Design Control Policy

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

[Company Name], Inc.

1. Purpose

The purpose of this policy is to establish the design control requirements for all medical device products handled by [Company Name], Inc. (hereinafter referred to as "the Company") to ensure that products are designed and developed in accordance with the Quality Management System Regulation (QMSR) 21 CFR 820 and ISO 13485:2016, thereby ensuring that residual risks in products are minimized to an acceptable level relative to their benefits and that products meet user needs and intended uses.
This policy establishes a systematic approach to design and development throughout the entire product lifecycle, from initial concept through design transfer to manufacturing, ensuring quality assurance and regulatory compliance.

2. Scope

This policy applies to all medical device products, including labeling and software, handled by the Company that require design control under QMSR 21 CFR 820.30 and ISO 13485:2016 Clause 7.3.
Note on QMSR Terminology:
Following the implementation of QMSR (effective February 2, 2026), this policy aligns with updated terminology:
• Design History File (DHF) → Design and Development File (DDF)
• Device Master Record (DMR) → Medical Device File (MDF)
• Device History Record (DHR) → Production Records (within MDF)
Throughout this policy, references to DDF, MDF, and Production Records should be understood according to QMSR 21 CFR 820.

3. Normative References

This policy is based on and complies with the following regulatory requirements and international standards:
• 21 CFR 820 Quality Management System Regulation (QMSR) - FDA, effective February 2, 2026
• ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
• ISO 14971:2019 - Medical devices - Application of risk management to medical devices
• IEC 62366-1:2015 - Medical devices - Application of usability engineering to medical devices
• IEC 62304:2006 - Medical device software - Software life cycle processes

4. Definitions

Term	Definition
Design and Development File (DDF)	A compilation of records that describes the design history of a finished medical device. Formerly known as Design History File (DHF) under 21 CFR 820.
Design Input	The physical and performance requirements of a medical device that are used as a basis for device design.
Design Output	The results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the Medical Device File (MDF).

Design Review	A documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.
Design Transfer	The process of transferring proven design outputs to manufacturing.
Design Validation	Establishing by objective evidence that device specifications conform with user needs and intended use(s) under actual or simulated use conditions.
Design Verification	Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
Medical Device File (MDF)	A compilation of records containing the specifications and procedures for a finished device. This replaces the Device Master Record (DMR) terminology from 21 CFR 820.
Production Records	Records maintained for each batch, lot, or unit manufactured. This replaces the Device History Record (DHR) terminology from 21 CFR 820.
Risk Management	Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (ISO 14971:2019).
Traceability Matrix	A document that correlates design inputs, design outputs, verification activities, and validation activities to ensure complete coverage and traceability throughout the design and development process.
Usability Engineering	Application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of medical devices (including software), systems and tasks to achieve adequate usability (IEC 62366-1:2015).

5. Design Review Meetings

5.1 Design Review Process

Design reviews shall be conducted at appropriate stages of design and development to:
• Evaluate the ability of the design and development results to meet requirements
• Identify and propose necessary actions for problems identified during the review
• Ensure all design requirements are properly addressed
• Identify risk management activities and their integration into design