GLOBAL QUALITY SYSTEM PROCEDURE

Document ID: SOP-700	**Title: Design and Development Controls**	**Revision: B**
Effective Date: 14-SEP-2019	**Owner:** VP of R&D Engineering	**Classification:** Confidential
Next Review Date: 14-SEP-2021	**Supersedes:** SOP-700 Rev A	**Page:** 1 of 15

1. APPROVALS

Role	Name/Title	Signature	Date
Author	Richard Doe, Principal Compliance Engineer	*[Electronically Signed]*	10-SEP-2019
Quality Approval	Jane Smith, Director of Quality Assurance	*[Electronically Signed]*	11-SEP-2019
Executive Approval	Mark Stevens, VP of R&D Engineering	*[Electronically Signed]*	12-SEP-2019
Regulatory Approval	Sarah Jenkins, Head of Regulatory Affairs	*[Electronically Signed]*	13-SEP-2019

2. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish and maintain a documented, systematic framework for the design and development of medical devices. This procedure ensures that devices are safe, effective, and compliant with the requirements of the Quality System Regulation (QSR). This document serves as the primary governing

procedure for the transition from clinical concept to commercial manufacturing, ensuring that all design outputs satisfy the pre-defined design inputs and user needs.

3. SCOPE

This procedure applies to all personnel (permanent, contract, and third-party) involved in the design and development lifecycle for:

1. **Class II and Class III Medical Devices:** Including hardware, consumables, and electromechanical systems.
2. **Software as a Medical Device (SaMD):** Standalone software applications.
3. **Embedded Software/Firmware:** Code residing within hardware devices.
4. **Major Product Modifications:** Any change to an existing product that affects its safety, efficacy, or intended use.
5. **Acquired Technology:** Integration of designs acquired through corporate mergers or acquisitions.

4. REGULATORY REFERENCES

- **FDA 21 CFR Part 820.30:** Quality System Regulation – Design Controls.
- **ISO 13485:2003:** Medical Devices – Quality Management Systems.
- **ISO 14971:2007:** Application of Risk Management to Medical Devices.
- **IEC 62304:2006:** Medical Device Software – Software Life Cycle Processes.
- **IEC 62366:2007:** Application of Usability Engineering to Medical Devices.
- **EU Medical Device Directive (MDD) 93/42/EEC:** (Note: Transition to MDR 2017/745 pending per 2020 timeline).
- **SOP-100:** Document Control and Records Management.

5. DEFINITIONS

- **Design History File (DHF):** A compilation of records which describes the design history of a finished device.
- **Design Input:** The physical and performance requirements of a 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 Device Master Record (DMR).
- **Design Review:** A documented, comprehensive, and 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 Verification:** Confirmation by examination and provision of objective evidence that design output meets the design input requirements.
- **Design Validation:** Confirmation by examination and provision of objective evidence

that the particular requirements for a specific intended use can be consistently fulfilled.
- **Design Freeze:** A designated milestone in the design process after which all design outputs are locked, and any further changes must be managed through formal Change Control (SOP-100).
- **Essential Design Output (EDO):** Characteristics of the design that are critical to the safe and effective use of the device.
- **User Needs:** The requirements of the user, patient, and clinical environment that the device is intended to satisfy.

6. RESPONSIBILITIES

6.1 Project Manager (PM)

- Develops the Design and Development Plan (DDP) and ensures cross-functional alignment.
- Coordinates resource allocation and monitors project milestones.

6.2 R&D Engineering

- Translates user needs into technical specifications (Design Inputs).
- Executes design activities and documents all results in the DHF.
- Leads the generation of Design Outputs (drawings, BOMs, specs).

6.3 Quality Assurance (QA)

- Provides independent oversight for Design Reviews.
- Reviews and approves V&V (Verification and Validation) protocols and reports.
- Conducts DHF audits to ensure 2019 regulatory readiness.

6.4 Clinical & Regulatory Affairs

- Defines the clinical intended use and user needs.
- Establishes the regulatory pathway and ensures global standard compliance.

