Design Change Management Policy

Role	Position/Department	Name	Date
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[Company Name], Inc.

Revision History

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	Department	XXX	XXX	XXX
	Position	XXX	XXX	XXX
	Name	XXX	XXX	XXX

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1. Purpose

The purpose of this policy is to establish the requirements for managing design and development changes for all medical device products handled by [Company Name], Inc. (hereinafter referred to as “the Company”), in compliance with the FDA Quality Management System Regulation (QMSR, 21 CFR Part 820, effective February 2, 2026) and ISO 13485:2016.

This policy ensures that design changes are systematically identified, evaluated, reviewed, verified, validated (where applicable), and approved prior to implementation, and that the significance of such changes is determined with respect to the function, performance, usability, safety, and applicable regulatory requirements of the medical device and its intended use.

2. Scope

This policy applies to all design and development changes for medical devices handled by the Company after design transfer. This includes changes to design inputs, design outputs, manufacturing specifications, component parts, manufacturing processes, test methods, and risk management documentation.

This policy applies to all changes subject to ISO 13485:2016 Clause 7.3.9 (Design and Development Changes) and the corresponding requirements of QMSR (21 CFR Part 820). Class I devices exempt from design controls per 21 CFR 862–892 are excluded.

3. Normative References

ISO 13485:2016 — Medical devices — Quality management systems — Requirements for regulatory purposes

21 CFR Part 820 (QMSR) — Quality Management System Regulation (effective February 2, 2026)

ISO 14971:2019 — Medical devices — Application of risk management to medical devices

4. Definitions

Term	Definition
4M	Refers to Material, Method, Machine, and Measurement. Man (personnel) is not included.
CAPA	Corrective and Preventive Action. Action to eliminate the cause of a detected nonconformity or other undesirable situation (corrective) or to eliminate the cause of a potential nonconformity or other potential undesirable situation (preventive). (ISO 13485:2016 Clause 8.5.2/8.5.3)
Design and Development Change	A change to design and development as defined in ISO 13485:2016 Clause 7.3.9. This includes any change affecting design inputs, design outputs, manufacturing specifications, component parts, manufacturing processes, test methods, or risk management.
Design History File (DHF)	A compilation of records which describes the design history of a finished device. As per QMSR, this is part of the Medical Device File (MDF) per ISO 13485:2016

	Clause 7.3.10.
Design Transfer	The process of translating the final device design into production specifications, as described in ISO 13485:2016 Clause 7.3.8, ensuring that the design output is suitable for manufacturing.
Medical Device File (MDF)	A file defined in ISO 13485:2016 Clause 7.3.10 that encompasses records from design and development activities, including the functions of the traditional DHF (Design History File), DMR (Device Master Record), and DHR (Device History Record).
Risk-Based Approach	An approach described in ISO 13485:2016 Clause 4.1.2(b) that applies risk to quality management system process management. In design changes, it evaluates the risk posed to product safety, performance, and regulatory compliance.
Significance of the Change	The degree of impact that a change has on the function, performance, usability, safety, and conformity to applicable regulatory requirements of the medical device. As per ISO 13485:2016 Clause 7.3.9, this must be determined prior to change implementation.
Unique Device Identification (UDI)	A system for adequate identification of medical devices through their distribution and use as required by 21 CFR Part 830.
Verification (Design Verification)	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled (ISO 13485:2016 Clause 7.3.6).
Validation (Design Validation)	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled (ISO 13485:2016 Clause 7.3.7).

5. Design Change / 4M Change Management

5.1 General Requirements

All design and development changes occurring after design transfer shall be managed in accordance with the Design Change Management SOP (MD-QMS-S405). Design and development changes shall be identified and records maintained.

In compliance with ISO 13485:2016 Clause 7.3.9, design and development change management shall be performed through documented procedures that systematically address the identification, evaluation, approval, and implementation of changes.

5.2 Determination of Significance

Prior to implementation of a design change, the significance of the change shall be determined with respect to the function, performance, usability, safety, and applicable regulatory requirements of the medical device and its intended use. The determination shall be documented in the Design Development File (MDF).

5.3 Pre-Implementation Requirements

Before implementation (design transfer) of any design and development change, the following activities shall be completed, as applicable: