Standard Operating Procedure

SOP Title: Internal Audit Checklist  
Document Code: FORM-VA-006  
Effective Date: 06May25  
Supersedes: [Previous Version if applicable]  
Approved By: [Name / Title]  
Review Date: [Annually or as needed]

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| ==========================================================  INTERNAL AUDIT CHECKLIST FORM‑VA‑006  Version: 1.0 Effective Date: 06May25  ========================================================== | | | |
| A. AUDIT HEADER  ----------------------------------------------------------  Audit No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_  Department / Area: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Audit Scope / Process: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Lead Auditor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Team: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Reference Documents: SOP‑\_\_\_\_\_\_\_, SOP‑\_\_\_\_\_\_\_, etc. | | | |
| B. CHECKLIST  ----------------------------------------------------------   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | # | Audit Question / Requirement | Reference (SOP / Reg) | Conformance (Y / N / N-A) | Evidence (Doc ID / Interview) | Auditor Comment | | 1 | SOP current version in use? | SOP-VA-\_\_\_ |  |  |  | | 2 | Batch records completed legibly & on time? | 21 CFR 211.188 |  |  |  | | 3 | Equipment cleaning log up‑to‑date? | SOP-VA-\_\_\_ |  |  |  | | 4 | Training records current for operators? | SOP-VA-102 |  |  |  | | 5 | Temperature/Humidity within spec? | ENV LOG |  |  |  | | 6 | Deviations handled per SOP‑VA‑104? | SOP-VA-104 |  |  |  | | 7 | Labeling complies with CCA rules? | VA CCA §\_\_\_\_ |  |  |  | | | | |
| C. OBSERVATION SUMMARY  ----------------------------------------------------------  Observation Category | Qty | IDs / Notes  --------------------------|-----|-----------------------------------------------  Critical | \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Major | \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Minor | \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Good Practice / Positive | \_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| D. IMMEDIATE ACTIONS / CAPA REQUIRED?  ----------------------------------------------------------  □ Yes □ No (If “Yes”, CAPA must be opened within 5 days)  CAPA / Deviation ID(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| E. AUDITOR & MANAGEMENT SIGN‑OFF  ----------------------------------------------------------  Lead Auditor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_  QA Manager Review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_  Department Manager Acknowledgement: \_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_  ================================================================ | | | |
| Version | Date | Change Description | Approved By |
|  |  |  | [Name / Title] |