

Qualityze Insider NEWSLETTER



July 2025 / Vol. 003



Welcome to the July 2025 Qualityze Insider

Your 5-minute espresso shot of quality wisdom, product news & company vibes.

Well, that quarter was fast—blink twice, and we're already closing the books on the second quarter! Time flies when you're rolling out new features, nailing audits, and high-fiving teammates across the globe.

We Have a Quick-Fire Trivia

According to the American Society for Quality (ASQ), organizations that still rely on traditional, mostly reactive quality programs can see the cost of poor quality—scrap, rework, returns, lost loyalty—eat up what share of their annual sales revenue?

- A. 3 – 5 %
- B. 10 – 12 %
- C. 15 – 20 %

Hold that guess—answer awaits at the bottom!

“Quality means doing it right when no one is looking.” — Henry Ford



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THANKS TO YOU

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BLOGS

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Be Among Innovation Leader with AI-Powered EQMS

Your Next-Gen Decision Making Engine for Quality, Safety & Compliance



Manual fixes are fine until your ecosystem balloons to dozens of plants, thousands of SKUs, and regulators that never sleep. That's why the entire Qualityze suite—20 interlocking modules spanning Quality, EHS, and Compliance—now runs on the same AI core:

- Spot anomalies in Nonconformance, Inspection, and Supplier Quality before they snowball.
- Predict failures in Maintenance and Calibration to cut unplanned downtime 20-40 %.
- Draft actions for CAPA, Complaints, and 8D using generative AI that explains every recommendation (audit-ready “why” included).
- Auto-classify risk across Incident, Adverse Event, and Permit workflows, directing resources where they matter most.

Early adopters see up to 49 % defect-rate drops in under four months when AI loops across production, safety, and compliance data. And because every decision is time-stamped and traceable, you satisfy ISO, FDA, and OSHA in a single pane of glass.

Hit REQUEST DEMO to see the dashboards on your own data—no slide decks, just live numbers.

PRODUCT RELEASE SERVICE PACK 16.9

Shipped in April 2025, Service Pack 16.9 focused on usability and standardization:

- Audit Checklist—New Design: A color-coded progress bar shows completed vs. pending sections, slicing prep time in half.
- Lightning Conversions: Training Program dashboard, GDPR console, and in-app Contextual Help now run on Salesforce Lightning for a 27% faster load time.
- Inspection Portal: External inspectors can enter data directly—no seat license required.
- License Management 2.0: Say goodbye to spreadsheet licensing; permission-sets now automate seat provisioning.

Three micro-patches followed to crush bugs and boost stability—you likely noticed pages snapping open ~18% quicker.



Development is sprinting toward the next Quarter drop. Highlights:

- Portal Enablement expands to Complaints, CSMS & Change Requests, letting suppliers update records in real time.
- US FDA Enhancements inside Complaints: electronic MedWatch templates + eMDR XML export.
- G-Drive & SharePoint 2-Way Sync: Attach evidence once and surface it everywhere.
- SQM Questionnaire—New UX: Card-based layout for quicker navigation and snapshot scoring.

Want early access? Opt-in via Support Team ➡ “Connect and Discover”

COMPLIANCE CORNER & INDUSTRY SPOTLIGHT



Life-sciences, aerospace, automotive, food & bev, and hi-tech all face tightening regulations in 2025.

If regulators aren't easing up in 2025, and your QMS shouldn't do it either. The [ISO 9001:2025 committee draft](#) introduces a sharper focus on data-integrity and digital traceability—clause 7.5 will now call for demonstrable controls over electronic records. Lucky for you, every Qualityze module already tags, timestamps, and audit-trails each field change out-of-the-box.

Meanwhile, the [FDA's January 2025 draft guidance on AI-enabled systems](#) stresses model “explainability” and a risk-based credibility framework for any algorithm supporting quality or safety decisions. Our AI Assistant logs every recommendation based on historical trends, so you can show inspectors exactly why an action was suggested.

Across the Atlantic, [EU MDR enforcement shifts into high gear: manufacturers must finalize new post-market-surveillance \(PMS\) procedures by 26 Sept 2025](#) or face market withdrawals. Qualityze Field Safety & Recall Management has got your back, ensuring global teams are perfectly in sync.

Regulations aren't the only variables this quarter. Let's zoom out on the market pulse for a minute.

MARKET PULSE

Tariffs & Geopolitics, Minus the Panic

Steel and aluminum duties just doubled to 50 %, and [Washington-Beijing trade talks](#) still ping-pong between handshake and hardball. Europe, meanwhile, is bracing for a 10 % “baseline” tariff in any future U.S.–EU deal. Yes, short-term cost spikes are real—[MRO](#) budgets and packaging lines feel the first hit. But analysts agree the long game is less dramatic: supply chains keep rewiring, diversified sourcing dampens shocks, and many levies get bargained down before they stick.

Bottom line? Expect some quarterly wobble, not a derailment. A nimble EQMS like Qualityze that tracks supplier risk in real time is still your best hedge. The configurable workflows and real-time supplier-risk dashboards, you can pivot sourcing, update supplier questionnaires and quality contracts, and even spin up new audits in hours, not months like earlier.



SERVICES & CUSTOMER CARE

Our mantra: “Query to clarity in under 30 minutes.”

