Qualio

How to build a quality culture

© Qualio — QMS for Life Sciences

Table of Contents

Introduction 3

What is a quality culture? 4

What quality cultures look like 5

Why should you have a quality culture? 6

The 3 elements of quality culture 7

#1 — Communication 7

#2 — Data-driven decision-making 7

#3 — Continuous improvement 8

Transforming into a quality culture 9

Bringing life-saving medical devices, therapeutics and pharmaceuticals to market is only possible with quality.

By prioritizing quality and baking it into the foundation of everything you do, you can ensure the products you ultimately bring to market are safe, effective, and deliver the desired results.

To achieve the best outcomes, quality can never be an afterthought. By building a quality culture and committing to continuous improvement, life science organizations can accelerate their efforts and fulfill their missions while delighting investors, shareholders and — most importantly — the patients they serve.

Kelly Stanton
Director of Quality, Qualio

What is a quality culture?

Simply put, a quality culture is a culture in which all employees — from the C-suite all the way down to office managers and everyone in between — prioritize quality.

In quality cultures, every employee is focused on adhering to quality guidelines, and they always see their peers taking quality actions and talking about quality, as a Harvard Business Review article points out.

When a quality culture is in place, quality permeates throughout the organization. All employees feel quality all around them, and it's everyone's shared responsibility to ensure quality is pervasive. You'll know you've achieved a true culture of quality when the organization stops talking about the quality team altogether because, at that point, every employee will be doing their part to ensure quality in every activity.

RESOURCES

Build a culture of quality in your organization now

Qualio blog — Make quality a core practice at your company ›

Quality in practice — See how leading life sciences organizations go beyond compliance ›

What quality cultures look like

Quality cultures are humble. They're continuously growing and evolving and never stagnant. And they're also purpose-driven. Healthy quality cultures aren't focused on quality just to appease regulators. Instead, they're focused on quality because it's the right thing for the business — and the right thing for the patients they're aiming to serve.

Quality cultures are cultures of ownership. There isn't any finger-pointing; teams are there to work with each other to drive innovation and risk-based thinking throughout the product development and commercialization processes. In other words, no one says that's not my job.

Organizations with quality cultures implement quality early on so that everyone can take credit for the great work they're doing, writing everything down in a format everyone agrees with. The quality team isn't seen as police officers or people checking boxes. Instead, they're teachers who help everyone facilitate teamwork, trust and communication.

To meet these aspirations, a robust quality management system (QMS) sits at the heart of quality. The QMS needs to support the culture, which means it needs to be easy for everyone to use productively.

Why should you have a quality culture?

Having a quality culture sets the tone for your organization's mindset, ensuring you stay proactive.

Putting quality first creates a positive business impact that aligns your processes and procedures with your ultimate objectives: bringing safe, compliant products to market and improving patient health outcomes.

As a result, quality cultures make it much easier to attract and secure VC money, partners and acquisitions. In many cases, companies seeking to add to their portfolios will overlook startups that don't have quality baked in.

You'll also need to have a quality culture if you want to attract and retain the best and brightest. After all, top talent wants to work for the most impactful companies. When you fail to prioritize quality, word will get out, and it'll be that much harder to hire the right people for the job.

The 3 elements of quality culture

There are three core pillars that support and sustain quality cultures, which we'll explore in this section.

#1 — Communication

Implementing and cultivating quality cultures starts with effective communication. Whenever a new employee comes on board, it's imperative to explain quality expectations from the outset.

This isn't just a matter of "do this because we say so." It's all about effectively conveying the why behind it all. Do this by explaining the bigger picture: "We're committed to quality because it helps us improve the safety and efficacy of the device, thereby helping patients achieve better health outcomes."

Building a successful quality culture starts with leadership championing the cause and openly sharing information with everyone on the team. Otherwise, they won't be setting the right example for employees. Without genuine buy-in from the team, it becomes that much harder for the organization to achieve its quality goals.

As you begin transitioning to a quality culture, it's important to make sure your team knows that it's perfectly fine to make mistakes. Consider mistakes opportunities for improvement and always encourage your team to explore alternatives.

#2 — Data-driven decision-making

Many teams believe that quality means twice the work. Far too often, they look for shortcuts and quick fixes instead of taking the time to truly diagnose an issue and understand the why behind the problem at hand.

> ***In quality cultures, quality is driven by process, and process is driven by data.***

When you incorporate quality into your processes from the outset, you write everything down and ensure savvy engineers and scientists are doing things the right way. This enables you to avoid the crippling cost of poor quality — which, in the extreme, can force organizations to recall their entire product lines. Even if

a commitment to quality might slow you down temporarily, that's a much better outcome than catastrophic delays.

There's a saying in QA: If you didn't write it down, it didn't happen. If you don't have something documented in a solid way, you won't be able to leverage it in the future. On the flipside, by viewing quality as a teacher and making sure all of your processes are captured, you'll have the real-time data you need to guide all of your decisions, saving time and money while bringing quality and innovation together under one roof.

