Qualio

Consumers & quality sentiment report

How your company's public image hinges on its quality system

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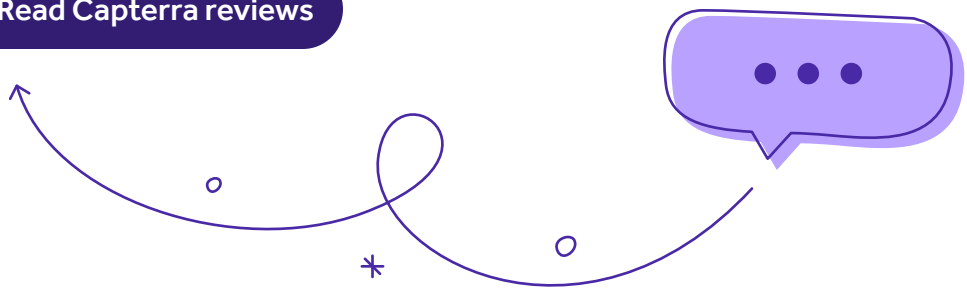
Qualio was founded in 2012 with a simple but important mission: to help life science organizations bring their vital products to market with a faster, stronger, more quality-centric approach.

Over 400 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.

Read G2 reviews

Read Capterra reviews



Medable

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THE RARE DISEASE COMPANY

Lunaphore
technologies

AVECTAS

Biofidelity.

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Quality professionals often feel siloed.

In a side office, poring over CAPA reports, doing document review or nervously preparing for that big upcoming audit, it can feel that the work we do goes unrecognized by the end user. The quality management system ticks on, invisible to everyone but us and our regulators.

But we spoke to 2,002 American consumers who told us otherwise.

We wanted to understand how life science product quality affects consumer trust and purchasing decisions – and the results of our survey were definitive.

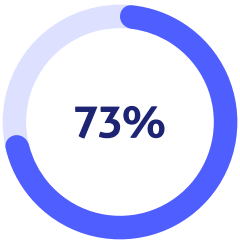
Customers and patients value the hard work done by life science quality professionals and, crucially, don't forget if things go wrong. They actively source and tune into product news, respond to recalls and use quality as the guiding light for their buying decisions.

In fact, the public wants to see more of life science companies' quality profiles.

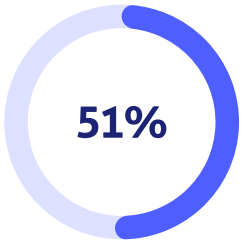
In short? Quality matters to the public – perhaps even more than you realized. This report breaks down our very interesting findings.

Kelly Stanton
Director of Quality, Qualio

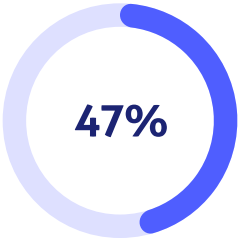
Public perceptions of life science quality management in 2022



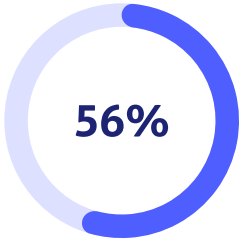
actively follow news and updates about healthcare products they use



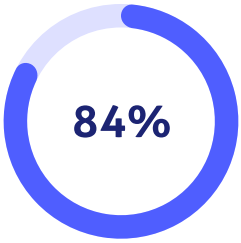
are unlikely to use a healthcare product post-recall, even if the issue is addressed



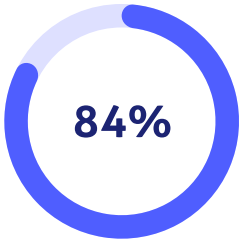
who thought J&J was a lower quality brand than Pfizer did so because of their FDA vaccine pause



want an entirely digital approach to life science quality management



want the FDA to publicize QMS data about a manufacturer's entire operation



would rely on a public-facing quality culture score

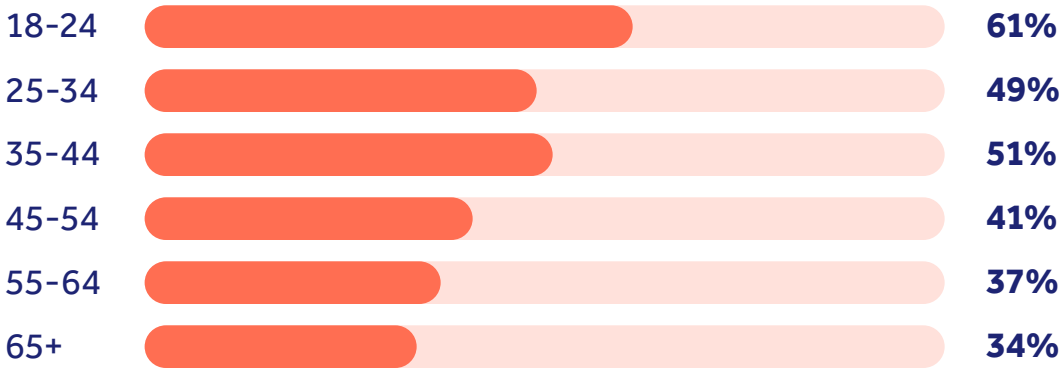
Awareness of quality

Our survey revealed that **73%** of consumers actively follow updates about the prescriptions and healthcare products they use.

43% 'frequently' or 'always' search for news about these products.

