

CAPA Effectiveness Checklist: 10 Signs Your Medical Device CAPA System May Fail an Audit

1. CAPAs Keep Reappearing

If the same issue returns repeatedly, the root cause may not have been properly identified or addressed.

2. Root Cause Analysis Stops at "Human Error"

Auditors expect deeper systemic investigation, not superficial conclusions.

3. CAPA Closure Is Based on Documentation Alone

Closing CAPAs without verifying real operational effectiveness creates major compliance risk.

4. Effectiveness Checks Lack Objective Evidence

Statements like "issue resolved" are not enough. Evidence must be measurable and traceable.

5. CAPA Timelines Constantly Slip

Repeated delays often indicate poor ownership, weak prioritization, or unclear workflows.

6. Different Teams Handle CAPAs Inconsistently

Inconsistent investigations and closure criteria create gaps auditors quickly identify.

7. Complaints and CAPAs Are Not Connected

Complaint trends should feed directly into CAPA evaluation and escalation processes.

8. Internal Audits Keep Finding Similar Issues

Recurring audit findings are a strong indicator that corrective actions are ineffective.

9. CAPA Risk Prioritization Is Weak

Not all CAPAs carry the same regulatory or business risk. High-risk issues need stronger controls.

10. Your Team Cannot Clearly Explain CAPA Decisions

During FDA or ISO 13485 audits, unclear rationale behind investigations and actions raises immediate concerns.