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]  
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# 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

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| Version | Date | Change Description | Approved By |
|  |  |  | [Name / Title] |