

10 Signs Your Medical Device Nonconformance Process May Fail an Audit

1. Nonconformance reports are completed differently by different teams

If every investigator documents issues differently, your process may lack consistency and traceability.

2. Root cause analysis stops at “human error”

Repeatedly blaming operator error without identifying systemic causes is a common audit concern.

3. Similar deviations keep happening again

Recurring issues often indicate ineffective investigations or weak corrective actions.

4. CAPAs are opened inconsistently

Some serious issues are ignored while minor issues trigger unnecessary CAPAs.

5. Closure decisions are made without effectiveness checks

Closing records too early creates major regulatory and quality risks.

6. Risk assessments are missing from deviation investigations

Investigators should evaluate whether the issue impacts product safety, performance, or compliance.

7. Teams struggle to retrieve historical NC records quickly

Poor traceability becomes highly visible during audits and inspections.

8. Supplier-related nonconformances are poorly documented

Weak supplier NC handling can directly impact audit outcomes and product quality.

9. Trending and recurring issue analysis is not performed

Without trend analysis, systemic quality problems remain hidden.

10. Your team is unsure what regulators expect in an NC investigation

If expectations are unclear internally, audit findings become far more likely.