PURPOSE

This procedure documents and defines the Design and Development Controls. The company utilizes a phase gate design review system in the development of new products and the modification of existing products.

SCOPE

This procedure applies to all design and development activities for products intended for commercial distribution. Applicability of specific phases or deliverables is dependent on the complexity of the product (e.g. product improvement, major modification, or fully designed new product.)

1. **GENARAL**

    1. **DEFINITIONS**

    Device History Record (DHR) – Compilation of records containing the production history of a finished device

    Device Master Record (DMR) – Compilation of records containing the procedures and specifications for a finished device. Specifics are contained in 21CRF820.181

    Design Input – Physical and performance requirements of a device that are used as a basis for device design

    Design Output – 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. The total finished design output consists of the device, its packaging and labeling, and the device master record.

    Design History File (DHF) – Compilation of records containing the design history of a finished device

    Design Review – 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 Review Board – a panel of specific named individuals designated to review each phase of each project to make a GO/NO GO decision to advance to the next project phase.

    Validation – Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

Risk Management – Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, and controlling risk.

Master Validation Plan – High level outline of how the design verification, design validation, process validation, and if required, software validation requirements will be met.

Process Validation – Establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

Design Validation – Establishing by objective evidence that device specifications conform to user needs and intended uses.

Design Verification – Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

1. **RESPONSIBILITIES**

Sales and Marketing – shall have the primary responsibility for determining customer need requirements and developing input specifications, however, all departments are expected to support the development of input requirements and subsequent specifications.

Operations – is responsible for overseeing the contract manufacturer in executing the transferred design into a salable product, assuring manufacturability and establishing manufacturing requirements. Operations is further responsible for ensuring the creation and maintenance of all DHRs.

Quality Assurance / Regulatory – has the responsibility of ensuring that product development efforts adhere to Design Control requirements and that all aspects are appropriately documented. QA is further responsible approval and maintenance / auditing of all DHRs, DMRs, and DHFs. RA is responsible for regulatory submissions and maintaining compliance to applicable regulatory requirements.

Product Development/Engineering – has the responsibility for developing and transferring to the Contract Manufacturer a design that is manufacturable and repeatable. Product Development/Engineering is also responsible for overseeing the development of the DMR, adherence to the Design Control procedures as detailed in this document, responsible for overall project management and for the establishment of project teams and team leaders.

Project Leader – is responsible for the project timeline and completion of the deliverables from other departments, for conducting the project team meetings and ensuring that the minutes are taken,

issued, and filed, and is responsible for the creation of the Design History File (DHF).

1. **EQUIPMENT AND MATERIALS** – Equipment and materials vary according

   to the specifics of each development project.

2. **SAFETY PRECAUTIONS** – Use appropriate safety precautions and

   Personal Protective Equipment required for the processes under development and the equipment that will be used during development.

3. ## TRAINING REQUIREMENTS – All personnel responsible for completing and/or approving product designs shall be trained to this procedure.

4. ## RECORD MANAGEMENT – All records associated with the Design Control Process are maintained within the Design History File (DHF) and managed by the Quality Department.

5. ## ASSOCIATED DOCUMENTS AND REFERENCES

21 CFR 820 FDA – Quality System Regulations

MDR 2017/745 – EU Medical Device Regulation

MDD 93/42/EEC – EU Medical Device Directive

SOR/98-282 – Canadian Medical Device Regulations

ISO 13485 – Medical Device Quality Management Systems

ISO 14971 – Medical Devices – Application of Risk Management to Medical Devices

QF-0002-1 – Design Review Phase Checklist

QP-0009 – Change Control Process

1. **DESIGN PHASE GATE PROCEDURE**

   The following phase gate system is utilized to control the product design and development process.

Phase I	**Phase 2**	**Phase 3**	**Phase 4**	**Phase 5**
Feasibility & Concept	**Design Inputs & Development**	**Verification & Validation**	**Transfer to MFG (Commercialization)**	**Post Market Assessment**
NPD Project Plan/Schedule	NPD Project Plan/Schedule	NPD Project Plan/Schedule	NPD Project Plan/Schedule	NPD Project Plan/Schedule
Design Review Minutes	Design Review Minutes	Design Review Minutes	Design Review Minutes	Design Review Minutes
Customer Needs Document	Marketing Launch Plan	Design / Usability FMEA's	Training	Technical File
Business Case & Feasibility	Manufacturing & Operations Plan	Sterilization & Shelf-Life Testing.	Process FMEA	Declaration of Conformity
Design Concept	Pkg. & Labeling Requirements	Biocompatibility Testing	Process Validation	Production Status Report
Regulatory Strategy	Quality Plan	Software Validation	Final Traceability Matrix	Customer Feedbac
	Initial Risk Assessments	Product Safety and EMC Testing	DHR & DMR	Risk Analysis Review
	Initial Risk Assessments	Product Performance Validation	Regulatory Approval	Clinical Evaluation Review
	Initial Traceability Matrix	Usability Validation	Design Transfer ECO	
		Clinical Validation		
		Packaging Validation		
		Regulatory Submission		

1. **Design Planning:**

   1. Once Executive Management determines that the opportunity is worthy of resources, a Project Team Leader is selected to lead the project and personnel resources from QA/RA, Engineering, Operations, Sales & Marketing and Finance as needed are assigned to form the core project team.

2. The Project Team Leader shall chair individual project team meetings, assigning action items, with completion dates, to the appropriate team members with detailed planning and tracking of tasks.

3. As a guidance and tracking tool, the Project teams will utilize the Design Review Phase Checklist to navigate correctly through the phase gated design and development process.

4. A NPD Project Plan/Schedule shall be developed by the Project Manager and shall include all key project tasks, individual assignments, major milestones such as Phase completion, overall timeline/product launch estimated target, and expected resources. The NPD Project Plan/Schedule shall be reviewed and updated as necessary at each stage of the phase gate process.

2. **DESIGN PHASE REVIEW MEETING REQUIREMENTS:**

1. Design Phase Review meetings are formal meetings with designated key knowledgeable representatives from a cross section of all disciplines within the company (as applicable to the product), and are intended to update the Leadership Team regarding the project meeting the requirements of the specific phase and gaining approval, or receiving disapproval, to move the project to the next Design Phase.

2. The Design Phase Review Checklist is utilized as the agenda for the phase review meetings and the meeting minutes are recorded.

3. At each Design Phase Review, each item for the specific phase must be reviewed on the checklist and where possible the link for each document shall be listed on the checklist. If an item is not required for a specific product, a brief justification should be listed on the checklist.

4. The Design Review Phase Checklist and meeting minutes are the official records of Design Phase Reviews and shall become part of the Product Design History File (DHF).

5. At any point in this process the design project may be terminated or suspended as authorized by the Design Review Board. Reason for termination or suspension shall be recorded in the project Design History File (DHF).

3. **PHASE 1 - FEASIBILITY & CONCEPT**

   In Phase 1 the project team's efforts are focused on ensuring that the opportunity makes good business sense by conducting due diligence and completing the following documents to make this determination:

1. **Customer Needs Document:** Developed by Marketing to provide

   customer analysis and needs, physical appearance, functionality for intended use, any needed user training, and general packaging/labeling requirements for the new product.

2. **Business Case/Feasibility Study:** Developed by Marketing to

   summarize the business opportunity, market analysis, how the product will be brought to market, and estimated pricing and project return on investment.

3. **Design Concept:** Conceptual product representations and

   configurations, developed by Engineering, intended to meet identified design requirements.

4. **Regulatory Strategy:** Completed by QA/RA to determine the product

   classification and regulatory requirements for FDA, MDD/MDR, CMDR, and all other applicable authorities. Outline the intended regulatory path for market approval in target markets.

1. **PHASE 2 – DESIGN INPUTS AND DEVELOPMENT**

   In Phase 2 the project team focuses on further defining the new product concept through development of the following documents:

1. **Marketing Launch Plan:** Developed by Marketing describing the

   launch to market plan in terms of product versions, market segments, time-lines and quantities.

