Medical Device Design Control

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Design controls

- Set of quality practices and procedures incorporated into the design and development process
- Control the design process (premarket and postmarket) to assure that the device meets
  - User needs
  - Intended uses
  - Specified requirements
- Can improve and prevent future issues

When to Start?

- Where research ends and design begins
- After Feasibility/“Proof of Concept”
- When planning to bring device to market
- Premarket
- Prior to commencement of any Clinical Investigation
- Mechanism of change/revision during any Clinical Investigation

Design Control

- Design & Development Planning
- Design input
- Design output
- Design review
- Design verification
- Design validation
- Design transfer
- Design changes
- Design history file

Design planning

- **Establish, maintain and document**
- Describe or reference design and development activities
- Identify, describe, and define interfaces, responsibilities, and functions/activities impacting device design
- Review, document, approve, and update as development and changes evolve

Design Input

- Design inputs are the physical and performance characteristics of a device that are used as a basis for device design
- Establish and maintain procedures
  - Ensure requirements are appropriate by addressing user needs and intended use(s) in terms that are measurable.
  - Address incomplete, ambiguous, or conflicting requirements.
  - Document, review, and approve input requirements.

Design inputs

- Functional, performance, usability and safety requirements, according to the intended use
- Applicable regulatory requirements and standards
- Applicable output(s) of risk management;
- Information derived from previous similar designs
- Other requirements essential for design and development of the product and processes

Sources of design input

- Customers, focus groups
- Regulatory requirements, Standards, Guidance
- Competitors' products
- Preliminary Risk Assessment activities
- Failure Investigations of Complaints, MDRs, CAPAs, Recalls
- Marketing and Clinical studies and surveys, sales feedback

Design Input

- User Needs
  - what & why stated in user terms
- Marketing Requirements
  - measurable, engineering terms

Examples of Design Input

- Device functions , physical characteristics
- Performance, safety, reliability
- Human factors
- Labeling & packaging
- Maintenance
- Sterilization
- Compatibility with other devices
- Environmental limits
- Regulatory requirements

Requirements to Top-Level Specifications

- Traceability
  - Traceability from requirements to specifications to design verification and validation tests and test results is essential for good failure investigations
  - Traceability should be started during design input and updated as the design progress through remaining phases
  - Traceability should include Requirements, Specifications and Hazard Mitigations

Design Output

- Results of a design effort at each design phase and at the end of the design effort.
- Establish and maintain procedures for Design Output
  - Define and document design output to allow an adequate evaluation of conformance to design input
  - Reference definable/measurable acceptance criteria
  - Identify design outputs essential for the proper functioning of the device.
  - Review, approve, and document design output before release

Design outputs

- meet the input requirements for design and development;
- provide appropriate information for purchasing, production and service provision;
- contain or reference product acceptance criteria
- specify the characteristics of the product that are essential for its safe and proper use.
- outputs shall be
  - in a form suitable for verification against the design inputs
  - shall be approved prior to release
- *finished design output is the basis for Device Master Record* (DMR).
- *total finished design output consists of the device, its* packaging, labeling, and DMR

Design review

- Systematic reviews shall be performed in accordance with planned and documented arrangements to
  - evaluate *adequacy of the design requirements*
  - evaluate the ability of results of design to meet requirements
  - Identify any *problems*
  - identify and propose necessary actions
- Participants in such reviews shall include
  - representatives of functions concerned with the design stage being reviewed
  - other specialist personnel.
- Records of the results of the reviews and any necessary actions shall be maintained in Design History File (DHF) and include
  - identification of the design under review
  - the participants involved and the date of the review

Design verification

- Design verification is confirmation by objective evidence that design output meets design input
- Verification plans include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.
- Verify together with accessories
- Establish and maintain procedures
  - Confirm through measurable means (e.g., test reports, etc.).
  - Review, approve and document in DHF

Design validation

- Design Validation establishes by objective evidence that specifications (specified requirements) conform with user needs and intended use(s).
- Performed in accordance with planned and documented validation plans include
  - methods, acceptance criteria
  - statistical techniques with rationale for sample size
- Establish and maintain procedures for Design Validation
  - Under defined operating conditions
  - On initial production units, lots, or batches (or their equivalents)
  - Under actual or simulated use conditions
- Conducted on representative product
  - Representative product includes initial production units, batches or their equivalents
  - The rationale for the choice of product used for validation shall be recorded.