#3 — Continuous improvement

A quality culture is a culture that's committed to continuous improvement. As you begin transitioning to a quality culture, it's important to use all of your data and examine your procedures on a regular basis to determine how you're doing, what you've done to miss the mark, and what you could do better. Remember, you don't have to document everything — just what's important. By doing so, you can take preventive actions to make your processes better and better over time.

Doing this requires cultivating a feedback-driven culture where all employees are encouraged to stop to pause and look back on their work to see what could be improved. When you empower your team by making sure they're being heard, you can create a continuous feedback loop within your organization, which enables you to leverage insights from front-line workers who are in the trenches every day — and not just managers who never leave their offices.

In quality cultures, internal audits are more than just a check box. They're valuable tools that help you identify gaps in processes and determine the best way to address them. At the end of the day, it's important to realize that we're all human, and people make mistakes. In healthy quality cultures, this is understood perfectly, and everyone feels safe to come forward and contribute to overall quality. As quality becomes an ongoing process, organizations with quality cultures maintain audit-readiness throughout the year.

Continuous improvement should be driven by risk. As you begin embracing continuous improvement, identify the highest areas of risk and bite off small pieces one at a time. Figure out where you get the biggest bang for your buck and take it from there.

To make sure your efforts fuel your quality engine, be sure to publicize all improvements to quality and celebrate the victories in public ways to further fortify your quality culture.

Transforming into a quality culture

If your goal is to create a quality culture, the worst thing you can do is not write something down. Don't worry about the format; just write everything down somewhere. You can also take a picture or draw a flowchart — whatever you need to do to make sure everything is documented.

Ensuring your efforts succeed starts with finding a champion somewhere at the top of the organization. The key to a quality culture is getting buy-in from management. When leadership is committed to quality, it becomes that much easier for everyone else to get on board.

At the core, quality cultures run on robust quality management systems. As you begin implementing a new QMS, don't do it all at once. Start small and grow your footprint over time because you can't jam the whole thing into place and expect great results.

This is why it's much easier for pharma, biotech, medical device, and life sciences companies to implement a QMS in the early stages. By using a QMS as the bedrock of your quality culture, the technology grows alongside your organization — and you get the peace of mind that comes with knowing quality is always top of mind for everyone.

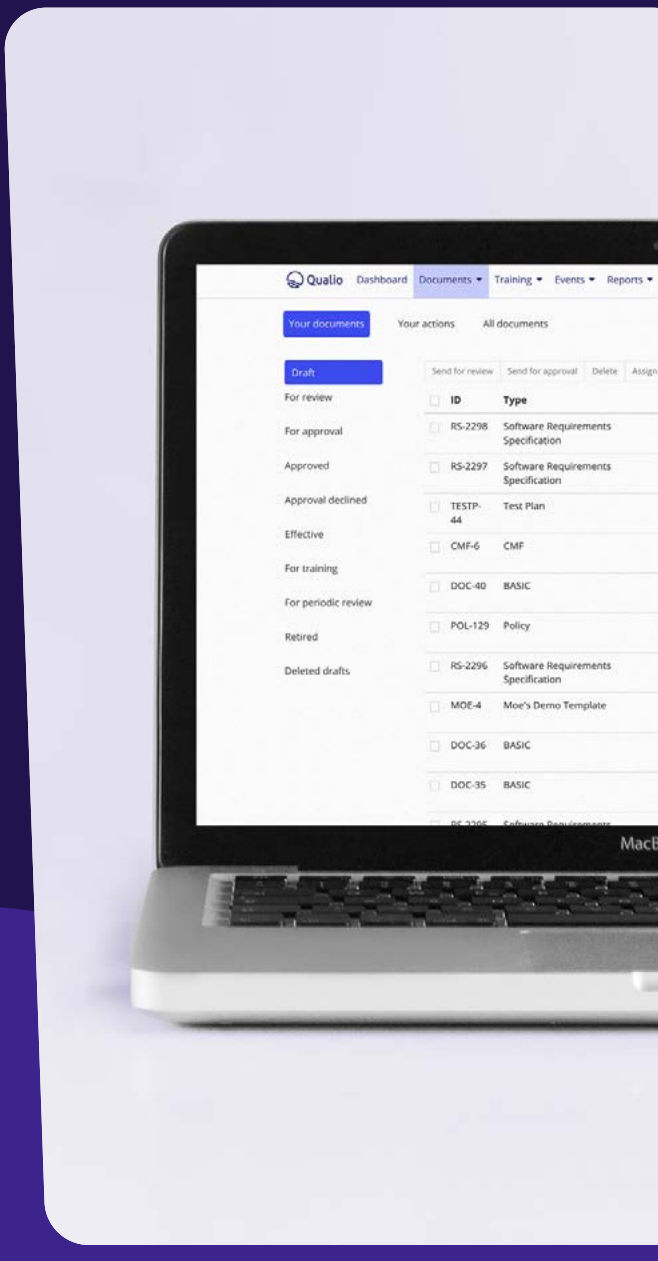
Qualio

See Qualio in action

Qualio is the highest rated eQMS on the market and ranked as the easiest to use.

Want to learn why leading life sciences companies rely on Qualio for a quality-centric route to market?

Request a demo today



Call us today
1.855.203.2010 • +353 1 697 1522