2. **Manufacturing / Operational Plan:** Developed by Operations

   describing the overall manufacturing plan from receiving dock door to shipping dock door. This is typically in the form of a flow chart. May include imitation of Supplier Qualification, if applicable.

3. **Packaging & Labeling Requirements:** Developed by Marketing to

   clearly define the packaging and labeling requirements, including artwork and design patterns.

4. **Quality Plan:** Quality developed plan describing how quality will

   be controlled throughout the design process, project phases, design review meetings, expected outputs to match design inputs,

and an outline or description of the overall master validation plan illustrating what verification/validation activities will be performed (e.g. design verification, design validation, process validation and where necessary software validation activities).

5. **Initial Risk Assessments:** Initial drafts of risk assessments

   documenting the product/design use, potential risks, and associated mitigating actions. These assessments are documented within design, process and usability Failure Modes and Effects Analyses (FMEA's).

6. **Initial Traceability Matrix:** Initial drafts of spreadsheet

   developed by the Project Manager or Engineering linking the required documents throughout the project to the appropriate pre-requisite documents. At this stage, the spreadsheet should clearly illustrate which design outputs will satisfy specific design inputs.

1. **PHASE 3 – VALIDATION & VERIFICATION**

   In Phase 3 the project team plans and executes verification and validation activities to prepare for design transfer to manufacturing in Phase 4. The team verifies that the design outputs meet the design input requirements and validates the final design meets the user needs and intended use of the device. Devices that are intended to be used with other medical devices shall be verified while connected or interfaced. Design verification and validation shall be conducted on representative product including initial production units, batches, or their equivalents with documented rationale for the selection.

1. **Design and Usability Risk Assessments:** Team effort led by the

   Project Leader assessing and documenting the design and usability risks and associated mitigation actions. These activities are documents in FMEA's

2. **Sterilization and Shelf-Life Testing:** Engineering documentation

   of the verification of the product sterilization and shelf-life requirements. Sterilization is applicable only if the product is intended to be distributed sterile or able to be sterilized.

3. **Biocompatibility Testing:** Engineering documentation of the

   verification of the product biocompatibility requirements. Standards such as ISO 10993 provide industry accepted testing methodology.

4. **Software Validation:** Engineering documentation of the

verification of the software design and the validation methods utilized to validate that the software conforms to user needs and intended use. Applicable only if design incorporates software to achieve functional requirements. Standards such as IEC 62304 provide methodology.

5. **Product Safety and Efficacy Testing:** Engineering documentation of the execution of any product safety testing and/or certifications necessary for the release of the device, i.e. IEC 60601-1, IEC 60601-1-2, etc.

6. **Performance Validation:** Engineering documentation of the verification test methods that will be utilized to verify the performance of the new product design (i.e. precision, accuracy, interference, etc).

7. **Usability Validation:** Engineering documentation of the validation methods to be utilized to validate that the design is safe to be used by the intended parties and these parties can effectively use the device.

8. **Clinical Validation:** Engineering documentation of the validation that the design conforms to user needs and intended use. May include Clinical Performance Studies, Clinical Evaluation, Clinical Interference Studies, etc.

9. **Packaging Validation:** Engineering documentation of the validation that the packaging of the product is sufficient to preserve to product during handling, storage and distribution to user and maintain function necessary for intended use.

10. **Regulatory Submission:** Actual product submission document (i.e. 510(k), PMA, etc) developed by QA/RA for submission to the appropriate regulatory bodies.

1. **PHASE 4 – DESIGN TRANSFER TO MANUFACTURING (COMMERCIALIZATION)**

   In Phase 4 the project team validates that the design and process are correctly translated into production specifications, Item Masters, BOM's, Work Instructions and acceptance criteria for the characteristics essential to device functionality. This phase ensures, that the design is complete, and approved, for meeting the product's intended use, that the design is documented in the DMR, and is fully placed under change control with a design transfer ECO and completion of the following documents and activities:

1. **Training:** Operations documentation of the completion of training to all parties responsible for the manufacturing of the final release product. These include: manufacturing technicians/operators, quality inspectors, final labelers, etc.

