational values › Managers periodically emphasize the importance of quality and share information on quality topics and the need for patient-focused excellence › When quality issues are weighed against business issues, both aspects are considered by management before taking a decision › QRM is applied with adequate decision-making, but there is less evidence of routine risk reviews › Managers regularly support line workers to help them improve quality and make the connection with the corporate vision and values › Managers model the desired behavior of "doing the right thing" on issues of quality and patient focus. › Managers exhibit and foster an inclusive environment, often ensuring all employees voices are equally heard.	**Employee Behaviors** › Employees periodically speak up with an emphasis on quality topics, the importance of continual improvement and patient-focused excellence. › Employees can articulate the company vision and values and what it means for their role. They demonstrate understanding of the target behaviors. › When quality issues are weighed against business issues, employees can observe that risks and impacts of both aspects are considered by management before taking a decision. › Employees can attest that they are regularly supported and encouraged to help improve quality. › Employees can observe their managers modeling the desired behavior of "doing the right thing" on issues of quality, continual improvement, and patient - focus. › Employees periodically speak up to share improvement ideas through a systematic process.

And once you have your measured elements in place, the Guide contains some helpful ingredients for an action plan, including:

- Risk and impact assessment templates
- Action tracking
- Current and target cultural maturity scores
- Training and upskill requirements

Consider applying the ACT model:

A

Apply

What will I do to measure and gauge our quality culture?

C

Communicate/change

What will I communicate to others in my organization so that learnings can be applied? How will I change cultural behaviors?

T

Transform

How will (and should) our culture of quality transform our organization's performance by modeling and measuring the right behaviors?

Chapter 4

Conclusion

A culture of pharmaceutical quality is ultimately about sharing aligned goals, promoting transparent organization and governance, managing and continuously improving performance, and sharing knowledge, risk and reward business-wide.

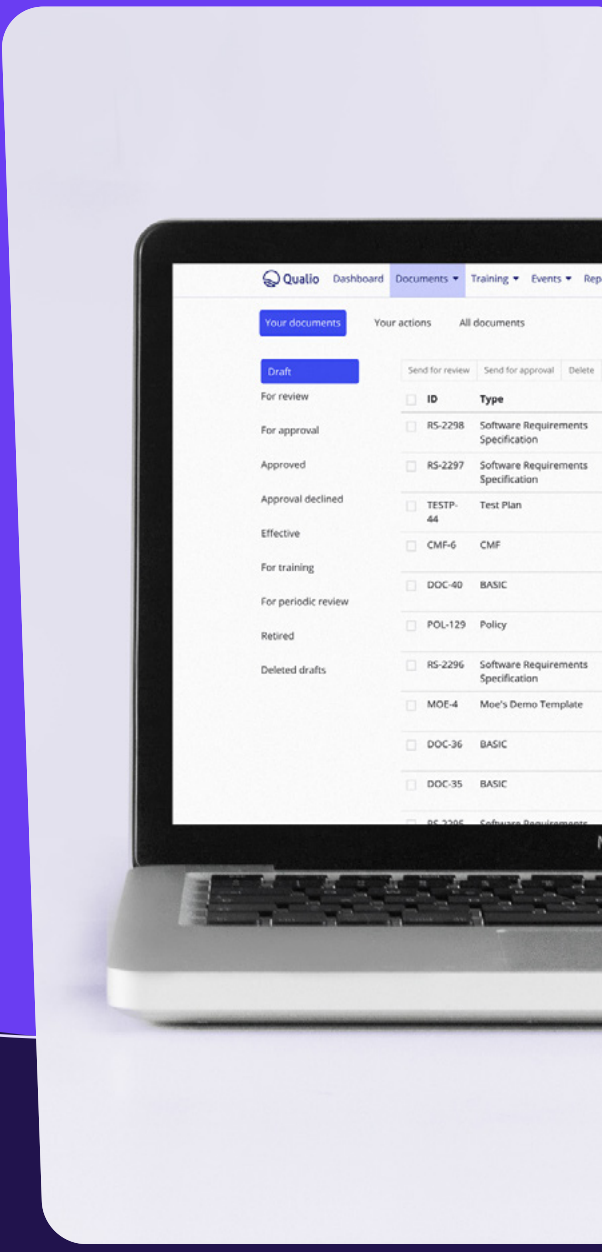
This guide has offered a few starting points for your own culture-building, with particular emphasis on how knowledge and behavior are promoted and spread across your organization.

Initiatives like the QMM program will reward pharmaceutical and biotech companies that put a quality culture front and center of how they do business. The time to start thinking about, measuring and crafting a quality-cultural approach is now.

Qualio

Prepare for 2024 with optimized, digitized quality

Learn more



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