Design validation

- Perform clinical evaluations or performance evaluations in accordance with applicable regulatory requirements
- A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer
- Validate together with accessories
- Validation shall be completed prior to release for use of the product to the customer.
- Records of the results and conclusion of validation and necessary actions shall be maintained

Verification/Validation and CAPA

- The results of verification and validation tests should be available for use to address issues raised via the CAPA system
- Traceability from requirements to specifications to verification tests and test results are helpful in identifying true design flaws versus misuse or identification of an unknown failure mode

Design - Verification vs. Validation

- **Design Verification**
  - **Output meets Input**
  - "I made the product right."

- **Design Validation**
  - **Specifications meet user needs and intended use(s)**
  - "I made the right product."

Design transfer

- Establish and maintain procedures to ensure correct Design Transfer into production specifications.
  - Is the Design accurately transferred to Production?
  - A final stage of development is frequently done to ensure all outputs are adequately transferred

Design transfer

- document procedures for transfer of design and development outputs to manufacturing
- procedures shall ensure
  - design outputs are verified as suitable for manufacturing before becoming final production specifications
  - production capability can meet product requirements.

Design Transfer Documents

- Process FMEA Report
- Process Design of Experiments
- Process Validation Protocol
- Process Validation Test Report

Design Transfer Method

- Process Flow
- Process Map
- Production Line Set-Up (with space, equipment and location defined)
- Process Hazard Analysis
- Process FMEA
- Review and Conformance to Design FMEA

Design Transfer: Essential Elements

- Product Risk documentation shows what failure modes, components, parts, etc. should be monitored and trended.
- Identification of essential elements further identifies what needs to be monitored and trended
- Design and Process Validations indicate critical control points for manufacturing and design

Design Changes

- Establish and maintain procedures for
  - identification, documentation, validation or where appropriate verification, review
  - approval of design changes before their implementation
- Depending on the scope and impact of the change, the change may require a new Premarket Submission with NB involvement, Supplement, or Study

Control of design changes

- Document procedures to control design changes
- Determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.
- Design changes shall be identified. Before implementation, the changes shall be
  - reviewed
  - verified
  - validated, as appropriate
  - approved
- Review of design changes shall include
  - evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management
  - product realization processes

Control of design changes

- Changes made to correct or compensate for faults found during any testing should follow the same procedures and controls as for any other change
- This data should be made readily available for assessing CAPA issues
- Changes will be assessed to determine the extent of validation or verification requirements
- All changes shall be documented, controlled and where applicable be linked or referenced in the DHF

Changes - Tasks

- Problem identification, evaluation and resolution tracking
- Determine impact to appropriate documents (e.g., Requirements, Preliminary Risk Assessment, FMEA, etc.)
- Impact assessment and testing to determine change impact to the whole design
- Testing to evaluate correctness of the implemented change
- Re-verification and re-validation of the device or device components after changes are implemented
- Documentation update

Design History files

- Maintain a design file for each medical device type or medical device family from beginning to end
- The DHF contains the documentation necessary to assure changes to design or process for manufacture of the device
  - do not adversely impact the device design
  - lead to improvement in design and process
- Include or reference records
  - demonstrate conformity to requirements for design
  - demonstrate that the design was developed in accordance with the Design Plan and Quality System requirements
  - design changes

Design History File

- Becomes a mixture of living documentation and historical records
- Living documents for the device family
  - Describe the current state of the device
  - Examples are requirements, specifications, risk, documentation and traceability.
  - Updated in whole when a change occurs (i.e. new revision)