Deviation process

🔲 1. PROBLEM STATEMENT

Clearly and briefly describe the deviation.

- Is the issue described in factual, objective terms (no assumptions)?
- Have you included relevant data or evidence (e.g., logs, reports)?
- Is the affected product, system, or process identified?
- Is the date the issue was identified recorded?

🖉 **Enter:**

- ☐ Deviation Title
- ☐ Date Identified
- ☐ Affected Area/Process
- ☐ Short Problem Description

🔲 2. DEVIATION DETAILS

Document all facts related to a single deviation.

- Is this deviation documented separately (not combined with another)?
- Have you listed the personnel involved?
- Are impacted departments, systems, or batches noted?
- Have you described the urgency or potential risks?
- Is the required resolution timeline stated?

🖉 **Enter:**

- ☐ Date(s) of Incident
- ☐ Immediate Action Taken
- ☐ Risk/Impact Description
- ☐ Urgency/Deadline for Completion

☐ 3. ROOT CAUSE ANALYSIS (Optional if not required)

- Was an RCA performed (e.g., 5 Whys, Fishbone Diagram)?
- Is the true root cause clearly stated (not just symptoms)?
- Are contributing/systemic factors identified?

✎ **Enter:**

- ☐ RCA Method Used
- ☐ Root Cause(s)
- ☐ Contributing Factors

☐ 4. RESOLUTION / FINAL ACTION

- Are all corrective actions clearly listed?
- Are preventive actions documented to avoid recurrence?
- Are affected documents or SOPs identified for revision?
- If applicable, has the product disposition been recorded (scrapped, reworked, etc.)?
- Are all actions assigned with deadlines?

✎ **Enter:**

- ☐ Corrective/Preventive Actions
- ☐ Document/SOP Revisions
- ☐ Product Disposition (if any)
- ☐ Final Completion Date

☐ 5. SIGN-OFF / DOCUMENT CONTROL

- Is the report signed and dated by the author?
- Is the deviation approved by the appropriate reviewer(s)?
- Are no signatures or dates backdated?

🖉 **Enter:**

- ☐ Author Name / Signature / Date
- ☐ Reviewer / QA Signature
- ☐ Final Closure Date

🔲 **6. ATTACHMENTS (Check all that apply)**

- Supporting data (charts, logs, screenshots)
- CAPA forms
- Change control records
- Test results
- Other: _____

✅ **Final Check Before Submission:**

- All fields complete
- No missing or backdated signatures
- Resolution aligns with QMS or regulatory requirements
- Deviation is audit-ready and self-contained