Introduction to the Quality System Regulation and Design Controls

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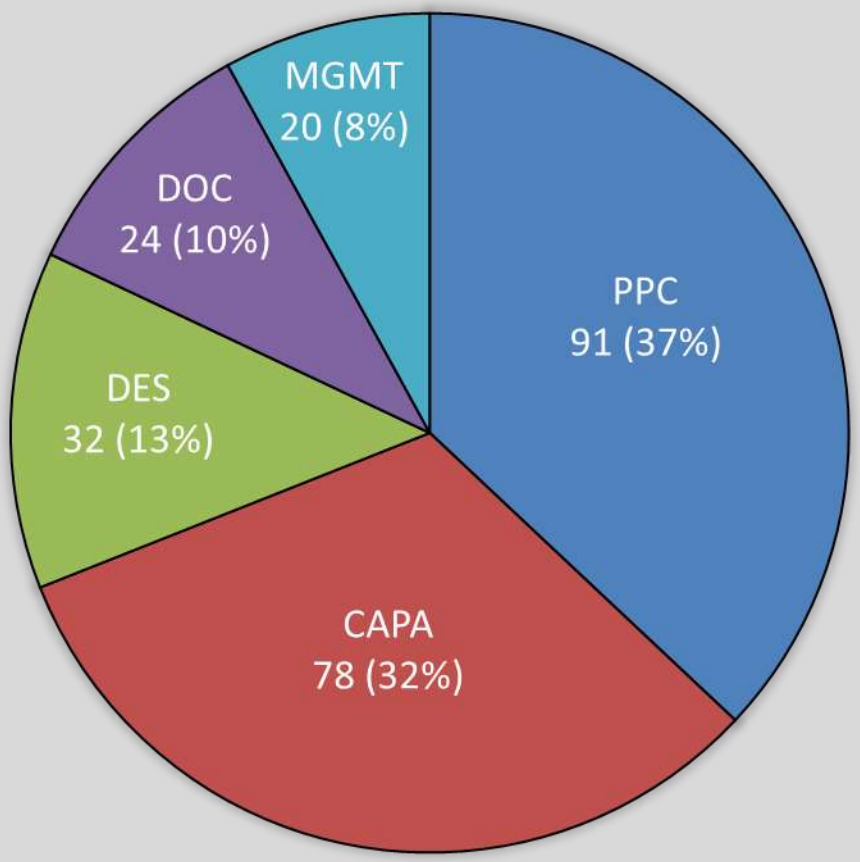
FY 2017 Annual FDA Medical Device Quality Data

245 QUALITY SYSTEM CITATIONS IN WARNING LETTERS



DES= Design Controls

CAPA= Corrective and Preventive Actions

PPC= Production and Process Controls

MGMT= Management Controls

DOC= Document Controls

Learning Objectives

- Background Information
- Review Key Terminology
- Explain the purpose of a Quality System (QS)
- Explain the QS Regulation using the 7 Major subsystems approach
- Explain the purpose of Design Controls subsystem
- Provide an overview of the Design Controls subsystem
- Review Warning Letter examples

Poll

How many years have you been involved in work using the Quality System Regulation?

A. Less than 1 year

B. 1-5 years

C. 5-10 years

D. 10-15 years

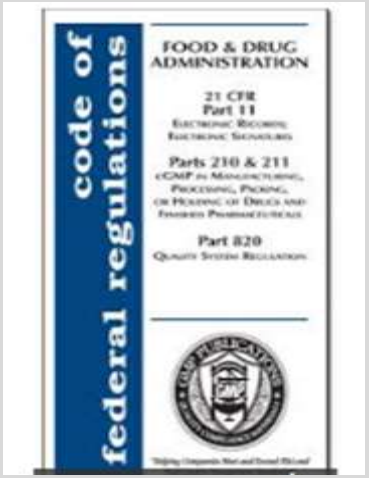
E. More than 15 years

F. Not at all

Background

The Quality System Regulation

- Effective June 1, 1997
- Replaces the 1978 GMP Regulation for medical devices
- Requirements are not prescriptive
- Provides framework of basic requirements
- Preamble to the 1997 regulation - VERY Important



