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| --- | --- |
| 1. Purpose | This procedure is intended to describe the design control process and define responsibilities by which new products are developed and design changes are completed. |
| 1. Scope | This document applies to all company product development practices and activities associated with the planning, design, development and transfer of new and modified products.  This document does not apply to investigational research and development prior to project funding and approval. |
| 1. External References | Associated references imply the most current version at the time of this document’s approval:   * 1. FDA, CDRH, “Design Control Guidance for Medical Device Manufacturers”   2. ISO 13485, Medical devices – Quality Management Systems – Requirements for regulatory purposes   3. MDD 93/42/EEC, European Medical Device Regulations concerning medical devices   4. IEC 62340, Medical Device Software – Software Life Cycle Process   5. ISO 14971, Medical Devices- Application of Risk management to medical devices |
| 1. Internal References | * 1. SOP-XXX, Document Controls   2. SOP-XXX, Purchasing Controls   3. WI-XXX, Engineering Change Order Work Instruction   4. WI-XXX, Verification and Validation Work Instruction   5. QS-XXX, Quality Systems Manual |
| 1. Key Terms | * 1. **Defined User Needs** – Qualitative requirements derived from market needs.   2. **Design and Development Plan (DDP)** – Documentation of goals and objectives of a project including identification of specific tasks, resources, responsibilities and project schedule.   3. **Design History File** – A compilation of records which describes the design history of a finished device   4. **Design Input** – Physical and performance requirements of a device that are used as a basis for device design   5. **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.   6. **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.   7. **Device master record (DMR)** – compilation of records containing the procedures and specifications for the finished device.   8. **Process Validation** – Establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.   9. **Validation** – confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.   10. **Verification** – Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. |
| 1. Roles and Responsibilities | * 1. Project Leader - creates design/ project plans and schedules regular project meetings (including Project Design and Phase Reviews) to facilitate the progress of the project activities in accordance with the project plan(s) and to implement the requirements during product development.   2. Project Team – Completes assigned development and design deliverables and ensures project requirements are adequately fulfilled. A typical project team includes:      1. Product Manager      2. Design Engineer      3. Manufacturing Engineer      4. Quality Engineer      5. Purchasing Lead      6. Operations Lead      7. Regulatory Affairs Lead |

1. Process Flow Chart

**Phase 1**

Planning

**Phase 2**

Design and Development

**Phase 3**

Verification and Validation

**Phase 4**

Design Transfer

Figure 1. Product Development Process Flow

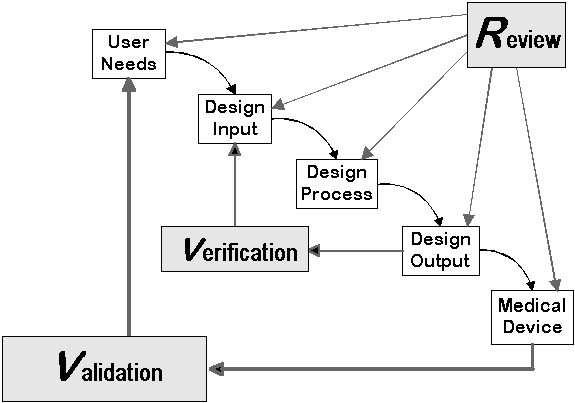


Figure 2. Cascading design control process as stated in FDA Design Control Guidance Document.

1. Procedure
   1. General Principles

Product development should, in principle, follow the waterfall model as seen in Figure 2. The waterfall model is an ideal model that applies, in practice, to the development of medical devices.

The company implements Design Controls through the Design and Development process as defined in this SOP. The different requirements of Design Controls are implemented in Phases as discussed in this procedure.

