Corrective and Preventive Action (CAPA) Record

CAPA number: _____
Date opened: _____
Owner: _____
Source: _____
Risk classification: _____

1 — Problem description

Factual statement only: what was observed, when, where, how many units, which product/lot. No cause, no proposed fix

2 — Immediate correction / containment

What you did to stop the bleeding — quarantine, rework, customer notification. This is CORRECTION, not corrective action

3 — Investigation and root cause

Method used (5 Whys, fishbone, fault tree) · evidence examined · verified root cause, not the first plausible one

4 — Risk assessment

Impact on product and patient/user · does this trigger a reporting or field-action decision · risk before and after

5 — Corrective action (ISO 13485 clause 8.5.2)

Action that eliminates the CAUSE of the detected nonconformity · owner · due date · proportionate to the risk

6 — Preventive action (ISO 13485 clause 8.5.3)

Where else could this occur? Action on a POTENTIAL nonconformity elsewhere — a separate clause, not a copy of section 5

7 — Change control and documents updated

SOPs, work instructions, drawings, risk file, training records · reference the change request number

8 — Effectiveness verification

How you will prove it worked · acceptance criterion stated BEFORE the check · review date · evidence attached

9 — Closure and approval

Closed by · date · management review reference — records in this section are inspectable under the QMSR

Free CAPA form — 5xwhys.com/articles/rca/capa/ · A CAPA closed without a stated acceptance criterion is a CAPA that will reopen.