7. PROCEDURE

7.1 Design and Development Planning

Each project begins with a formal **Design and Development Plan (DDP)** approved by the Project Steering Committee.

1. The DDP must define the design phases, the core team, and the organizational interfaces.
2. The plan shall assign responsibility for each design activity and include a schedule for formal reviews.
3. *Legacy Note:* The DDP is a static document. Any deviation from the plan requires a

manual revision and re-approval via the Change Control Board (CCB).

7.2 Design Inputs (The DIS)

Design inputs are the foundational requirements for the device.

1. Engineering shall compile a **Design Input Specification (DIS)**.
2. Inputs must be measurable, unambiguous, and address: functional, performance, safety, and regulatory requirements.
3. Design inputs must address risks identified in the preliminary Hazard Analysis.
4. Approval of the DIS occurs during the Gate 1 Design Review.

7.3 Design Outputs

Design outputs shall be documented and shall be expressed in terms that allow for adequate evaluation of conformance to design input requirements.

1. Outputs include drawings, specifications, software code, and Instructions for Use (IFU).
2. Engineering must identify **Critical-to-Quality (CTQ)** components.
3. *Legacy Note:* Design outputs must be approved by the Engineering Manager before they are used for formal Verification.

7.4 Formal Design Reviews

Formal reviews are conducted to evaluate the adequacy of the design.

1. **Frequency:** Reviews are mandatory at the end of each design phase (Concept, Input, Output, V&V, and Transfer).
2. **Attendance:** Requires a cross-functional team including at least one individual who does not have direct responsibility for the design stage being reviewed (the "Independent Reviewer").
3. **Documentation:** Minutes must include the date, participants, design revision being reviewed, and action items.

7.5 Design Verification (DV)

DV confirms that the design output meets the design input.

1. All DV testing must be conducted according to pre-approved protocols.
2. Testing must be performed on "representative" prototype units.
3. *Legacy Sampling Rule:* Statistical sampling for verification shall be based on a fixed confidence/reliability of 95/95 as per the 2018 Statistical Policy.

7.6 Design Validation (VAL)

VAL confirms the device meets user needs and intended uses.

1. Validation testing must be performed on initial production units or their equivalents produced under simulated production conditions.

2. Validation must include clinical evaluation or summative usability testing in the intended environment.
3. Testing must ensure that the device remains safe and effective for the duration of its stated shelf life.

7.7 Risk Management Integration (Compliance Trap)

Risk management is conducted as a separate track within the design process.

1. **Preliminary Hazard Analysis (PHA):** Conducted at project kickoff.
2. **FMEA:** A Failure Mode and Effects Analysis (dFMEA) shall be performed *after* the Design Output phase is complete and prior to Design Freeze.
3. **Risk/Benefit Analysis:** Compiled into a final Risk Management Report (RMR) at the end of the project.
4. *Note for AI Update:* The new QSMR (alignment with ISO 13485:2016) requires risk management to be iterative and integrated into *every* design decision, rather than a point-in-time "check" after outputs are generated.

7.8 Design Transfer

Design transfer ensures that the design is correctly translated into production specifications.

1. The Engineering Lead shall finalize the **Device Master Record (DMR)**.
2. Production lines must be validated (Installation, Operational, and Performance Qualification - IQ/OQ/PQ).
3. Transfer is considered complete when the Plant Manager and Quality Director sign the physical Design Transfer Certificate.

7.9 Design History File (DHF) Management

The DHF is the repository for all design-related records.

1. The Engineering Lead maintains a **DHF Index** (Form-701) which tracks all document versions.
2. *Legacy Format:* The DHF is maintained as a physical "Master Binder" in the Central Vault, with digital backups in the legacy document management system.
3. **Retention:** DHFs shall be retained for 10 years after the product is discontinued.

8. REVISION HISTORY

Rev	Date	Description of Change	Author
A	10-JAN-2018	Initial Release of corporate-wide	J. Smith

		design control procedure.	
B	14-SEP-2019	Updated to include SaMD requirements and revised DHF retention policy.	R. Doe

[END OF DOCUMENT]