Design Controls

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Overview

I. Introduction to Design Controls

II. Requirements for Design Controls

1. Design planning
2. Design input and output
3. Design verification and validation
4. Design review
5. Design changes
6. Design transfer
7. Design history file

III. Resources and FDA contacts

I. Introduction to Design Controls

Design Controls – What are they?

- A set of quality control practices and procedures incorporated into the design and development process

- Control the design process to assure that device specifications meet:
  - User needs
  - Intended use

Design Controls – Why?

- **44%** of voluntary recalls from October 1983 through September 1989 - may have been prevented by adequate design controls.

  Sources: ‘‘Device Recalls: A Study of Quality Problems’’ (see 55 FR 21108, May 22, 1990)

- **90%** of all software related device failures from 1983 through 1989 were due to design related error.

  Source: “FDA Medical Device Regulation from Premarket Review to Recall” (FDA/HHS OEI 09-90-0040, February 1991)

Design Controls- Regulatory History

- **Safe Medical Device Act of 1990** authorized FDA to add **Design Controls** to the current Good Manufacturing Practice (cGMP) requirements for devices.

- The QS Regulation became effective on **June 1, 1997**, *replacing* the 1978 GMP for medical devices.

- Preamble to the QS regulation: extremely important for *understanding* Design Controls.

Quality Systems - Key Definitions

- **Design History File (DHF)** - compilation of records which describes the ***design history*** of a finished device.
- **Device Master Record (DMR)** - compilation of records containing the ***procedures*** and ***specifications*** for a finished device.
- **Device History Record (DHR)** - compilation of records containing the ***production history*** of a finished device.