* 1. Phase Overview

Design Controls at the company is executed in four major phases:

|  |  |  |
| --- | --- | --- |
| **Phase** | **Phase Title** | **Phase Objectives** |
| I | Planning and Definition | * To identify the Project Manager and Project Team * To establish defined user needs * Translate the defined user needs into design inputs * Develop a Design Development Plan (DDP) * Develop a Risk Management Plan (RMP) * Establish initial draft of the Hazards Analysis (HA) * Establish a System Architecture Specification (SAS) * Initiate the Design History File (DHF) and Device Master Record (DMR) * Identify regulatory requirements and strategy for clearance/ approval |
| II | Design and Development | * Translate the Design Inputs into detailed requirements specifications including Software Requirements Specifications, Hardware Requirements Specifications, etc. * Implement the Design Development Plan (DDP) including separate functional plans * Complete Risk Management activities per the RMP including the identification and implementation of risk controls/ mitigations. |
| III | Verification and Validation | * Complete design verification to verify that design outputs meet design inputs. * Complete design validation to confirm that device specifications conform with user needs and intended uses. * Complete verification of Risk Management activities * Complete process verification of manufacturing and test processes. * Complete regulatory submissions once supporting deliverables are completed. |
| IV | Design Transfer | * Complete transfer of the design into production and service. * Ensure all training materials and labeling are released and ready for market. * Build product inventory. * Obtain necessary regulatory approvals or clearances. * Launch product – this may include a phased approach staring with a Limited Launch to obtain early market feedback from users. |

* 1. Phase Reviews

A phase review shall be conducted at the completion of each phase. Each review shall end with a summary of action items that are required to be completed before phase sign-off. Once the approvals are obtained, the Phase Review minutes shall be submitted to Document Control.

Phase reviews should also be used to review open action items from the prior and current phase of the project. Minutes of phase review meetings should be recorded. Results and corrective actions along with otherwise relevant documents are to be placed in the DHF behind the associated phase approval document. This collection of documents demonstrates that the design was developed in accordance with this procedure and applicable regulations and standards.

* 1. Phase 1 - Planning

All new products shall start with Phase 1 to identify a plan for product development. Deliverables for Phase 1 shall include:

1. Design Development Plan
2. Defined User Needs Document
3. Design Input/Product Requirements Document
4. Risk Management Plan
5. Regulatory Strategy Plan
6. Software Documentation
   * 1. Design and Development Plan

The Project Leader shall create a design and development plan at the start of the project. The plan, includes documentation of the goals and objectives of the project, identification of tasks, resources, individual and organizational responsibilities, a schedule to demonstrate conformance to time constraints, identification of major reviews and decision points, and approvals as a project evolves. The plan specifically shall identify which of the major tasks defined in this SOP will be executed as part of the project at hand.

* + 1. Defined User Needs

This is an analysis of the different needs of the product that will be translated into Design Inputs. Different studies may be performed based on the complexity of the project including patent screening, product benchmarking, concept reviews, and/or an analysis of similar prior projects.

* + 1. Design Inputs

Evaluate the defined user needs and translate them into quantifiable design inputs that can be used for Phase 2, Design and Development and Phase 3, Verification and Validation. To create design inputs, evaluate the defined user needs, software development plan and software requirement specifications if device contains software.

* + 1. Risk Management Activities

Risk Management begins in Phase I and shall continue throughout the lifecycle of the product. The Phase I Risk Management deliverable is met by completing a Risk Management Plan and an initial revision of the Hazard Analysis table.

* + 1. Software Requirements

For devices containing software, the company shall follow IEC 62340, Medical device software development, which includes developing:

* + - 1. System Architecture Specification
      2. Software Detailed Design Document
      3. Software Development Plan (SDP may be included in the overall Design Development Plan)
      4. Software Requirement Specifications
      5. Off-the-Shelf Risk Assessment
      6. Software Architecture Document
  1. Phase 2 – Design and Development

R&D activities and main design effort shall be completed in Phase 2 of the Product Development Cycle. Deliverables for Phase 2 include:

1. A review of all Phase 1 deliverables and action items
2. Device Master Record
3. Labeling Review
4. Hazard Analysis
5. Clinical Trial Activities
6. Test protocols for the following verification and validation activities:
   1. Functionality
   2. Reliability
   3. Sterility
   4. Biocompatibility
   5. Cleanability and Disinfection
   6. Latex
   7. Electrical Safety
   8. EMC
   9. Software Validation
   10. Packaging Validation
   11. System Compatibility
   12. Process Validation
       1. Device Master Record

