

The QMSR Era Begins  
Quality used to be documented.  
Now it is measured.



## From the Editor

A note on what changed this quarter and why it matters.

QMSR is now enforceable. The question regulators are asking has shifted permanently from “Do you have a process?” to “Can you prove what actually happened?”

That one change is rewriting how quality systems are built, audited, and judged. This edition covers what we shipped in Q1, what’s coming, and where the industry is heading — so you stay ahead.

## The QMSR Shift

What FDA’s Quality Management System Regulation means for your team right now.

*“Do you have the process?” is no longer the question.  
“Can you prove what happened and that it won’t happen again?” is.*

— QMSR Era, effective February 2, 2026

## In this edition

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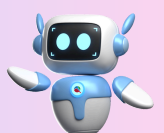
Events & Conversations

Why AI Is Changing Quality Now

 [info@qualityze.com](mailto:info@qualityze.com)

 [www.qualityze.com](http://www.qualityze.com)

 +1-877-207-8616



## What changed

FDA's QMSR amends 21 CFR Part 820 and incorporates ISO 13485:2016 by reference, with additional FDA-specific requirements.

The effective date was February 2, 2026. From that date, FDA can inspect:

- Supplier audit reports and approval logic
- Management review records
- Quality audit documentation
- CAPA effectiveness evidence, not just closure

Organizations that were "preparing" for audits are now being evaluated against a higher standard of defensibility.

## The two-minute check

If an auditor asks today:

"Show me how this issue was detected, investigated, corrected, and prevented from recurring."

Can your system trace it across CAPA, risk, training, and documents — with timestamps and approvals — instantly?

Or does your team start assembling evidence manually?

That gap is exactly where QMSR pressure shows up.

## Three patterns we see across customers

- ✗ Manual evidence compilation that does not scale
- ✗ CAPA gaps invisible until an audit surfaces them
- ✗ Speed of detection not tracked as a compliance metric
- ✓ Complaints, CAPA, risk, and training connected in one system
- ✓ Evidence generated continuously, not assembled later
- ✓ Effectiveness verified against real, measurable outcomes

## Product Update

What we shipped in Q1, and what's coming in Q2.

2

Patches shipped in Q1

8+

New languages in SP 16.11

4

New tools Release in 17.0

2026

FrontRunners recognized

## Q1 Patches — shipped

Two focused patches improved what teams experience every day:

- Improved system stability in high-volume environments
- Faster approval workflows across all modules
- Smoother user experience across core quality events

Less friction in daily execution means fewer delays closing deviations, CAPAs, and audits.

## Service Pack 16.11 — end of Q1

Quality does not operate in one language. SP 16.11 brings full platform support for:

- Spanish · Chinese · Korean · Hebrew Malay
- Portuguese · French · Hungarian

Consistent quality execution across global teams without interpretation gaps.



This is the release where Qualityze makes the shift from a workflow platform to a connected quality intelligence system.

- Enhanced AI capabilities across all workflows
- Electronic Batch Record (EBR)
- Internal Scorecard for performance visibility
- PPAP — Production Part Approval Process
- FMEA — Failure Mode & Effects Analysis
- Design Control & APQP

### Why 17.0 matters

These are not just new modules. PPAP, FMEA, and Design Control bring quality upstream — into engineering and product development — so issues are caught before they become deviations, not after.

EBR connects batch execution directly to your quality record. Scorecard makes quality performance visible to leadership. Together, they close the loop between execution and proof.

## Top Reads from Q1

The Qualityze blogs getting the most traction in quality teams right now.

*QMSR · SUPPLIER QUALITY · February 2, 2026*

### What 'Approved Supplier' Must Mean Under QMSR 2026

QMSR makes supplier audit reports inspectable from day one. This blog breaks down what 'approved' must produce on demand: risk tier, criteria, evidence, and ongoing monitoring — not just a name on a list.

*CAPA · SOFTWARE GUIDE · March 5, 2026*

### Top 5 CAPA Management Software Systems in 2026

Not all CAPA software is the same. This guide covers what separates best-in-class platforms from average ones — automated workflows, structured RCA, real-time dashboards, and end-to-end traceability.

*QUALITY ASSURANCE · AI · February 16, 2026*

### Emerging QA Trends in 2026: Predictive, Connected, Always-On

QA in 2026 is a strategic function tied to customer retention, brand trust, and compliance readiness. This blog unpacks the most strategic QA trends — from predictive analytics to continuous validation.

*INTEGRATED QMS · STRATEGY · February 27, 2026*

### What Is an Integrated Quality Management System (IQMS)?

From document control to supplier oversight in a single unified framework — how IQMS eliminates siloed quality, safety, and compliance systems and replaces them with shared workflows and a single source of truth.

## Recognition in Q1 2026

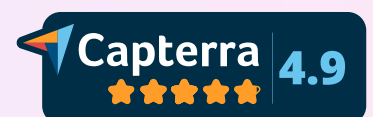
Qualityze was recognized across Quality Management, Risk Management, and Document Management this quarter, including:

- FrontRunners 2026 — Quality Management
- Capterra Shortlist — Risk & Document Management
- Best Ease of Use
- Most Recommended

### What the recognition reflects

These awards are based on verified user reviews — not analyst rankings.

They reflect how teams actually use the system: faster closures, cleaner audits, less manual work.



## Why AI Is Changing Quality Now

The shift from visible problems to predictable ones.

