

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]

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 <hr style="border-top: 1px dashed black;"/> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; border-bottom: 1px solid black;">Observation Category</td> <td style="width: 10%; border-bottom: 1px solid black;">Qty</td> <td style="width: 10%; border-bottom: 1px solid black;">IDs</td> <td style="width: 50%; border-bottom: 1px solid black;">Notes</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Critical</td> <td style="border-bottom: 1px solid black;"> __ </td> <td colspan="2" style="border-bottom: 1px solid black;"></td> </tr> <tr> <td style="border-bottom: 1px solid black;">Major</td> <td style="border-bottom: 1px solid black;"> __ </td> <td colspan="2" style="border-bottom: 1px solid black;"></td> </tr> <tr> <td style="border-bottom: 1px solid black;">Minor</td> <td style="border-bottom: 1px solid black;"> __ </td> <td colspan="2" style="border-bottom: 1px solid black;"></td> </tr> <tr> <td colspan="4" style="border-bottom: 1px solid black;">Good Practice / Positive __ _____</td> </tr> </table>				Observation Category	Qty	IDs	Notes	Critical	__			Major	__			Minor	__			Good Practice / Positive __ _____			
Observation Category	Qty	IDs	Notes																				
Critical	__																						
Major	__																						
Minor	__																						
Good Practice / Positive __ _____																							
D. IMMEDIATE ACTIONS / CAPA REQUIRED? <hr style="border-top: 1px dashed black;"/> <p> <input type="checkbox"/> Yes <input type="checkbox"/> No (If “Yes” , CAPA must be opened within 5 days) </p> <p> CAPA / Deviation ID(s): _____ </p>																							
E. AUDITOR & MANAGEMENT SIGN-OFF <hr style="border-top: 1px dashed black;"/> <p> Lead Auditor Signature: _____ Date: _____ </p> <p> QA Manager Review: _____ Date: _____ </p> <p> Department Manager Acknowledgement: _____ Date: _____ </p> <p> ===== </p>																							
Version	Date	Change Description	Approved By																				
			[Name / Title]																				