Device Master Record review is conducted to ensure that the Product is completely defined. This requirement is completed when an approved table of released part numbers (ex: BOM) is provided for the packaging drawing, final assembly drawing, sub-assembly drawing(s), component drawing(s), software part(s), labeling drawing(s), manufacturing procedure(s), inspection procedure(s), packaging procedure(s), and the Device History Record (DHR).

* + 1. Labeling

Labeling review is conducted to ensure that the claims, instructions, and product identification contained in all printed material accompanying the device and used to market the device is complete, accurate, and conforms to any relevant standards. Labeling review may be performed in two stages, the first for all English based labels and the second when the translated labels are reviewed for completeness.

* + 1. Hazard Analysis

Intended for the evaluation of risk control options regarding the overall product design for hazards and potential harms, and to review plans on how these are mitigated or reduced in the design. Refer to ISO 14971 for Risk Management techniques.

* + 1. Functionality

Functionality (Performance Characteristics) testing is performed to demonstrate that the derived engineering specifications of a product, such as physical dimension, physical configuration, limits of mechanical power, range of motion, controls, limits of electrical power, electronic performance, optical performance and fluid properties meet their requirements.

* + 1. Reliability

Reliability is demonstration that an item will perform a required function under stated conditions for a stated period of time (typically, at least the labeled warranty period).

* + 1. Sterility

The sterility of a device is defined in terms of a Sterility Assurance Level (SAL), a measure of the likelihood that a unit or article will remain contaminated when processed under specified conditions. A device is considered sterile when the SAL is demonstrated to be 10-6: this indicates that the device has a one in a million chance of having a viable microorganism on it after sterilization..

For reusable products, sterilization validation of the product when sterilized by itself and when sterilized in the desired sterilization tray shall be established or a rationale provided if not established.

* + 1. Cleanability and Disinfection

Cleaning is the removal, usually with detergent and water, of adherent visible soil from the surfaces, crevices, joints, and lumens of a device and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination. The adequacy of a sterilization cycle for a reusable instrument is predicated on its cleanability.

Disinfection is the destruction of most recognized pathogenic and other microorganisms by physical or chemical means. While it does destroy pathogenic microorganisms, it does not necessarily destroy all microbial forms (e.g. bacterial spores). Disinfection processes do not ensure the margin of safety associated with sterilization processes.

* + 1. Biocompatibility

The biological responses of the materials selected for use in medical devices are tested to ensure the device will be suitable for Intended Use.

* + 1. Latex

Latex is a known “Sensitizer” in that a certain percentage of patients and users react negatively (including death) to the natural rubber proteins. The device design must therefore be reviewed to ensure that no part of the device containing latex or natural rubber comes into direct contact or fluid pathway contact with the patient. This requirement is satisfied through supplier documentation attesting to the composition of any questionable component of the device. Should latex or rubber be required in the device or packaging design, consultation with Regulatory Affairs is necessary to prepare the required labeling.

* + 1. Electrical Safety

Electrical safety is achieved when the patient or user is protected from the various effects of the use of electrical power in medical electrical equipment (including: electrical shock, leakage current, thermal effects, ignition of flammable gas, etc.).

* + 1. EMC

Electromagnetic compatibility is the ability of medical electrical equipment and/or systems to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to anything in that environment.

* + 1. Software Validation

Software VALIDATION is the sum of all activity documenting the successful completion of the Software Design Life Cycle (SDLC). The primary goal of software validation is a demonstration that the completed software end product complies with established software system requirements. Software validation must take into consideration the entire life cycle of the software/firmware; the depth of challenge (i.e. normal and abnormal use) should be commensurate with the risk inherent in product use.

