Design Controls

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Learning Objectives

- Understand the importance of design controls in device quality and why they are a quality system requirement.
- Know the Quality System Regulation requirements for design controls and learn how its sections interact with one another and the rest of the quality system.
- Understand the continual role design controls play in both premarket and postmarket device development.

Design Controls – What are They?

- Set of quality practices and procedures
- Control the design process to assure that the device meets:

  -User needs
  -Intended uses
  -Specified requirements

- Can improve and prevent future issues.

Design Controls – Why?

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

  Source: "Device Recalls: A Study of Quality Problems" (see 55 FR 21108, May 22, 1990) and "QS Regulations (Final Rule)" (see 61 FR 52602, October 07, 1996)

- The most frequent causes for recalls are related to Design, Software, and Non-Conforming Materials/Components.

  Source: "Medical Recall Report FY2003 to FY2012" (CDRH Office of Compliance, Division of Analysis and Program Operations)

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 medical devices.
- The Quality System (QS) Regulation became effective on June 1, 1997 and replaced the 1978 GMP for medical devices.
- Preamble to the QS Regulation is extremely important for understanding the intent of Design Controls.

Design Controls 21 CFR 820.30

Design controls apply to:

- *All* **Class II** and **Class III** medical devices
- Only these Class I medical 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 - When to Start?

- Where research ends and design begins
- After Feasibility/“Proof of Concept”
- When you plan to bring your device to market
- Prior to start of any Investigation Device Exemption (21 CFR 812)
- Premarket
- Mechanism of change/revision

Requirements for Design Controls

Design Controls – Where to Start?

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 21 CFR 820.30(c)

- Design inputs are the physical and performance characteristics of a device that are used as a basis for device design.
- Establish and maintain procedures for Design Input:
  - 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 Input: Example

User Need Example: "**Portable**"

- Define as "End user must hand carry device"
- Consider dimensions and weight
- Identify conflicting requirements (different units of measure)
  - 5 **lbs** ± 1 **kg**
- Resolve discrepancies
  - 5 **lbs** ± 1 **lbs**

Human Factors

Human factors are the study of the interactions between humans and device (i.e., interface) and the subsequent design of the device-human interface. It plays an important role in Design Control.

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

Design Output 21 CFR 820.30(d)

- Design outputs are the results of a design effort at each design phase and at the end of the total design effort.
- 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 definable/measurable acceptance criteria.
  - Identify design outputs essential for the proper functioning of the device.
  - Review, approve, and document design output before release.

Design Review 21 CFR 820.30(e)

Design Review is a documented, comprehensive, systematic examination to:

- Appropriately review the design at appropriate stages
- Include appropriate representation
- Evaluate adequacy of the design requirements.
- Evaluate capability of the design to meet requirements.
- Identify any problems.

Design Verification 21 CFR 820.30(f)

- Design verification is confirmation by objective evidence that design output meets design input.
- 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 Validation 21 CFR 820.30(g)

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

- **Design Verification**
  - Output meets Input
  - “I made the product correctly.”
- **Design Validation**
  - Specifications meet user needs and intended use(s)
  - “I made the correct product.”

Risk Analysis

QS Regulation: Design validation shall include software validation and risk analysis, where appropriate

- "Where Appropriate": required unless manufacturer can justify otherwise
- Almost always appropriate to perform risk analysis
- Perform initial risk analysis earlier during design inputs

What is Risk Analysis?

Intent of Risk Analysis per Preamble Comment #83:

- Identify possible hazards, including use error
- Calculate risk, under normal and fault conditions
- Determine risk acceptability
- Reduce unacceptable risks to acceptable levels
- Ensure changes made do not introduce new hazards

Additional Resources on Risk

- Implementation of risk management principles and activities within a Quality Management System - GHTF - 2005

www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n15r8-risk-management-principles-qms-050520.pdf

- ISO 14971:2007/(R)2010 Medical Devices – Application of risk management to medical devices

Design Transfer 21 CFR 820.30(h)

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 Controls Continual Role in Premarket and Postmarket Device Development

Design Changes 21 CFR 820.30(i)

Establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

Design History File 21 CFR 820.30(j)

Design History File (DHF) means a compilation of records which describes the design history of a finished device.

- 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 System requirements.

Additional Design Controls Resources

- **Design Control Guidance For Medical Device Manufacturers**

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm

- **Human Factors and Medical Devices**

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

Call to Action

- Meet your regulatory requirements for design controls per 21 CFR 820.30.
- Use cross functional teams to design your device.
- Ensure you design controls address user needs, intended use and defines appropriate specifications .
- Use design controls to build quality, safety, effectiveness and savings into your medical device.

Industry Education Resources

Three Resources

1. **CDRH Learn – Multi-Media Industry Education**
   - over 115 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

   www.fda.gov/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE


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