AUDIT PREPARATION PROCEDURE

Standard Operating Procedure

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Regulatory Basis:	ISO 13485:2016	ISO 19011:2018	FDA 21 CFR 820

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1. PURPOSE

This procedure defines the systematic approach for preparing the organization for external quality audits (certification, surveillance, customer, and regulatory). It ensures consistent preparation, clear responsibilities, and effective communication before, during, and after audits.

2. SCOPE

This procedure applies to preparation for:

• Initial certification audits (ISO 13485, ISO 9001)
• Surveillance and recertification audits
• Customer and supplier audits
• Regulatory inspections (FDA, Notified Body)
• Unannounced audits (abbreviated preparation)

5. AUDIT PREPARATION PROCESS

5.1 Pre-Audit Planning (8-4 weeks before)

Week	Activity	Responsible
8	Confirm audit date, scope, and auditor(s)	Quality Manager
7	Distribute audit notification to departments	Quality Manager
6	Begin Self-Assessment against audit scope	Department Heads
5	Identify gaps from Self-Assessment	Quality Team
4	Develop action plan for gap closure	Quality Manager

5.5 AUDIT DAY MANAGEMENT

Key activities during the audit:

• **Opening Meeting:** Introduce key personnel, confirm scope and schedule
• **Escort Protocol:** Designated escorts for each auditor at all times
• **Communication Rules:** Answer only what is asked, offer to find information if unsure
• **Real-time Documentation:** Record all findings and observations as they occur
• **Daily Debrief:** Internal team meeting at end of each audit day
• **Closing Meeting:** Review findings, clarify any misunderstandings

This sample shows the document structure and first sections. The complete document contains additional sections with detailed procedures, forms, and implementation guidance.

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