Standard Operating Procedure

SOP Title: Internal Audit SOP
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Approved By: [Name / Title]
Review Date: [Annually or as needed]

1. Purpose

To define a systematic, risk-based process for planning, conducting, reporting, and following up on internal audits to ensure ongoing compliance with cGMP, Virginia Cannabis Control Authority (CCA) regulations, and the facility's Quality Management System (QMS).

2. Scope

Applies to all departments, processes, documents, and records within the Verano Virginia facility that can impact product quality, patient safety, or regulatory compliance.

3. Definitions

Term	Definition
Internal Audit	Independent, documented assessment performed by trained personnel who are not responsible for the area being audited.
Audit Plan	Annual schedule detailing audit scope, criteria, team, and timelines.
Audit Report	Formal record summarizing observations, classifications, and required actions.
Observation Grades	• **Critical** – Regulatory breach or patient-safety risk • **Major** – Potential product-quality impact • **Minor** – Good-practice improvement

4. Responsibilities

Role	Key Responsibilities
QA Audit Coordinator	Develops annual Audit Plan, assigns auditors, maintains audit log.
Internal Auditors	Conduct audits objectively, document observations, submit report.
Department Managers	Provide access to records/areas; respond to audit findings with CAPA.
QA Manager / CAPA Board	Approves audit reports, tracks CAPA actions to closure.

5. Records

5.1 Audit Planning

1. QA drafts Annual Audit Plan based on risk ranking (high-risk areas ≥ 2× per year).
2. Plan approved by QA Manager and distributed to department heads.

5.2 Audit Preparation

- Auditors review relevant SOPs, previous audit reports, deviations, and KPIs.
- Prepare checklist (FORM-VA-006 Internal Audit Checklist).

5.3 Audit Execution

- Conduct opening meeting; state scope and objectives.
- Examine documents, observe operations, interview personnel.
- Record each observation with evidence reference (batch #, log ID, etc.).

5.4 Audit Classification & Reporting

- Assign observation grades (Critical / Major / Minor) per Definitions.
- Draft Audit Report within **5 working days**; include CAPA deadlines:
    - Critical = 10 days, Major = 30 days, Minor = 60 days.
- QA Manager issues final report to affected departments and CAPA Board.

5.5 Corrective & Preventive Actions (CAPA)

- Department submits CAPA plan via FORM-VA-004 (Deviation & CAPA Form).
- QA verifies implementation; closes audit item when CAPA proven effective.

5.6 Audit Follow-Up & Trend Analysis

- QA reviews audit trends quarterly; repeat issues escalate to management review.

6. Records

- Annual Audit Plan (SOX)

- Audit Checklists (FORM-VA-006)

- Audit Reports (QA\Audit\Reports\YYYY)

- CAPA Forms linked to audit findings

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

7. Revision History

Version	Date	Change Description	Approved By
			[Name / Title]