OpsPilot

CAPA Register — User Manual

Nonconformity Closure With Effectiveness · ISO 9001 / 21 CFR 820 · AI Engineering Co-Pilot

What this guide covers — what a CAPA is, how the OpsPilot module drives it to verified closure, what to have ready, and the record you receive.

> **Professional accountability.** The quality function bears professional accountability for CAPA adequacy and closure. OpsPilot structures the documentation to be audit-defensible; it does not replace the quality professional's judgement or the required sign-offs.

1. What is a CAPA?

A CAPA — Corrective and Preventive Action — is the disciplined response to a nonconformity: contain it, find why it happened, fix it, prevent it recurring elsewhere, and — the step everyone skips — verify the fix actually worked before closing it. The failure mode that auditors hammer is the CAPA closed on the strength of “action taken” with no evidence it was effective. A CAPA without effectiveness verification is just paperwork; with it, it's a closed loop.

OpsPilot structures it to *ISO 9001 cl.10.2, 21 CFR Part 820 (FDA), ISO 13485, IATF 16949, ICH Q10 and AS 9100* — defensible against ISO, FDA, TGA or notified-body audit.

2. The CAPA workflow

#	Step
1	Nonconformity characterisation — what exactly is wrong
2	Containment — stop the immediate bleeding
3	Investigation — root cause (links to the RCA module)
4	Corrective action — fix this occurrence
5	Preventive action — where similar exposure exists elsewhere
6,Effectiveness verification — prove the fix worked,[object Object]	
7	Closure

3. What the OpsPilot module does

Role	Responsibility
🎯 **AI Coach — Quality Manager (OpsPilot)**	Structures each CAPA element to be audit-defensible — characterisation, containment, investigation, corrective and preventive action, and (the element most often missing) effectiveness verification before closure.
👷 **Quality Manager / Engineer / Owner (you)**	Provide the NC facts, containment decisions, investigation findings, action commitments and verification evidence. You bear the professional accountability.

4. What you will be asked — have this ready

- The nonconformity — precisely what's wrong, found how, against what requirement.
- The containment taken (or needed) to stop the immediate problem.
- The root-cause investigation findings (use the RCA module for the depth).
- The corrective and preventive actions, and how their effectiveness will be verified.

5. What you receive — the output

A complete CAPA record (Word): NC characterisation, containment, investigation, corrective action, preventive action where similar exposure exists, effectiveness verification and closure — structured to stand up to certification, FDA, TGA or notified-body audit.

6. Worked example (illustrative)

A batch of parts ships out of tolerance. Containment: quarantine the remaining stock and recall the suspect batch. Investigation (via RCA): a gauge drifted out of calibration and the calibration was overdue. Corrective action: recalibrate the gauge and re-inspect affected parts. Preventive action — the bit that matters: every other gauge on the same overdue-calibration risk gets checked, and the calibration-scheduling gap that let it lapse is fixed. Then effectiveness verification: audit the next calibration cycle to confirm none are overdue, and check the parts now measure in tolerance. Only then does it close. A CAPA that stopped at “recalibrated the gauge” would leave the systemic gap — and the auditor — wide open.

7. Getting the best result

- **Always verify effectiveness.** “Action taken” is not closure — prove it worked.
- **Don't skip preventive.** If the same failure can happen elsewhere, the CAPA isn't done.
- **Investigate properly.** A CAPA built on a shallow cause fixes a symptom — use real RCA.
- **Keep the evidence.** Each element needs an evidence reference, or it won't survive audit.