INTERNAL AUDIT PLAN

1. Audit Information

Audit ID:	IA-2026-XXX
Audit Type:	☐ Process Audit ☐ System Audit ☐ Follow-up Audit
Audit Date(s):	
Lead Auditor:	
Audit Team:	
Auditee:	
Department/Area:	

2. Audit Context and Risk Assessment

Why is this audit performed now?	☐ Scheduled (per annual audit plan) ☐ Risk-triggered (specify): _____ ☐ Following process/system changes (specify): _____ ☐ Previous NC follow-up (CAPA #): _____ ☐ Customer complaint related (Complaint #): _____ ☐ Regulatory preparation / External audit preparation
Process Risk Level	☐ High (critical to product safety/efficacy) ☐ Medium (moderate impact on quality) ☐ Low (administrative/support process)
Risk Justification	[Explain why this risk level was assigned]

3. Audit Scope

Process(es) / Area(s) to be audited:

Exclusions (if any):

4. Audit Criteria

Standards and Regulations:

☐ ISO 13485:2016 ☐ FDA 21 CFR 820 ☐ EU MDR 2017/745 ☐ ISO 14971 ☐ Other: _____

Specific Clauses:

Standard	Clause(s)
ISO 13485:2016	
FDA 21 CFR 820	
Internal Procedures	

5. Audit Objectives

1. Verify compliance with applicable requirements
2. Assess effective implementation of QMS processes
3. Verify closure of previous audit findings (if applicable)
4.
5.

6. Audit Schedule

Time	Duration	Activity	Attendees
09:00	15 min	Opening Meeting	
09:15		Document Review	
		Process Observation	
		Personnel Interviews	
	30 min	Auditor Caucus	Audit Team only
	30 min	Closing Meeting	

7. Resources Required

Documents to be reviewed:

☐ Quality Manual
☐ Relevant SOPs and Work Instructions
☐ Training Records
☐ CAPA Records
☐ Previous Audit Reports
☐ Other: _____

8. Previous Audit Findings

Finding ID	Description	Status

9. Communication Plan

Audit Notification:	Sent on: _____
Report Due Date:	
CAPA Response Due:	

10. Approval

Role	Signature	Date
Lead Auditor:		
QM Representative:		

Compliant with ISO 13485:2016 Section 8.2.4