

313 Million Reasons to Act Earlier

What Medical Device Quality Leaders Can Learn from 2026 Recall Trends

Your Quality Metrics May Look Stable. Your Risk May Not Be.

Medical device quality leaders are not short on data.

They have complaints, nonconformances, CAPAs, supplier records, audit findings, FMEAs, risk files, and post-market signals.

The real challenge is recognizing what those records are collectively trying to tell you before an isolated issue becomes a much larger one.



The 2026 Wake-Up Call

313.1 MILLION

medical device units were recalled in the United States in the first half of 2026

That represents a **516.8% increase** from the first half of 2025.

H1 2026

H1 2025



219 recall events

were recorded for medical devices in Q1 2026, down **13.1%** from 252 in Q4 2025.



146.63 million units

were affected during the quarter. Despite a 55.7% quarter-over-quarter decline, that volume remained above the **five-year quarterly average of 112.75 million units.**

Source: [Sedwick.com](https://www.sedwick.com)



Takeaway

A lower event count does not automatically mean lower quality exposure.

One issue involving a widely distributed product, component, sterile barrier or convenience kit may affect millions of units.

What's Driving Medical Device Recalls?



41

device-failure event

Device failure was the leading cause of medical device recalls by number of events in Q1 2026.



24

software-related events

Software tied with mislabeling as the next most frequent cause, with 24 events in each category.



86.35 million

units affected by sterility issues

Sterility issues accounted for the largest volume of affected medical device units in Q1 2026.



Quality signals rarely arrive with a warning label

They may first appear as:

- A complaint that resembles three earlier complaints
- A recurring failure description recorded in different language
- A supplier issue limited to one component
- A software problem appearing across different product records
- A CAPA that closed, but did not stop recurrence
- A change that introduced risk somewhere else in the product lifecycle



The earlier those connections become visible, the more options a quality team has.



The Regulatory Lens Changed Too

QMSR became effective on February 2, 2026

The FDA's Quality Management System Regulation incorporated ISO 13485:2016 by reference into the medical device current good manufacturing practice requirements under 21 CFR Part 820. On the same date, FDA began using the inspection process described in updated Compliance Program 7382.850.

Source: [fda.gov](https://www.fda.gov)



QMSR

Quality Management System Regulation



Effective February 2, 2026



In 2026, proactive quality is no longer about producing another dashboard.

It is about seeing the relationship between signals early enough to act.

What if Your Quality System Could Help You See the Next Problem Forming?



Not predict every quality event.



Not replace professional judgment.



But help your team recognize recurrence, retrieve relevant evidence and bring risk context into the workflow **before an issue becomes harder to contain.**



From Quality Records to Quality Intelligence

1.

Capture a Better Signal at the Start



The challenge

Incomplete or inconsistent complaint and event descriptions can slow triage, create follow-up work and weaken downstream analysis.

How assistive AI helps

Convert conversational issue descriptions into more structured, consistent records that investigators can evaluate.

Why it matters



You cannot reliably detect a pattern in information that was never captured clearly.

2.

Find the Issues That Do Not Look Related



The challenge

The same emerging failure may be described differently across products, locations, teams and reporting channels.

How assistive AI helps

Surface similar historical complaints, nonconformances and investigations so qualified users can determine whether separate events require further examination.

Why it matters



The complaint your investigator is reviewing may not be the first. It may simply be the first one your system recognized.

3.

Bring Risk Evidence into the Investigation



The challenge

Investigators may have to search across FMEAs, product-risk records, control documents and historical failures to assemble the necessary context.

How assistive AI helps

Bring potentially relevant risk information closer to the quality event being evaluated while preserving established review and approval processes.

Why it matters



Risk-based decisions depend on having the right evidence before the decision is made, not after the event escalates.

4.

Give Investigators More Time to Investigate



The challenge

Experienced quality professionals can spend valuable time gathering records, comparing previous events and writing summaries.

How assistive AI helps

Support investigation summaries, historical record discovery and possible root-cause or action considerations for qualified users to review.

Why it matters



Your team's expertise is most valuable when it is applied to evidence and risk, not repetitive documentation.

Quality Leaders Are Already Testing the Opportunity

Based on the 2026 Axendia 'AI in Life Sciences: What the Industry Is Really Saying' Market Research Report, sponsored by ComplianceQuest.



of organizations surveyed had conducted **generative AI** pilots in quality workflows.



identified quality-trend forecasting and early-warning signals as a leading benefit of adding AI to the QMS.



identified deviation and investigation management as a leading AI use case.



Do Not Just Measure AI Adoption. Measure Whether Quality Is Improving.

The more meaningful question is:

“Are we finding risk sooner and responding more effectively?”



Track the movement:



Time from detection to containment



Investigation cycle time



Complaint and nonconformance recurrence



Repeat audit findings



Overdue CAPAs and quality actions



CAPA effectiveness-check outcomes



Supplier quality trends



Rework caused by incomplete records



Time spent finding historical evidence



AI Should Not Make the Quality Decision



It can help **surface** information.



It can help **identify** similarity.



It can help **organize** evidence.



It can help **prepare** a draft.



Qualified quality professionals **remain** responsible for **evaluating** evidence, **determining** root cause, **approving** actions and **making** final decisions.



Every quality event leaves a signal.

The question is whether your team sees it while there is still time to act.

See how **CQ.AI** helps medical device quality teams **connect** quality data, **recognize** recurring patterns and **bring** relevant context into investigations.

> See How CQ.AI Enables Proactive Quality in Action



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