1. **Process FMEA:** Team effort led by the Project Leader assessing and documenting the potential risks of the manufacturing process and associated mitigation activities.

1. **Process Verification & Validation Plans:** Engineering documentation defining the specific Process Installation, Operational, and Performance Qualification (IQ, OQ, and PQ) requirements for validating the manufacturing equipment and processes, including infrastructure and work environment, prior to release to Manufacturing. Final reports shall demonstrate that the process has met the pre-defined protocol requirements and produced product that meets pre-defined quality requirements.

2. **Requirements Traceability Matrix:** A spreadsheet developed by the Project Manager or Engineering linking the required documents throughout the project to the appropriate pre-requisite documents. This spreadsheet should clearly illustrate which outputs will satisfy specific input requirements.

3. **DMR & DHR:** Final development by the Project Manager of the Device Master Record (DMR) and Device History Record (DHR). The DMR documents all the validation activities, materials, inspections, processes, etc. that are required to development, manufacture, and release a medical device. The DHR documents the particular equipment, material(s), documentation, operator(s), etc. that produced a given medical device necessary to maintain traceability and evidence of acceptance.

4. **Regulatory Approval:** Document from the appropriate regulatory bodies providing clearance to market the product.

5. **Design Transfer ECO:** The Project Leader assembles all of the documents required for release to manufacturing into one ECO for approval (e.g. Item Masters, Drawings, BOM's Work Instructions).

1. **PHASE 5 – POST MARKET ASSESSMENT**

   This phase typically comes six to twelve months after product market launch and focuses on summarizing and analyzing feedback from the market, and manufacturing, to close the design and development

loop and determine if any revisions are required before moving this project formally out of the design and development process.

1. **Technical File:** Comprehensive technical file compiled by QA/RA for CE Marked products.
2. **Declaration of Conformity:** Statement from RA/QA declaring product conformity to the applicable standards and regulations.
3. **Production Status Report:** Document completed by Manufacturing outlining productivity, quality yield conformance to pre-established goals and identifying any open processing issues.
4. **Customer Feedback:** Summary review document completed by QA regarding customer issues and also any customer comments from Marketing.
5. **Risk Analysis Review:** Final documented review led by the Project Leader to assess overall product risk after six to twelve months in the field.
6. **Clinical Evaluation Review:** A documented review led by Project Leader to assess the impacts from the data obtained from the post market surveillance to the clinical evaluation and associated documentation.

1. **DESIGN CHANGES**
    1. The company shall identify, document, validate, or where appropriate verify, review, and approve design changes before their implementation.
    2. The process for design changes after exiting Phase 4 of Design Control is the ECO process. This process is specified in QP-0009 – Change Control Process.
2. **DESIGN HISTORY FILE (DHF)**
    1. The design history file for products or product families will contain all design activities/documents used to develop the product, accessories, major components, labeling, packaging, and production processes.
    2. A design history file will be established and maintained for each type of medical device or medical device family.
    3. The DHF shall contain or reference the records necessary to

demonstrate that the design was developed in accordance with the approved design plan and the requirements of the Quality System Regulation.

4. The results of a design review, including identification of the

   design, the date, and the individuals performing the review, shall be documented in the DHF.

5. Design verification and validation results, including

   identification of the design, method(s), the date, and the individual(s) performing the verification and/or validation, shall be documented in the DHF.

3. **CALCULATIONS**

   Statistical techniques that are appropriate for the project under development should be used during design and verification. Rationale for sampling plan selection must be documented.

1. **RECORDS**

   1. Project Plan Phase Checklist
   2. Design Review and Transfer Meeting Minutes
   3. Quality Plans for each Project
   4. Design Risk Management Reports (Risk Management File)
   5. Design Verification and Validation Reports
   6. Design Transfer to Manufacturing Records
   7. Design History File (DHF)

1. **Revision History**

Rev #	Doc #	Effective Date	CHO	Description of Change
01	QP-0002			Original Design Control Process