

17 Questions to Check If Your CAPA System Is Audit-Ready

Instructions: Go through each question and mark **Yes, Partially, No**

1. CAPA Review & Governance

- Do you have a defined CAPA review frequency (monthly/quarterly)?
- Are CAPA reviews actually happening as planned?
- Is there clear ownership for CAPA review and closure?

2. CAPA Aging & Backlog

- Are CAPAs closed within defined timelines?
- Do you actively track aging CAPAs?
- Is there a process to escalate overdue CAPAs?

3. Root Cause Quality

- Is the root cause clearly explained in each CAPA?
- Does the investigation go beyond symptoms?
- Are root causes consistent with the issue description and evidence?

4. Actions & Effectiveness

- Do actions directly address the identified root cause?
- Is effectiveness verification defined for each CAPA?
- Do you have evidence that actions actually worked?

5. Documentation & Audit Readiness

- Are CAPA records complete and easy to follow?
- Can a third party (auditor) understand the CAPA without explanation?
- Are closure decisions clearly justified and documented?

6. Trends & Recurrence

- Do you track recurring issues across CAPAs?
- Is CAPA data used for trend analysis and decision-making?

Scoring Guide

- 13–15 YES: Your CAPA system is in a strong position for audits
- 9–12 YES: Some gaps exist, may raise audit questions
- Below 9 YES: High risk of audit findings; CAPA governance needs attention