Design Controls

FDA Small Business
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Learning Objectives

- Understand the ***context*** of Design Controls within the Quality Systems

- Understand how effective ***use*** can contribute to quality and safety, thereby reducing cost

- Understand the ***mechanisms*** and continual role of Design Controls in device development (both Premarket and Postmarket)

Design Controls – What are they?

- A set/framework of quality practices and procedures incorporated into the design and development process.

- Control the design process – Premarket and Postmarket - to assure that device specifications meet *user needs* and *intended use(s)*.

- They set medical device Quality Systems apart from Good Manufacturing Practices.

cGMPs → QSRs

Design Controls – Scope

- Design controls apply to:
  - *All* **Class II** and **III**, and 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
- When do Design Controls Apply?
  - Premarket
    - *After* Feasibility/"Proof of Concept"/Prototyping
    - Point where you are designing the *final* product
    - *Prior* to commencement of any Clinical Investigation (21 CFR 812)
    - Mechanism of *change*/revision during any Clinical Investigation (21 CFR 812)

Risk Management and Human Factors

- **Risk Management/Analysis** is the systematic application of management policies, procedures, practices, insight/judgment, and experience to the *identification*, *analysis/evaluation*, *monitoring*, and subsequent *control/mitigation* of risk.
  - Risk Management and Analysis are integrated into the Design Control process, and are a key component and central requirement.

(see also recognized consensus standards, AAMI/ANSI/ISO 14971 and IEC TR80002)

- **Human Factors** is the study of the interactions between *humans* and *product* (i.e., *interface* and *machine*) and the subsequent design of the machine-human interface. It plays an important *symbiotic* role with Risk Management in Design Control.

General Requirements

21CFR 820.30(**a**)

- 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**)

- Procedures are established, maintained, and documented to:
  - 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**)

- ***Design inputs*** are the physical and performance ***characteristics*** of a device that are used as the *basis* for device design. Procedures are established and maintained to:
  - 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 Output

21CFR 820.30(**d**)

- ***Design outputs*** are the *results* of a design effort – final or otherwise. Procedures are established and maintained to:
  - Define and document design output to allow *adequate evaluation* of conformance to *design input. (i.e., input = output)*
  - Reference *definable/measurable* ***acceptance criteria***.
  - Identify design outputs essential for proper function.
  - Review, approve, and document design output before release.
- 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).

Design Review

21CFR 820.30(**e**)

- ***Design Review*** is a documented, comprehensive, systematic examination to:
  - Evaluate *adequacy* of the design requirements.
  - Evaluate *capability* of the design to meet requirements.
  - Identify any *problems.*
- Establish and maintain procedures, plan and conduct formal documented ***Design Reviews*** of design results at appropriate stages, including at each design review:
  - Representatives of all functions concerned and specialists as needed.
  - Individual(s) without **direct responsibility** for the stage being reviewed.
- Document results of design review in **Design History File (DHF)**, including identification of design, date, and individuals performing review.

Design Verification

21CFR 820.30(**f**)

- ***Verification*** is *confirmation* by examination and provision of *objective evidence* that output meets input requirements (i.e., **Input = Output**).
- Procedures are established and maintained to:
  - Confirm through measurable means (e.g., test reports, etc.).
  - Review, approve and document in Design History File (DHF).
- Many test reports associated with Design Verification are included in premarket submissions, including Premarket Notification [510(k)s], *de novos*, Premarket Approval Applications (PMAs), and Investigational Device Exemptions (IDEs)

Design Validation

21CFR 820.30(g)

- ***Design Validation*** is the establishment by *objective evidence* that specifications(*specified requirements)* conform with *user needs* and *intended use(s)*.
- Procedures are established and maintained:
  - Under defined operating conditions.
  - On initial production units, lots, or batches (or their equivalents).
  - Under actual or simulated use conditions.
- Perform *software validation* and ***risk analysis***, where appropriate.
- Review, approve, and document in Design History File.
- The results of Design Validation are typically submitted in Premarket Submissions (e.g., animal/cadaver/clinical study protocols/reports).

Verification vs. Validation

- **Design Verification**
  - Output meets Input
  - "Did I make the product *correctly*?"

- **Design Validation**
  - Specifications meet user needs and intended use(s)
  - "Did I make the *correct* product?"

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

Design Transfer

21CFR 812.30(**h**)

- Procedures are established and maintained to ensure correct and accurate ***Design Transfer*** into production specifications.

- 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)

- Procedures are established and maintained for the identification, documentation, validation and verification, review, and approval of ***Design Changes*** *before* their implementation.
- Is there a system in place to enact *future* changes?
- Often overlooked, but of critical importance.
- How can you improve your product if you have no system for change?
- Depending on the scope and impact of the change, the change may require a new Premarket Submission, Supplement, or Study.
- Changes must be communicated to FDA if the device is under premarket review or IDE review.

Design History File

21CFR 820.30(j)

- ***Design History File (DHF)*** is 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*.
- A Design History File must be established and maintained 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 ***subsystem*** – a subsystem within the main Quality System.

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

- **Goal** - Control the design process to assure that device specifications meet user needs and intended use(s).

QS Regulation and Guidance

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

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

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

Providing Industry Education

Three Resources

1. **CDRH Learn – Multi-Media Industry Education**
   - over 80 modules
   - videos, audio recordings, power point presentations, software-based "how to" modules
   - mobile-friendly: access CDRH Learn on your portable devices

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

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

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

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2014 or (301) 796-7100 (Live Agents 9am – 4:30 pm EST)
   - Web: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm

Questions?

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