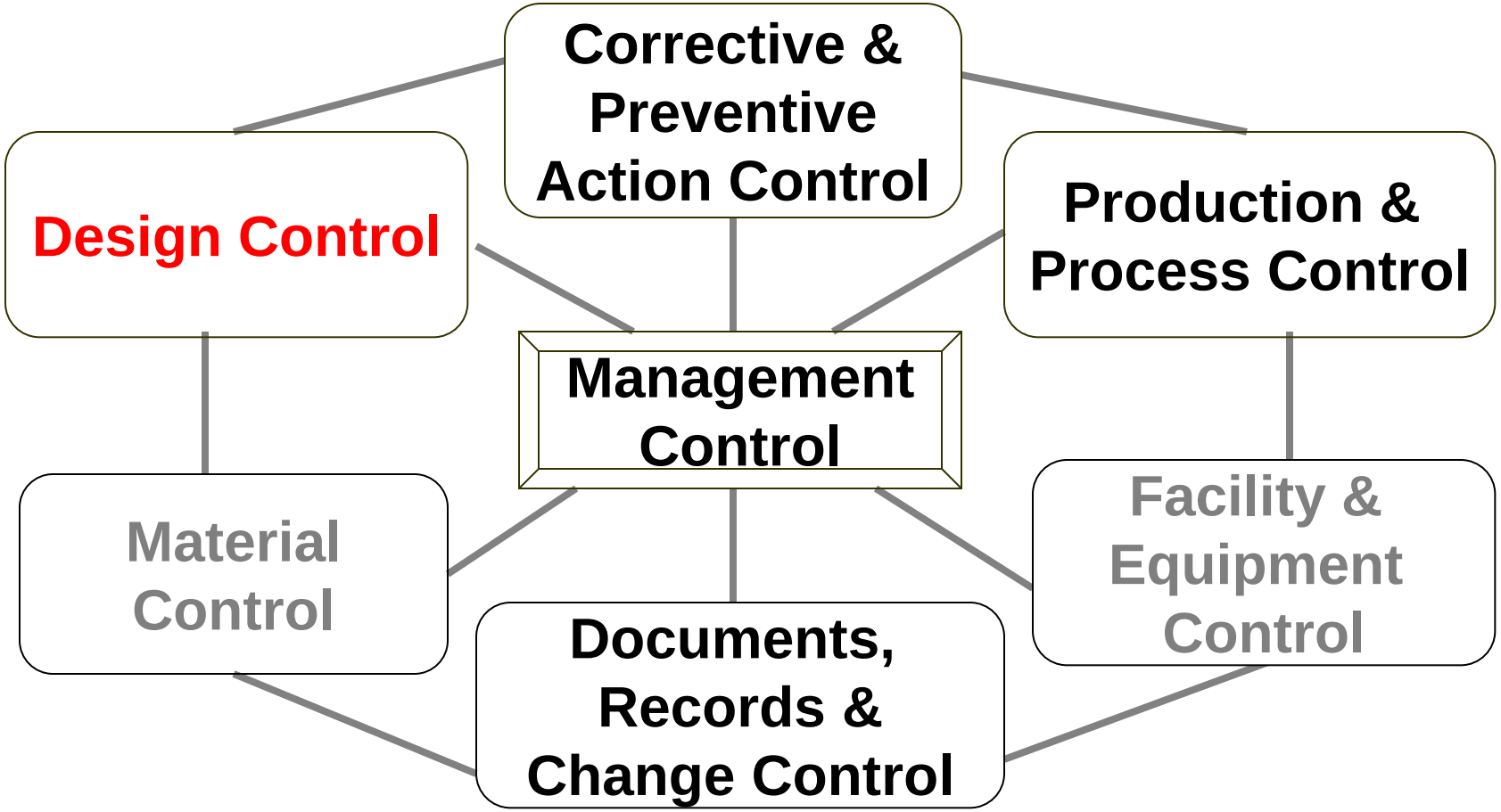
Design Controls – Scope

- Design controls apply to:
  - *All* **Class II** and **Class III** devices
  - The following **Class I** devices:
    1. Devices automated with computer software
    2. Tracheobronchial suction catheters
    3. Surgeon's gloves
    4. Protective restraints
    5. Manual radionuclide applicator system
    6. Radionuclide teletherapy source

Design Controls

- Design control is a Key Subsystem of Quality System
- Quality System (QS) Regulations: 21CFR 820
  - Management controls
  - **Design controls**
  - Production and process controls
  - Corrective and preventive actions
  - Documents, Records, & Change Control
  - Material Control
  - Facility & Equipment Control

7 Subsystems of the Quality System



Design Controls (21 CFR 820.30)

a) General requirements
b) Design and development planning
c) Design input
d) Design output
e) Design review
f) Design verification
g) Design validation
h) Design changes
i) Design transfer
j) Design history file

II. Requirements for Design Controls

General Requirements

21CFR 820.30(**a**)

Design Controls – General

- Establish procedures to control device design:
  - Define
  - Document
  - Implement
- Maintain procedures to control device design:
  - Review
  - Approve
  - Update

Design and Development Planning

21CFR 820.30(**b**)

Design & Development Planning

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

Design Input

21CFR 820.30(**c**)

Definition

- ***Design input*** means the physical and performance *characteristics* of a device that are used as a *basis* for device design.

Design Input

- Establish and maintain procedures for ***design input***:
  - Ensure requirements are *appropriate* by addressing user needs and intended use in terms of measurable
  - Address incomplete, ambiguous, or conflicting requirements
  - Document, review, and approve input requirements

Sources of Design Input

- Standards
- Focus groups
- Customers
- MDRs
- CAPA
- Service reports
- Complaints
- Marketing surveys
- Sales feedback
- Competitors' products

Including input from earlier/previous versions of a device

Examples of Design Input

- Device functions
- Physical characteristics
- Performance
- Safety
- Reliability
- Standards
- Regulatory requirements
- Human factors
- Labeling & packaging
- Maintenance
- Sterilization
- Compatibility with other devices
- Environmental limits

Example

Infusion Pump

- Infusion pump stops operating when high-voltage medical devices are operating in the vicinity.

