

📋 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

✗ **"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