Standard Operating Procedure

SOP Title: Record Retention Policy  
Document Code: SOP-VA-108  
Effective Date: 06May25   
Supersedes: [Previous Version if applicable]  
Approved By: [Name / Title]  
Review Date: [Annually or as needed]

# 1. Purpose

To define minimum retention periods and storage requirements for all cGMP and CCA‑related records generated at Verano Virginia.

# 2. Scope

Applies to physical and electronic records produced across production, QA, laboratory, distribution, and compliance activities.

# 3. Responsibilities

| **Role** | **Key Responsibilities** |
| --- | --- |
| **QA Document Control** | Maintains Master Retention Schedule; audits record storage compliance. |
| **Department Managers** | Ensure records are filed in approved locations and retained per schedule. |
| **IT / Facilities** | Provide secure electronic backups and climate‑controlled physical storage. |

# 4. Retention Schedule

| **Record Type** | **Retention** | **Reference** |
| --- | --- | --- |
| Master Batch Record & all attachments | **3 years** | 21 CFR 211.180(a); CCA Rules |
| COAs (lab reports) | 3 years | same |
| Deviations & CAPAs | 5 years | ICH Q10 §3.2 |
| Recall Files | 5 years from closure | SOP‑VA‑107 |
| Training Records | Duration of employment + 1 year | 21 CFR 211.25 |
| Equipment Calibration / Maintenance | Life of equipment + 3 years | 21 CFR 211.182 |
| Environmental Monitoring & Cleaning Logs | 3 years | cGMP Guidance |
| Audit Reports & Plans | 5 years | SOP‑VA‑105 |
| Supplier Qualifications | Active supplier term + 3 years | FDA QSR |

(If state law or contracts require longer retention, follow the longer period.)

# 5. Storage & Access

- **Electronic records** stored on secure QA server with automatic nightly backup and restricted access rights.

- **Physical records** kept in locked, fire‑rated cabinets in the QA archive room (temperature ≤ 25 °C, RH < 60 %).

- Scanned PDFs are acceptable provided originals are archived for at least one audit cycle.

# 6. Disposition Procedure

1. QA Document Control issues a monthly “Records Due for Destruction” report.

2. Department Manager reviews list; removes any records subject to holds (e.g., open CAPA, litigation).

3. Records approved for destruction are shredded (paper) or securely deleted (electronic).

# 6. References

- 21 CFR 211.180 – General Recordkeeping

- 21 CFR 211.182 – Equipment Cleaning & Use Logs

- ICH Q10 §3.2 – Documentation

- Virginia CCA Regulations – Document maintenance

- ISO 9001:2023 Clause 7.5 – Documented Information

- SOP‑VA‑101 Document Control SOP

- SOP‑VA‑107 Product Recall SOP

- QM‑VA‑001 Quality Manual

# 7. Revision History

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| --- | --- | --- | --- |
| Version | Date | Change Description | Approved By |
|  |  | Aligned with updated Quality Manual QM-VA-001 and Master Batch Record SOP. | [Name / Title] |