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 \textit{correctly}?”

• Design Validation
  – Specifications meet user needs and intended use(s)
  – “Did I make the \textit{correct} product?”
**Example - Infusion Pump**

**User Need**
Pump must function in an operating room environment.

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

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

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**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](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](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](mailto: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](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm)
Questions?

Please complete the session survey:

survey monkey.com/r/DEV-D2S3