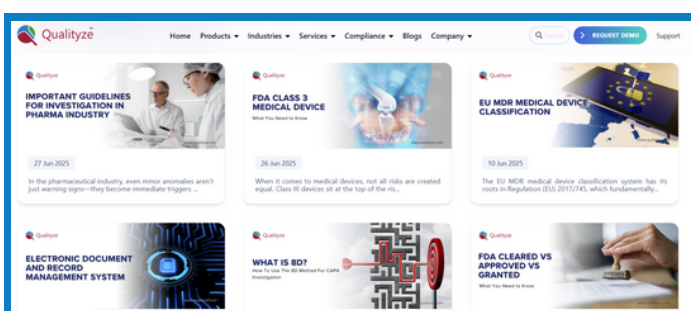
- 24 × 5 Global Helpdesk—chat, email, phone.
- Dedicated CSMs for the accounts.
- Success Accelerators: free virtual workshops on Change Control, Supplier Portals, and Audit Readiness.
- Contextual Help (top-right of every screen) helps you navigate through the system smoothly even if you are a first-time user.

Got an idea? Email us the features you would like to see us roll out in the coming Quarters and we will come back with a solution for you!

Quarter's Most-Read Blogs

- [Benefits & ROI of QMS Software](#) – Plug your own numbers into the interactive ROI calculator and see how a modern EQMS slashes COPQ and audit prep hours.
- [Out-of-Specification \(OOS\): What You Need to Know](#) – Follow a best practice checklist that aligns with FDA/EMA guidance so OOS results never escalate into recalls.
- [AI in Pharma & Biotech](#) – Benchmark your digital maturity with a self-assessment grid that maps AI use-cases from discovery to post-market surveillance.
- [Pharmaceutical Regulations: The Ultimate Guide](#) – Download a side-by-side comparison table of global rules—FDA, EMA, MHRA, CDSCO—plus direct links to each regulation.
- [Automate CAPA with RCA & 5 Whys](#) – Grab a fill-able 5 Whys worksheet and see how automated routing cuts closure times by double-digit percentages.
- [ISO Audit Guide: How to Prepare](#) – Use the internal-audit readiness toolkit (checklists + evidence log) to walk into ISO 9001 or 13485 audits with zero last-minute scrambles.
- [FDA Form 483 vs Warning Letters](#) – Keep the response-timeline cheat sheet handy so every corrective step lands before the clock (and regulators) catch up.

Missed one? Binge read them all on the [Qualityze Blog](#).



PEOPLE & CULTURE



Fun Fridays & Birthday Shout-outs (Monthly)

The last Friday of every month still belongs to playlists, trivia, and cake. Teams from DevOps to Marketing log off early to swap memes, celebrate birthdays, and battle it out in lightning-round quizzes. A little laughter resets the brain and reminds us that great code—and great quality—start with happy humans.

Cricket Tournament

Nothing bonds cross-functional squads like friendly rivalry on the pitch. Twelve mixed-department teams swung for bragging rights (and a glittery trophy that now lives on the CAPA team's desk). Beyond sixes and wickets, we saw real-time lessons in strategy, resilience, and rapid root-cause analysis—aka “why did we drop that catch?”

“Talk with the CTO” AMA Series (Quarter-long)
Our CTO regularly catches up for 30 minutes of Ask-Me-Anything. Road-map sneak peeks, AI ethics, dark-mode demands—nothing's off-limits. The result? Radical transparency and faster alignment across product, support, and customers.

International Yoga Day

At sunrise, laptops closed and mats unrolled. A certified instructor guided breathing and stretches that loosened sprint-tight shoulders and refresh mindsets. One hour later, we reopened Slack feeling calmer, clearer, and a tad more flexible—literally and figuratively. Together these rituals fuel a culture where learning, wellness, and a dash of competitive fun power the quality we deliver every day.

Trivia Answer

C. 15 – 20 % — [ASQ's Cost-of-Quality guidance](#) note that many companies burn 15 – 20 % of sales on poor-quality costs, with laggards spiking as high as 40 %. Automated, AI-driven prevention is how leading firms claw that margin back.

Need a Hand? We're Right Here

Whether you're hunting for a quick answer, want to see a live demo, or just need a QMS expert to talk to, start at [qualityze.com](#). Our search bar pulls up videos, guides, and release notes in seconds, and the Request Demo button puts you face-to-face with a product expert—no fluff. Stuck on something? Ping our support team from the portal (chat replies average under 30 minutes).

Prefer email? Drop us a line anytime at info@qualityze.com—we read and respond to every message.

Simple, direct, human. That's how we roll.



Looking Ahead — Painting the Rest of 2025 Together

We look forward to the second half of 2025 as a blank canvas—and quality is the brushstroke that will color every corner of it. Over the next six months you'll see:

- Service Pack 16.10 and beyond — deeper portals for Complaints, CSMS, and Change Requests; FDA-ready eMDR exports; and two-way G-Drive/SharePoint sync so evidence lives exactly where auditors want it.
- The next wave of AI — predictive models that not only flag deviations but recommend preventive maintenance slots, auto-prioritize supplier audits, and translate regulatory actions into plain-English task lists.
- Radical usability — Lightning-quick page loads, a universal search bar that finds everything (docs, tickets, videos, even Slack threads), and a sleeker companion to manage quality processes remotely — maintaining the integrity, efficiency, and effectiveness.
- Community fuel — quarterly AMAs with our CTO, roadmap votes you actually see reflected in sprints, and customer councils shaping our risk algorithms.

Our mission stays simple: make quality management friction-free, proactive, and measurably valuable for your teams, partners, and customers. Thank you for walking this journey with us—let's turn the rest of 2025 into a masterpiece, together.

Questions, ideas, or moon-shots? We're all ears at info@qualityze.com.

— The Qualityze Team