Background

Design Controls

- Faulty design attributed to 44% of recalls analyzed between 1983 and 1989
- Requirements authorized by SMDA and codified in the Quality System Regulation
- Major subsystem of the quality system

Background

Design Controls:

- Not intended to be retroactive
- Not intended to apply to feasibility studies
- Do apply to investigational device exemption (IDE) devices

Key Terminology

- **Finished device [21 CFR 820.3(l)]:**

means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Key Terminology

- **Manufacturer [21 CFR 820.3(o)]:**

means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repackaging, or specification development, and initial distributors of foreign entities performing these functions.

Key Terminology

- **Establish [21 CFR 820.3(k)]:**

means define, document (in writing or electronically), and implement.

- **D**efine
- **D**ocument
- Implement **(Do)**

Purpose of Quality System

Govern the methods used in, and the facilities and controls used for:

- Design
- Manufacture
- Packaging
- Labeling
- Storage
- Installation
- Servicing

…of all finished devices intended for humans.

Bottom line…
It's Your Quality System!

A manufacturer must develop a Quality System (QS) commensurate with:

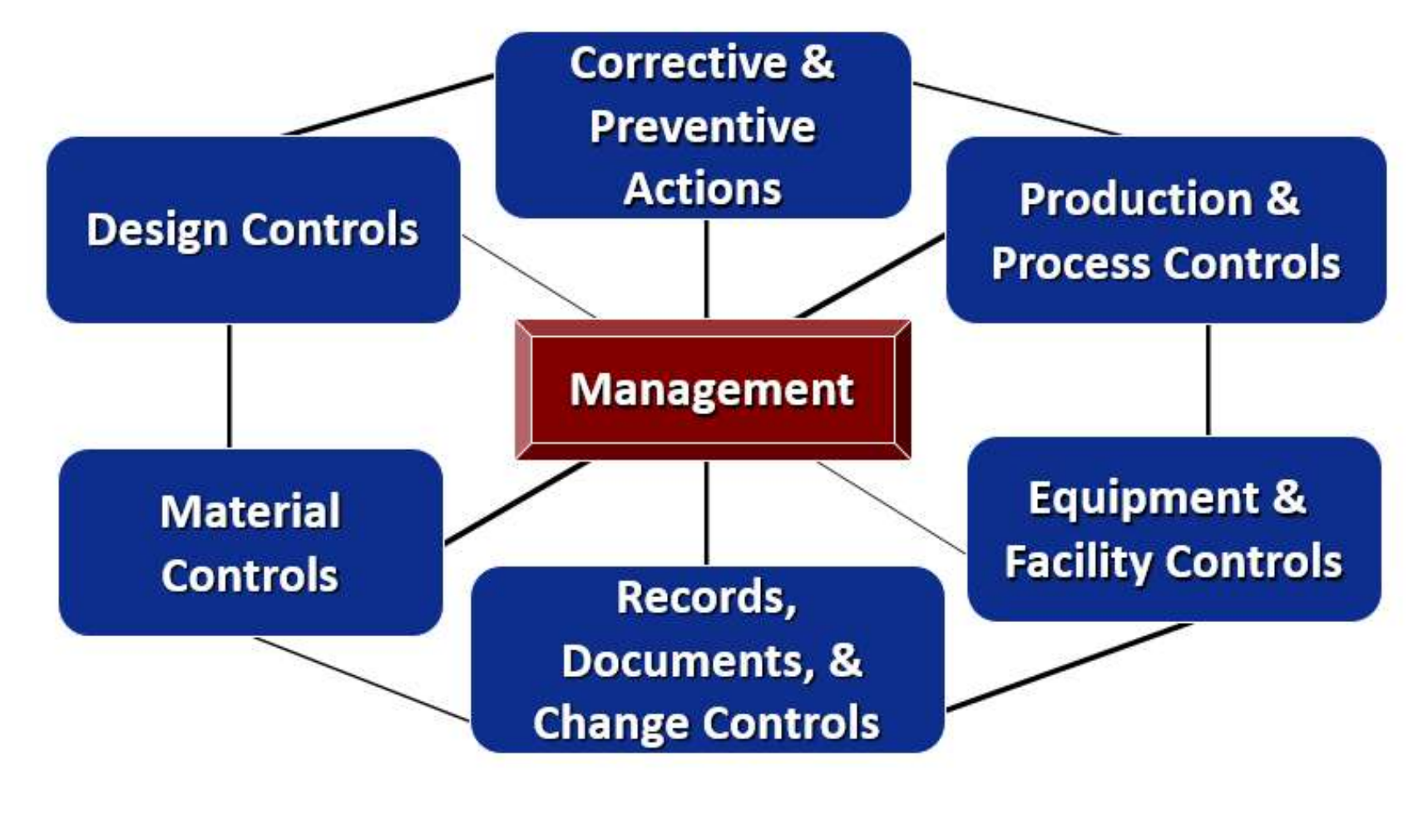
- risk presented by the device

Bottom line …
It's Your Quality System!

A manufacturer must develop a Quality System (QS) commensurate with:

- complexity of device and manufacturing processes
- size and complexity of manufacturing facility

7 Subsystems of a Quality System



4 Major Subsystems

- Corrective and Preventive Action (CAPA)
- Management Controls
- Production and Process Controls
- Design Controls

Quality System

- Management is central to the quality management system and processes
- Quality management system processes are continuous
- Manufacturers should:
  - PLAN to define and implement effective procedures
  - DO what they say they are going to do
  - CHECK the system and make necessary changes (corrections, corrective actions, and preventive actions)
  - ACT upon those changes and ensure they are implemented

