Standard Operating Procedure

SOP Title: Deviation & Corrective/Preventive Action (CAPA) SOP
Document Code: SOP-VA-104 – Deviation & CAPA SOP
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Approved By: [Name / Title]
Review Date: [Annually or as needed]

1. Purpose

To provide a systematic approach for identifying, documenting, investigating, and resolving deviations from approved procedures and for implementing corrective and preventive actions (CAPAs) to prevent recurrence.

2. Scope

Applies to all unexpected or non-conforming events—including cGMP, safety, or CCA compliance deviations—occurring in production, packaging, laboratory testing, facilities, equipment, or documentation at the Verano Virginia facility.

3. Definitions

Term	Definition
Deviation	Any departure from an approved SOP, specification, or regulatory requirement.
Planned Deviation	A pre-approved, temporary change (e.g., maintenance overlap) managed via Change Control.
Unplanned Deviation	An unexpected event requiring immediate investigation.
CAPA	Corrective and Preventive Action; systematic approach to eliminate root cause and prevent recurrence.
Root Cause Analysis (RCA)	Structured investigation (e.g., 5 Whys, Fishbone) to identify underlying cause.

4. Responsibilities

Role	Key Responsibilities
Initiator / Witness	Immediately notifies supervisor and completes Deviation Report section A.
Department Manager	Ensures immediate containment; reviews initial report for completeness.
Quality Assurance (QA)	Logs deviation, assigns investigation lead, tracks CAPA effectiveness.
Investigation Lead (SME)	Performs root-cause analysis, proposes CAPA plan, and documents findings.
CAPA Board (QA + Cross-functional)	Reviews investigation, approves CAPA actions, and verifies closure.

5. Procedure

5.1 Deviation Reporting

1. Upon detection, cease affected activity if product quality may be compromised.
2. Complete *Deviation & CAPA Form* (FORM-VA-###) – Section A within **24 hours**.
3. Notify QA; QA assigns unique Deviation ID and logs into CAPA database.

5.2 Initial Assessment & Classification

- **Critical** – Potential product safety/efficacy impact or regulatory breach; escalate to QA Director and VP Compliance within 24 hr.
- **Major** – May affect product quality but contained; investigate within 5 days.
- **Minor** – No product quality impact; correct and close within 30 days.

5.3 Investigation & Root Cause Analysis

- Investigation lead conducts RCA using 5 Whys or Fishbone diagram.
- Gather relevant data (batch records, maintenance logs, QC results).
- Define root cause(s) and contributing factors.

5.4 Corrective & Preventive Action Plan

- Draft CAPA (Section B of form) with specific actions, owners, and due dates.
- CAPA Board reviews and approves plan.
- Implement corrective actions first to contain issue; then preventive actions to avoid recurrence.
- Update affected SOPs or training if required via Change Control (SOP-VA-103).

5.5 Effectiveness Check & Closure

- QA conducts follow-up audit or data review to confirm CAPA effectiveness.
- If effective, QA signs Section C and marks deviation **Closed** in database.
- Ineffective CAPA requires escalation and revision.

6. Records

- Deviation & CAPA Form (FORM-VA-###)
- RCA worksheets (5 Whys, Fishbone, etc.)
- CAPA database log
- Supporting evidence (COA results, maintenance tickets, training records)

Retention: **5 years** minimum, or per Record Retention Policy (SOP-VA-108).

7. References

- 21 CFR 211.192 – Production Record Review

- ICH Q10 – Pharmaceutical Quality System

- Virginia CCA Regulations – Quality & Compliance requirements

- SOP-VA-103 Change Control SOP

- QM-VA-001 Quality Manual

8. Revision History

Version	Date	Change Description	Approved By
			[Name / Title]