The problem in quality is no longer visibility. Most teams can see what happened. The problem is the speed and consistency of decision-making after something is detected.

When AI sits across a connected quality system — spanning nonconformance, CAPA, risk, training, and documents — the change is structural:

### Before: reactive quality

- ✗ Issues detected after they escalate
- ✗ Root cause based on isolated, manual investigation
- ✗ Evidence assembled under audit pressure
- ✗ CAPA closed — but recurrence not verified
- ✗ Teams preparing for audits

### After: connected quality intelligence

- ✓ Patterns identified across sites and products in real time
- ✓ Root cause correlated across complaints, CAPA, and risk signals
- ✓ Evidence generated continuously, not retrospectively
- ✓ Effectiveness tied to measurable, verified outcomes
- ✓ Teams always audit-ready

**The shift is not from manual to automated. It is from reactive to provable.**

— Qualityze · Q1 2026

## Events & Conversations

### SupplySide Connect New Jersey

April 14–15, 2026

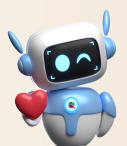
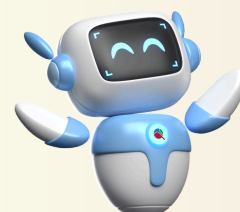
The conversations at this event are no longer about which system teams use. They're about:

- How fast can you prove control?
- Where do audits actually fail?
- How do you prevent repeat issues at scale?

We'll bring insights from those conversations back in the Q2 edition.

### What's next — Q2 Preview

- What actually fails during QMSR audits
- How leading teams structure closed-loop quality
- Real examples of audit-ready workflows in practice
- Major Release 17.0 — full details



# People & Culture

A look inside Qualityze Q1 2026.

## Health Check-Up Camp · Feb 13

In partnership with Sparsh Hospital, Bengaluru, Qualityze organised a free health screening camp for 40+ employees. Screenings included blood pressure, blood sugar, eye exams, dental check-ups, and medical consultations.



## Training & Development

Internal and external trainers ran sessions across departments, covering cyber security, ISO 27001, POSH compliance, fire safety, business communication, problem-solving, and time management.

## Celebrations

- International Women’s Day · March 8 — virtual and onsite, with reels, pep talks, retro dress, and cake
- Republic Day — patriotic dress code day and team decoration competition, judged by the Zuri Panel
- Potluck Lunch · March 27 — Bengaluru office team culinary showcase
- Fun Fridays & birthday celebrations — every month end, virtual and onsite



***Quality used to be documented. Now it is measured. And increasingly, it is judged in real time.***

### Run a QMSR Readiness Check

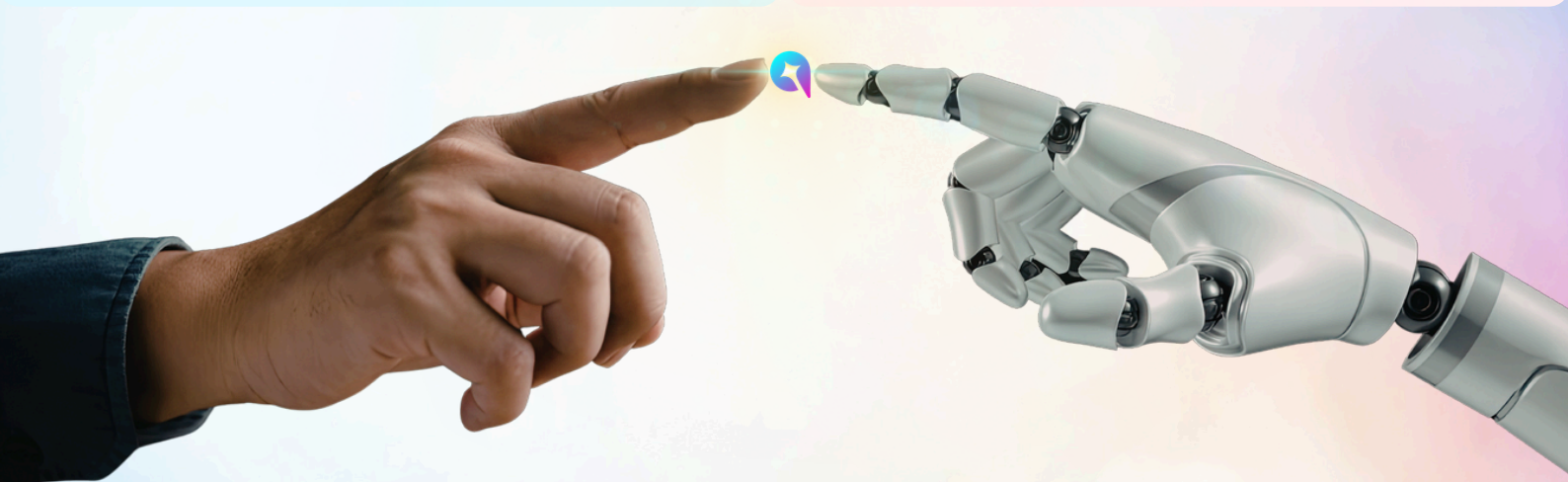
See where your system has gaps before the auditor does.

[Get started →](#)

### Book a Live Demo

See Qualityze Intelligent EQMS in action, live.

[Schedule now →](#)



**Transform Your QMS Into Quality Decision Making Engine**