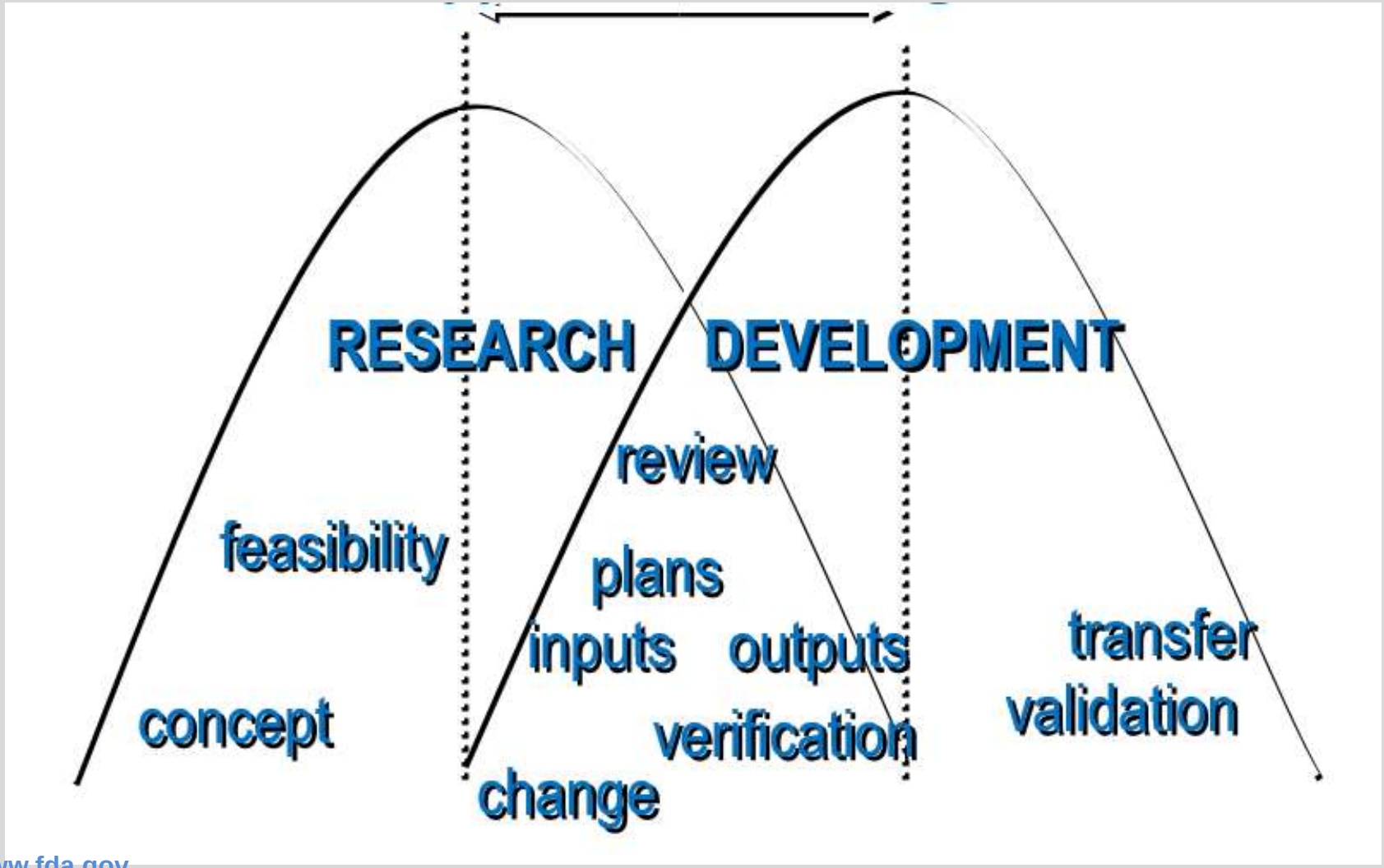
Purpose of Design Controls

- Control the design processes
- Assure the device design meets:
  - user needs
  - intended uses
  - specified requirements

Design Controls

- Apply to:
  - Class II
  - Class III
  - Class I, per 820.30 (a)(2)

Application of Design Controls



Design Changes

Obligations regarding medical devices that were marketed prior to June 1, 1997 and have changed:

