

# Document Control Policy

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[Company Name], Inc.

## Revision History

Ver.	Effective Date Revision Details Author/Reviewer/Approver
Version 1.0	Effective Date: 20XXMM00DD00YYYY Reason: Initial Release Content: Initial Release Affected Documents: N/A Author: XXX   Reviewer: XXX   Approver: XXX

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PREVIEW  
Not for production use

## 1. Purpose

The purpose of this Document Control Policy is to establish requirements for the management of Quality Management System (QMS) documents and records at [Company Name], Inc. (hereinafter referred to as "the Company") to ensure systematic and efficient organizational operations while enabling information sharing through documented procedures. This policy ensures compliance with the FDA Quality Management System Regulation (QMSR: 21 CFR Part 820) and ISO 13485:2016 "Medical devices — Quality management systems — Requirements for regulatory purposes," implementing a risk-based approach to document and record management. This policy also aligns with applicable Japanese pharmaceutical regulations including QMS Ministerial Ordinance requirements where relevant.

This policy fulfills the requirements of ISO 13485:2016 Clause 4.2.4 "Control of documents," Clause 4.2.5 "Control of records," and QMSR §820.10 and §820.35. Specific content requirements for complaint records, service records, and other specialized records are supplemented in related procedures.

NOTE: This policy clearly distinguishes between "QMS Documents" and "Records." Regulatory requirements recognize two types of documents: documents that provide instructions and documents that constitute records. QMS Documents provide instructions for performing work activities, while Records document the results of work performed. Due to their different characteristics, QMS Documents and Records require different management approaches. This policy addresses each separately.

## 2. Scope

This policy applies to all documents and records within the Company's medical device QMS. By reference to FDA QMSR (21 CFR Part 820) and ISO 13485:2016 requirements, this policy applies throughout the medical device product lifecycle including design and development, manufacturing, storage, distribution, installation, servicing, and final disposal.

## 3. Normative References

- 1) ISO 13485:2016, Medical devices — Quality management systems — Requirements for regulatory purposes
- 2) 21 CFR Part 820, Quality Management System Regulation (QMSR)
- 3) 21 CFR Part 11, Electronic Records; Electronic Signatures
- 4) ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

## 4. Definitions

Term	Definition
<b>QMS</b>	Quality Management System. Part of a management system with regard to quality. (ISO 9000:2015, 3.5.4)
<b>QMS Document</b>	Documents that implement the QMS. Includes quality manual, policies, procedures, and forms.
<b>Document</b>	Information and its supporting medium. (ISO 9000:2015, 3.8.5)

<b>Record</b>	Document stating results achieved or providing evidence of activities performed. (ISO 9000:2015, 3.8.10)
<b>Controlled Document</b>	A document managed by the Document Control Manager with assurance that the current version is distributed.
<b>Uncontrolled Document</b>	A document without assurance that the current version is distributed.
<b>Obsolete Document</b>	A previous version or discontinued document.
<b>Effective Date</b>	The date when document content becomes applicable.
<b>External Document</b>	Documents obtained from outside the organization that are necessary for system operation (standards, drawings, contracts, specifications, manuals, etc.).
<b>Review</b>	Determination of the suitability, adequacy, or effectiveness of an object to achieve established objectives. (ISO 9000:2015, 3.11.2)
<b>Verification (Review)</b>	Performing document review.
<b>Approval</b>	Performing document review and authorizing document release based on content appropriateness before document issuance.
<b>Electronic Record</b>	Records created by electronic means, magnetic means, or other means not recognizable by human perception, intended for information processing by computer systems. Specifically refers to digital records stored on memory, magnetic tape, magnetic disks, optical disks (CD-ROM, etc.).
<b>Medical Device File (MDF)</b>	Compilation of documentation for a specific finished device. In the U.S. regulatory context, includes Design History File (DHF) and Device Master Record (DMR).
<b>Device History Record (DHR)</b>	A compilation of records containing the production history of a finished device. (21 CFR §820.3(j))
<b>Device Master Record (DMR)</b>	A compilation of records containing the procedures and specifications for a finished device. (21 CFR §820.3(k))
<b>Design History File (DHF)</b>	A compilation of records which describes the design history of a finished device. (21 CFR §820.3(l))
<b>Unique Device Identifier (UDI)</b>	A unique numeric or alphanumeric code that includes a device identifier and may include a production identifier. (21 CFR §830.3)

## 5. QMS Document Hierarchy

The Company's QMS documentation is structured in a hierarchical format to ensure clarity of requirements and consistency of implementation across the organization. The hierarchy facilitates understanding of the relationships between different document types and supports efficient document control.

Level	Document Type	Document ID Format
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