And a generational trend is visible:

Consumers searching for news about healthcare products and drugs they use



With 'millennial' and 'Generation Z' respondents enjoying greater access to healthcare information than their predecessors, and a greater willingness to use it, we can only expect this active scrutiny by the public of the products they put into their bodies to increase into the future.

Recalls and warning letters

Chapter 4-1-13 of the FDA's Regulatory Procedures Manual, dealing with freedom of information, allows the public to view FDA-issued warning letters without submitting formal FOIA requests.

Unsurprisingly, warning letters have a powerful effect on public perception – with **80%** at least 'somewhat unlikely' to use a product which has received one, and over half **(52%)** 'very unlikely' to or certain not to.

Crucially, this perception bleeds into the surrounding organization's brand, and the public generally holds the broader organization accountable for specific product issues. **80%** said they were 'somewhat unlikely' to use *any* product from a manufacturer that had faced a warning letter, and **47%** were very unlikely to or certain not to.

Got a 483 from the FDA?

Learn how to respond, and prevent a warning letter arriving after it, with our guide ›

of U.S. adults won't use a recalled drug or healthcare product again, even if the issue is fixed

For consumers, a product recall means:

It's a poor-quality product

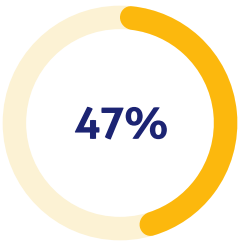
It's been poorly researched

Its quality can't be trusted

It's facing a temporary issue that'll be fixed

Are recalls less offputting if they're for rare issues?

61% say no



of the respondents who felt J&J was a lower quality brand than Pfizer did so because of their COVID-19 vaccine's temporary pause by the FDA

The public and quality management

Our survey revealed considerable appetite for deeper, more transparent and more public-facing quality data from life science companies via the FDA.

In March 2022, the FDA called for comments on changes to its previously proposed Quality Metrics Reporting Program, which includes analysis of quality management performance across pharmaceutical manufacturing companies.

Our survey responses show agreement with this trend toward greater quality metric reporting:

84% believe the FDA should collect and publish quality management data about a manufacturer's entire operation, not just specific products or departments.

The same percentage said they'd include an FDA 'score' of a life science company's culture of quality in their purchasing decisions.

Closely connected to this appetite for transparency and control, **56%** called for the entire quality management system to be digitized within life science companies.

Though many life science companies could view this as overreach by the FDA, it's undeniable that the public want to see the FDA assume more of a mediating role between public and provider, with some kind of judgment mechanism not unlike a restaurant health score in place. Whether this sentiment is eventually transformed into operational change is unclear, but the CDER, incidentally, is pursuing this very idea itself. Its April 2022 Quality Management Maturity (QMM) whitepaper suggested a kind of objective 'score' for pharmaceutical manufacturers to strengthen the overall ecosystem, and the CDER is currently working on building a framework for capturing and acting on this score data.

What will the consequences of this be? On one hand, compliance burden could increase for life science companies as the strength of public scrutiny is magnified. On the other hand, life science organizations will be forced to take quality even more seriously, and companies that get it right can use their QMS as a customer-facing differentiator in an unprecedented way.

Thoughts & recommendations

Our survey revealed 3 facts:

1. The public pays close attention to life science product quality, including active following of news and updates
2. Recalls, warning letters and bad press have a considerable and measurable impact on public sentiment and purchasing decisions, with quality mishaps directly eroding consumer trust – often irreparably
3. Consumers seem to favor the evolution of quality from business and process management enabler to an increasingly accountable, public-facing metric which informs usage decisions as much as product specs or peer reviews

All this is to say: strong quality management is becoming increasingly vital and may well be beginning to take on a new role in how life science companies grow their reputation, differentiate and take market share.

Getting the mechanisms in place to mitigate risk, avoid recalls and warning letters, and consistently meet customer and patient needs with a robust quality system will separate successful life science organizations from those that fail to meet the ever-growing demands of public scrutiny.

The Qualio quality team compiled some key recommendations for businesses looking to respond to the findings of our survey:

1. Invest in a culture of quality

'Soft' quality metrics, like how your company culture enables and promotes quality, are becoming just as important as the 'hard' quality tools your business uses.

Consider and start acting on:

- How quality is promoted and communicated in your business
- How (and if) your business leaders actively engage with and promote quality
- Incentives, rewards and culture-enabling technology to help a quality culture coalesce
- Current strengths and weaknesses in your cultural approach to quality

Try our culture of quality toolkit to get you started ›

2. Benchmark against your peers

How are other quality professionals managing quality, preparing for the future, staying on top of industry news and more?

We ran another survey in February 2022 to find out. Download it here and dive into more interesting findings.

3. Consider upgrading your quality approach

With the majority of our survey respondents in favor of an entirely digital quality approach, it's clear that modern quality management technology has outstripped traditional tools and earned the trust of the public as a more robust and controlled way to manage quality. Do a thorough audit of your own QMS to identify potential areas of digital optimization. Look for things like:

- Overreliance on paper, spreadsheets and unspecialized tools like Dropbox
- Trouble retrieving and acting on quality information
- Recurring process issues around document version control, training record management, quality event close-out, supply chain integrity, etc.

If you're experiencing issues with your legacy system and aren't 100% confident in your QMS, it may be time to upgrade to an eQMS.

Try our guide to the 12 questions you should ask potential vendors to make sure you find a system that works for you.

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Access more life science quality resources at

qualio.com/resources

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