* + 1. Packaging Validation

Packaging validation demonstrates that a product will remain usable following the challenges of transportation and storage. Products intended to be delivered to the user in a sterile condition require expiration date testing and sterility durability testing in conjunction with packaging validation. This requirement is satisfied through the approval of test results under an approved protocol.

* + 1. System Compatibility

System testing will be conducted with the associated devices that will be used in conjunction with the intended device.

* 1. Phase 3, Verification and Validation

Design verification or testing is conducted according to the specifications of standards or internally approved protocols in order to demonstrate that design input requirements have been met to the extent required by standards or internally approved protocols. It is normally planned after a design freeze takes place.

Statistical methods (21 CFR Part 820.250) and Good Laboratory Practice (GLP) (21 CFR Part 58) shall be applied as necessary. Every test shall have an approved written protocol that clearly defines the objective and all methods prior to conducting tests. Test conclusions shall be verified by the individuals performing testing. Test reports shall include all data or a reference to the data produced regardless of its support for or detraction from the goal of the test.

Design and process validation ensures that device performance conforms to the defined user needs and intended use. Design and process validation must be performed on devices built according to released manufacturing procedures and inspected according to released quality procedures. Simulated use testing should be commensurate with the risk involved from actual use of the product. Similar testing, such as Design and process verification, can be used to ensure all aspects of product development are considered. Design validation encompasses verification and extends the assessment to address whether devices produced in accordance with the design actually satisfy user needs and intended uses. Design validation should also consider usability issues. Usability is demonstration that the device meets the user’s needs and is useable by the different categories of users identified in the protocol.

Deliverables for Phase 3, Verification and Validation include:

1. Review of all Phase 2 deliverables for updates
2. Test reports for all verification and validation activities
3. Risk Management activities
4. Development of Manufacturing Process Instructions
5. Regulatory submissions
   * 1. Risk Management Activities

Risk Management activities include a review and update to the Hazard Analysis and the completion of a Risk Management Report per ISO 14971.

* + 1. Regulatory Submission

A regulatory decision must be made concerning the proper clearance or approvals from FDA, Notified Bodies or other governmental agencies to distribute the product under development. A submission through Regulatory Affairs may be required, or a letter documenting a non-filing decision must be obtained, signed by the Regulatory Head. Consultation with Regulatory Affairs must be made as early as feasible in the project to avoid delays. This requirement is satisfied by the submission of a 510(k) or a memorandum confirming the non-filing decision. It is not always possible to make an accurate decision on appropriateness of non-filing decisions until the product V&V is complete to ensure accuracy of the decision.

* + 1. Test Reports

All verification and validation activities must be documented via an approved protocol and test report

* 1. Phase 4 – Design Transfer

Design Transfer is the collective set of activities conducted to transfer the product from R&D to manufacturing. The transfer activities ensure that the functional specifications of the device are properly transferred into productions specifications. The activities confirm that the device manufacturing process is repeatable and produces units that are safe and effective for its intended use. The design of the production process should be largely concurrent with the design of the product.

Deliverables for Phase 4 include:

1. Review of all Phase 3 deliverables for updates
2. Manufacturing Process Instructions (MPIs)
3. Risk Management Report
4. Risk Management File
5. Process Validation Report
6. Device Master Record
7. Design History File
8. Service Plan and Implementation
9. Technical File and Notified Body Submission
10. Usability File
11. Supplier Qualifications
12. Final Cost Roll
13. Final Product Release
    * 1. Manufacturing Process Instructions and Process Validation

MPIs must be developed and approved prior to product release. Process Validation establishes that the production process consistently produces a Product meeting its predetermined specification. Acceptance requirements, such as process capability targets, are defined in advance in a process validation protocol. Corrective actions are identified and closed through changes to component or assembly drawings, product specifications, inspection procedures, and/or manufacturing procedures are made as necessary. Process validation is confirmed when a test report, documenting process performance against evaluation criteria and corrective action, is approved.

