

Medical Device Quality Management System

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Internal Audit Policy

Role	Position/Department	Name	Date
Author			DD YYYY
Reviewer			DD YYYY
Approver			DD YYYY

[Company Name], Inc.

Revision History

Ver.	Effective Date	Revision Details (Reason, Changes, Affected Documents)	Author/Reviewer/ Approver	
Version 1.0		Initial Release		
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1. Purpose

The purpose of this policy is to establish the requirements and framework for conducting internal audits of the Quality Management System (QMS) at [Company Name], Inc. (hereinafter referred to as "the Company"). Internal audits verify that the QMS conforms to applicable regulatory requirements and international standards, that records are adequate and appropriate, and that the QMS is effectively implemented and maintained. This policy ensures compliance with 21 CFR Part 820 (Quality Management System Regulation, QMSR), ISO 13485:2016 Clause 8.2.4, and applicable FDA guidance documents.

2. Scope

This policy applies to all internal audit activities for the QMS governing medical devices handled by the Company. This includes audits of all departments, processes, and functions that affect product quality, safety, and regulatory compliance. The scope encompasses scheduled (routine) audits, unscheduled (for-cause) audits, and follow-up (re-) audits.

NOTE: Under the QMSR (effective February 2, 2026), the exemption from FDA inspection for management review records, internal audit (quality audit) records, and supplier audit reports previously provided under QSR Section 820.180(c) has been eliminated. All internal audit records are now subject to FDA inspection.

3. Normative References

ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (Clause 8.2.4: Internal audit)

21 CFR Part 820 Quality Management System Regulation (QMSR)

ISO 19011:2018 Guidelines for auditing management systems

ISO 9000:2015 Quality management systems - Fundamentals and vocabulary

4. Definitions

Term	Definition
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Internal Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (ISO 9000:2015, 3.13.1). In the context of this policy, internal audits verify that: (1) the QMS conforms to QMS Ordinance, QMSR (21 CFR Part 820), and ISO 13485:2016; (2) the QMS is effectively implemented and maintained; and (3) records created under the QMS are adequate and appropriate.
Audit Program	Set of one or more audits planned for a specific time frame and directed toward a specific purpose. The audit program defines audit criteria, scope, frequency, and methods (ISO 9000:2015, 3.13.4).
Audit Criteria	Set of policies, procedures or requirements used as a reference against which audit evidence is compared (ISO 19011:2018, 3.7).
Audit Evidence	Records, statements of fact or other information which are relevant to the audit criteria and verifiable (ISO 19011:2018, 3.9).
Audit Finding	Results of the evaluation of the collected audit evidence against audit criteria. Audit findings can indicate conformity, nonconformity, or opportunities for improvement (ISO 19011:2018, 3.10).
Audit Subject (Auditee)	The department, process, function, or responsible person(s) subject to the internal audit.
Re-audit (Follow-up Audit)	An audit conducted on a specific department or process when deemed necessary to verify the implementation and effectiveness of corrective actions taken in response to nonconformities identified during a prior internal audit.
QMSR	Quality Management System Regulation. The amended 21 CFR Part 820 rule effective February 2, 2026, which incorporates ISO 13485:2016 by reference and replaces the former Quality System Regulation (QSR). Under QMSR, internal audit records, supplier audit reports, and management review records are subject to FDA inspection (the former QSR Section 820.180(c) exemption has been removed).
Nonconformity	Non-fulfillment of a requirement (ISO 9000:2015, 3.6.9).
Correction	Action to eliminate a detected nonconformity (ISO 9000:2015, 3.12.3).
Corrective Action	Action to eliminate the cause of a nonconformity and to prevent

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