Example – Questions to Consider

- What are the user needs?
- In what environment is the infusion pump supposed to function?
- What other kinds of equipment will it be used with?
- What kinds of design input are needed to avoid this problem?

Example - Infusion Pump

User Need

Pump must be capable of functioning in an electromagnetic environment (e.g., hospital).

Design Input

Pump must function uninterrupted when used with other products that generate an electromagnetic field.

Design Output

21CFR 820.30(**d**)

Definition

- ***Design output*** means the *results* of a design effort at each design phase and at the end of the total design effort.

Design Output

- Establish and maintain procedures for ***design output***
  - Define and document design output in terms that allow an *adequate evaluation* of conformance to *design input*
  - Reference ***acceptance criteria*** (i.e., criteria that are definable, and measurable)
  - Identify design outputs essential for the proper functioning of the device
  - Review and approve design output before release.

In other words...

- ***Design outputs*** are the *design specifications* which must meet design input requirements, as confirmed during design **Verification** and **Validation** and ensured during design **Review** (more later).

Input ⇨ Output

Design Output

- Design Outputs are included in premarket submissions as **Device Specifications**.
- The *finished* design output is the basis for the **Device Master Record (DMR)**.
- The *total finished* design output consists of the device, its packaging, labeling, and the Device Master Record (DMR).

Example - Infusion Pump

User Need

Pump must be capable of functioning in an electromagnetic environment (e.g., hospital).

Design Input

Pump must function uninterrupted when used with other products that generate an electromagnetic field.

Design Output

- Circuit board with filtering or buffering circuit
- Pump EMI shield
- Software with signal filtering and error handling/correcting code

Design Review

21CFR 820.30(**e**)

Design Review

- ***Design Review*** means a documented, comprehensive, systematic examination to:
  - Evaluate *adequacy* of the design requirements.
  - Evaluate *capability* of the design to meet requirements.
  - Identify any *problems.*

Design Review

- Establish and maintain procedures
- Plan and conduct formal documented ***Design Reviews*** of design results at appropriate stages
- Include at each design review:
  - Representatives of all functions concerned and specialists as needed.
  - Individual(s) without **direct responsibility** for the stage being reviewed.

Design Review

- Document results of design review in **Design History File (DHF)**, including:
  - Identification of design
  - Date
  - Individuals performing review

Design Verification

21CFR 820.30(**f**)

Definition

- ***Verification*** means *confirmation* by examination and provision of *objective evidence* that output meets input requirements.

Input = Output

Design Verification

- Establish and maintain procedures for ***Design Verification***:
  - Confirm through measurable means (e.g., test reports, etc.).
  - Review, approve and document in Design History File (DHF).

Design Verification

- Many test reports associated with Design Verification are included in premarket submissions:
  - 510(k)s
  - de novos
  - Premarket Approval Applications (PMAs)
  - Investigational Device Exemptions (IDEs)

Example - Infusion Pump

User Need

Pump must function in an operating room environment.

Design Input

Pump must function uninterrupted when used with other products that generate an electromagnetic field.

Design Output

- PCB with filtering circuit
- Pump EMI shield
- Software signal filtering code and error handling code

Design Review

Design Verification

- Simulated EMI testing on hardware and software
- Dimensional verification of shield
- Verification of system error handling due to EMI

Design Validation

21CFR 820.30(**g**)

Definition

- ***Design Validation*** means establishing by *objective evidence* that specifications(*specified requirements)* conform with *user needs* and *intended use(s)*.

Specifications= user needs

intended use(s)

Design Validation

- 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

Design Validation

- Perform *software validation* and *risk analysis*, where appropriate.
- Review, approve, and document in Design History File.

Verification vs. Validation

- **Design Verification**
  - Output meets Input
  - “Did I make the product right?”

- **Design Validation**
  - Specifications meets user needs and intended use(s)
  - “Did I make the right product?”