* + 1. Risk Management

Phase 4 Risk Management deliverable is met by creating a Risk Management Report and File per ISO 14971. This is intended to confirm that the collective verification and validation efforts have resulted in acceptable Overall Residual Risk for the product and that Essential Outputs have been identified and communicated through Design Output documentation.

* + 1. Technical File and Notified Body Submission

The Technical File is a collection of documentation (including an MDD checklist of essential requirements and risk analysis) required by the Medical Device Directive (MDD) for CE mark declaration. The Technical File is applicable to MDD 93/42/EEC class I, IIa and IIb devices while the Technical Dossier is applicable to MDD 93/42/EEC class III devices only. Both documents reference test reports and include clinical evaluation.

A completed MDD checklist and a copy of the signed Product Description Form (PDF) are added to the technical file.

If required, the Technical File is submitted to the notified body for review.

If the product per MDD 93/42/EEC is Class I, or is Class IIa or IIb and does not require a notified body submission, the Technical File must be completed with at least English-based labels. This will ensure that the product can be CE marked for English speaking countries.

* + 1. Serviceability

A serviceability review is conducted to ensure prerequisites for proper servicing of the product have been addressed prior to release of the parent product. A review of serviceability requirements should be completed by Phase 4.

* + 1. Usability Engineering File

The Usability Engineering File documents records and traceability of the usability engineering process of the respective medical device or accessories. The Usability Engineering File is applicable to all medical devices or accessories classified by MDD 93/42/EEC with the 2007/47/EC amendment. The Usability Engineering File is an additional tool to ensure the development of safer, more effective and easier to use medical devices through the analysis or review of human behavior, abilities, limitations, and other characteristics related to the design of medical devices or systems. The Usability Engineering File is a living document that is applicable to all phases of development and post market surveillances.

* + 1. Supplier Qualifications

Supplier review is conducted to ensure that all components used in product assembly originate from approved suppliers who maintain a satisfactory supplier rating. Additionally, whether or not purchasing agreements should be created or renegotiated due to increased volumes should be evaluated. These activities usually begin in Phase I with the identification of potential suppliers.

* + 1. Final Cost Roll

This requirement is satisfied when the final cost roll and list price are entered into the ERP system, and confirmed when accounting and customer approves.

* + 1. Design History File

The Design History File provides a central repository for project-orientated documentation, especially the Design Inputs and Design Outputs, as specified in this procedure. For the purposes of this document, the Design History File is defined with the limited scope that follows:

All documentation necessary to demonstrate that the design was developed in accordance with this procedure, the approved DDP including separate functional plans and the requirements of the Quality System Regulation (QSR) and ISO 13485. This includes records of all Phase and Design Reviews. The Project Manager will ensure that Action Items have been resolved, necessary corrective actions are taking place and that records are complete.

The Design History File resides with and is maintained by the Project Manager until Market Release. At Market Release ownership of the DHF is transferred to Quality for the DHF Audit and maintenance. A final audit of the DHF will be completed within 30 days of product release, if not already completed.

1. Design Changes

Design changes are tracked on materials/components and product specifications. During the course of the New Product Design effort many changes can occur. Design changes are documented through the Engineering Change Order (ECO) system. The initial product development cycle, typically do not require significant change to product requirements or result in new risks. The ECO process provides an efficient Review and Approval process and can be leveraged to communicate status across the Team.

Near the end of the Development phase these design changes can impact Hazard Analysis, proposed Verification & Validation studies and subsequent Test Method Development. Product changes to a released device design/process may adversely affect device safety or performance and require adequate impact assessments to ensure coverage in these design control systems. The Product Development Team shall review all proposed changes with safety and efficacy of the product in mind. This impact on the design, any completed or in-process design verification testing, and any product already built shall be documented in the ECO process.

Adequate justification of design changes Post- Product Launch (On-Market) must be included as part of the ECO process. The ECO signatories for these changes are responsible for ensuring that changes are appropriately justified, risk analysis is completed and that any necessary test protocols, quantification studies, validations and design reviews are performed prior to implementation. All changes are reviewed for impact on the design, safety, and any required testing for the device.