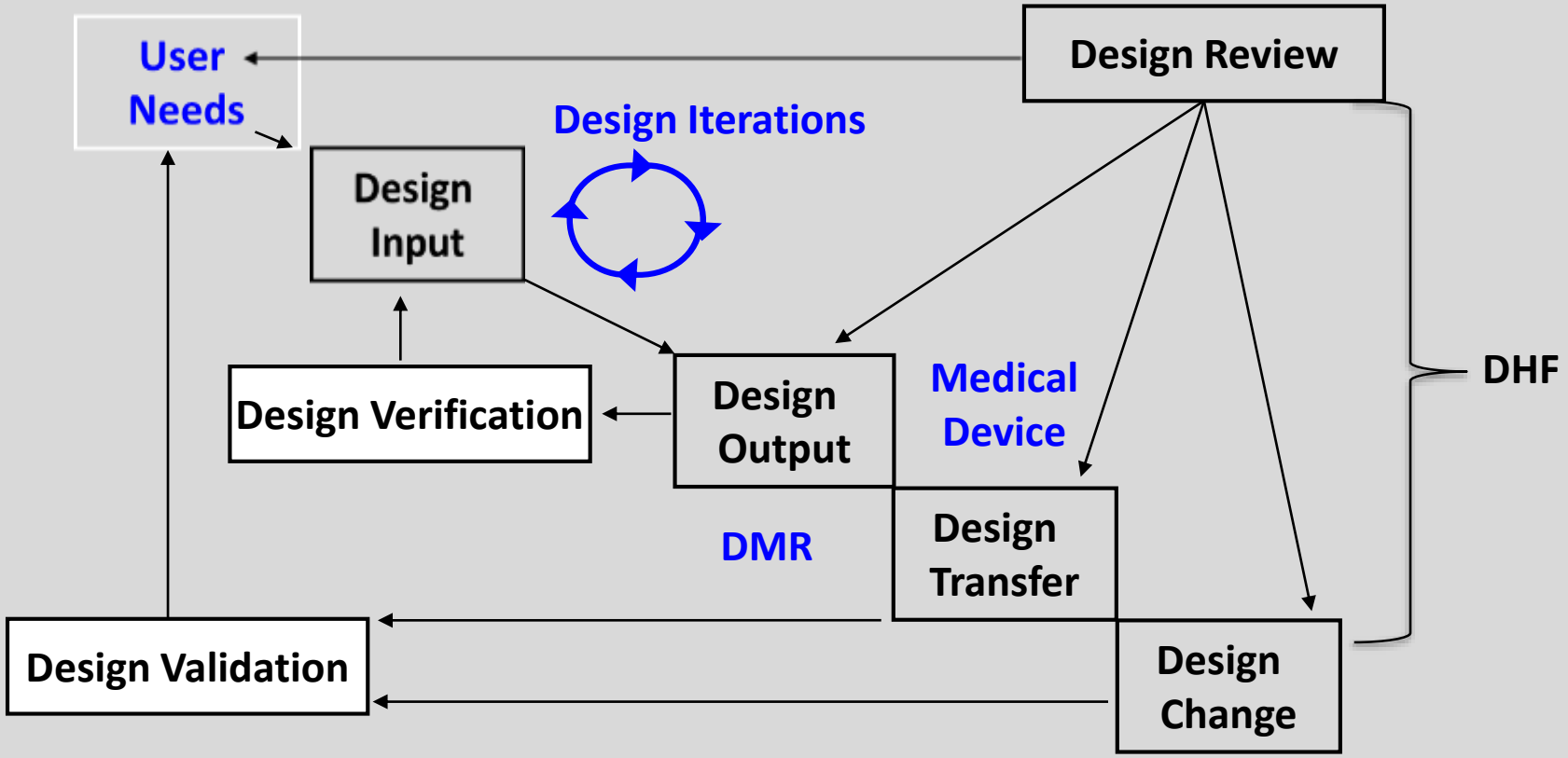
- "When changes are made to new or existing designs, the design controls of §820.30 must be followed to ensure that the changes are appropriate and that the device will continue to perform as intended."

(Preamble page 52616, response to comment #64)

Design Controls

- Understand the jargon
- Use the results of Risk Analysis
- Ensure linkages to other subsystems

Design Controls Overview



Example: Warning Letter

Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a).

- For example, your firm has not established design controls for the ABC device. There is no documentation to demonstrate that your firm has developed a design plan, design inputs, design outputs, and design verification or design validation testing criteria for these devices.

Summary

- Medical device manufacturers must comply with the Quality System Regulation
- FDA identified 7 subsystems of a Quality System
- Quality System Regulation includes requirements to implement design controls
- Design Controls is one of the 4 major subsystems

Summary

- Design controls control the design process to assure that devices meet:
  - User needs
  - Intended uses
  - Specified requirements as transferred during manufacturing
- Design Controls are linked to other quality system subsystems

References

- Quality System Regulation and Preamble
- CDRH Learn Module on design controls
- Quality System Inspection Technique (QSIT)
- Design Control Guidance For Medical Device Manufacturers
- Human Factors and Medical Devices
- Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff
- GHTF's *Essential Principles of Safety and Performance of Medical Devices* (SG1/N41:2005)

Questions

Please evaluate this session:

surveymonkey.com/r/DEV-D2S02

Your Call to Action

- Review quality system procedures for compliance
- Implement design controls
- Demonstrate interfaces between design controls and other quality system subsystems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