Design Validation

- The results of Design Validation are typically submitted in premarket submissions

- **Examples:**
  - Animal study protocols/reports
  - Cadaver study protocols/reports
  - Clinical study protocols/reports

Example - Infusion Pump

User Need

Pump must function in an operating room environment.

Design Input

Pump must function uninterrupted when used with other products that generate an electromagnetic field.

Design Output

- PCB with filtering circuit
- Pump EMI shield
- Software signal filtering code and error handling code

Design Review

Design Verification

- Simulated EMI testing on hardware and software
- Dimensional verification of shield
- Verification of system error handling due to EMI

Design Validation

- EMC testing to industry standards
- Simulated EMI testing in high EMI environment
- *Risk Analysis* concerning EMI
- *Software validation* for filtering code

Frequent Warning Letter Example

Failure to establish and maintain adequate procedures for ***Validating*** the device design and ***Risk Analysis***, where appropriate, as required by 21 CFR 820.30(g)

For example: The Design History Files for XXX did not include documentation that the device had ever been validated before production and marketing. When requested, the firm was unable to provide documentation that validation and risk analysis had been performed.

Design Transfer

21CFR 812.30(**h**)

Design Transfer

- Establish and maintain procedures to ensure correct ***Design Transfer*** into production specifications
- Is the Design accurately transferred to Production?
- Although ***Design Transfer*** happens throughout, there frequently is a *final stage* of development intended to ensure all outputs are adequately transferred.

Design Changes

21CFR 820.30(i)

Design Changes

- Establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of ***Design Changes*** *before* their implementation.
- Is there a system in place to enact *future* changes?
- Often overlooked, but of critically importance.
- How can you improve your product if you have no system for change?

Design Changes

- Depending on the scope and impact of the change, the change may require:
  - A new 510(k)
  - A new PMA, a PMA supplement, or a PMA 30-Day Notice
  - A new IDE or an IDE supplement
- Changes must be communicated to FDA if the device is under premarket review or IDE review

Design History File

21CFR 820.30(j)

Definition

- ***Design History File (DHF)*** means a compilation of records which describes the design history of a finished device.
- It is a *summation* record of all Design actions, from *start* to *transfer*, including *changes*.

Design History File

- Establish and maintain a design history file for each type of device
- Include in the DHF or reference records information necessary to demonstrate that the design was developed in accordance with the **Design Plan** and Quality Systems requirements

Design Controls - Summary

- Like the Quality Systems regulations themselves, Design Control should be viewed and understood as a ***system*** – a subsystem within the main System.

Design Controls - Summary

- **Processes** –A set of quality control practices and procedures incorporated into the design and development process

- **Goal** - Control the design process to assure that device specifications meet:
  - User needs
  - Intended use

III. Resources and FDA Contacts

- **CDRH Learn**

  Training videos focusing on overview, premarket, registration/listing, and post-market topics

  http://www.fda.gov/Training/CDRHLearn/default.htm

- **Device Advice**

  Website accompaniment to CDRH Learn

  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

QS Regulation and Guidance (General)

- **Quality System Regulation and Preamble**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm

- **Design Control Guidance For Medical Device Manufacturers**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm

- **Do it By Design – An Introduction to Human Factors in Medical Devices**
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095061.pdf

- **Guidance for Industry and FDA Premarket and Design Control Reviewers – Medical Device Use – Safety: Incorporating Human Factors Engineering into Risk Management**
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM094461.pdf

- **(DRAFT) Applying Human Factors and Usability Engineering to Optimize Medical Device Design**
  http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm259748.htm

QS Regulation and Guidance

- **Guidance for Industry: Part 11, Electronic Records; Electronic Signatures - Scope and Application**
  http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm

- **General Principles of Software Validation**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

- **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm

- **Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073778.htm

- **Guidance: Mobile Medical Applications**
  http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm263366.pdf

Need More Information?

Division of Industry and Consumer Education (DICE)
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm

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