

CAPA PROCESS FLOW

1. INITIATE

- Open CAPA, assign #, owner
- Classify priority & source

2. CONTAIN

- Stop the bleeding!
- Quarantine, notify, assess scope

3. INVESTIGATE

- Gather data & evidence
- Root Cause Analysis (5-Why)

4. CORRECT & PREVENT

- Implement actions
- Horizontal deployment

5. VERIFY & CLOSE

- Effectiveness check (30-90 days)
- Management Review & closure

PRIORITY & TIMELINES

CRITICAL	Patient safety → 30 days
HIGH	Regulatory/Major → 60 days
MEDIUM	Moderate impact → 90 days
LOW	Minor/Improvement → 120 days

5-WHY QUICK GUIDE

Problem: Wrong label on product

- Why 1?** Operator selected wrong template
- Why 2?** Templates have similar names
- Why 3?** No naming convention
- Why 4?** Process never standardized
- Why 5? No SOP exists**

→ **ROOT CAUSE:** Missing SOP for template management

CAPA SOURCES

- Customer Complaint
- Internal Audit
- External Audit
- Nonconformance / NC
- PMS / Vigilance
- Supplier Issue
- Process Deviation
- Management Review

GOLDEN RULES

X "Human error" is NEVER a root cause!
Ask WHY the error occurred

✓ Root cause must be ACTIONABLE
You can fix it with a specific action

✓ Evidence over assumptions
Base conclusions on DATA

✓ Verify effectiveness BEFORE closing
Wait 30-90 days, measure results