

Overview of the Quality System Regulation

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Do you want to

- Improve processes?
- Reduce waste?
- Identify training opportunities?
- Engage Your Staff?
- Set organizational-wide direction?
- Lower costs?

Learning Objectives

- Summarize Background Information
- Define Key Terminology
- Explain the purpose of a Quality System (QS)
- Explain the QS Regulation using the 7 Major subsystems approach

Background Information

QS Regulation: Background

- 1976: Medical Device Amendments to Federal Food, Drug, and Cosmetic Act (FD&C Act)
- 1978: Current Good Manufacturing Practices
- Late 1980s: FDA evaluates voluntary device recalls
 - from 1983 – 1989
 - determined that faulty design attributed to 44%
 - may have been prevented with adequate design controls

QS Regulation: Background

The Quality System Regulation

- 1990: Congress passes Safe Medical Device Act of 1990
 - gave FDA authority to add pre-production design controls to regulation
- FDA revised CGMPs, resulting in new regulation
 - titled Quality System Regulation, or QS Regulation
- Became effective on June 1, 1997
- Regulation found under 21 CFR 820

QS Regulation: Background

- Harmonized with ISO 9001 and 13485
- Requirements are not prescriptive
- Provides framework of basic requirements
- Preamble to the 1997 regulation - VERY Important

ISO = International Organization for Standardization

Preamble

- Reveals intent and FDA's interpretation of regulation
- Total of 204 Industry/Public Comments to proposed rule include:
 - FDA response
 - FDA rationale for agreeing or disagreeing
 - Changes made to regulation (from proposed to final)

Preamble Example

“A few comments stated that design controls should not be retroactive and that ongoing design development should be exempted. FDA agrees in part with the comments. FDA did not intend the design requirements to be retroactive, and Sec. 820.30 Design controls will not require the manufacturer to apply such requirements to already distributed devices. When the regulation becomes effective on June 1, 1997, it will apply to designs that are in the design and development phase, and manufacturers will be expected to have the design and development plan established.”

Preamble, Comment 64

Key Terminology

Key Terminology

- Establish - [21 CFR 820.3\(k\)](#)
 - Define
 - Document (in writing or electronically)
 - Implement (**Do**)

Key Terminology

- **Finished device** - [21 CFR 820.3\(I\)](#)

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

Finished Device



Accessory



Key Terminology

- **Component** - [21 CFR 820.3\(c\)](#)

any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device

Example:

- reagents in an *in vitro* diagnostic test kit

Key Terminology

- **Manufacturer - [21 CFR 820.3\(o\)](#)**
 - any person who designs, manufactures, fabricates, assembles, or processes a finished device
 - includes, but is not limited to, those who perform functions of contract sterilization, installation, relabeling, remanufacturing, repackaging, or specification development, and initial distributors of foreign entities performing these functions

Example:

- Sterilization Facility

Key Terminology

- **Quality System - [21 CFR 820.3\(v\)](#)**

organizational structure, responsibilities, procedures, processes, and resources for implementing quality management

Example:

Establishment has the following documents:

- Procedures for making a device
- Documents of employee roles and responsibilities
- Documents of individuals assigned to roles

Key Terminology

- **Quality Control**

Test and inspect components or finished products against approved specifications

Example:

- Does red light appear when you press power button?

- **Quality Assurance**

Manufacture quality into product

Purpose of a Quality System

Purpose of Quality System

Governs methods used in, and facilities/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 consistent with risk presented by device
- Device risk will determine depth/level of actions

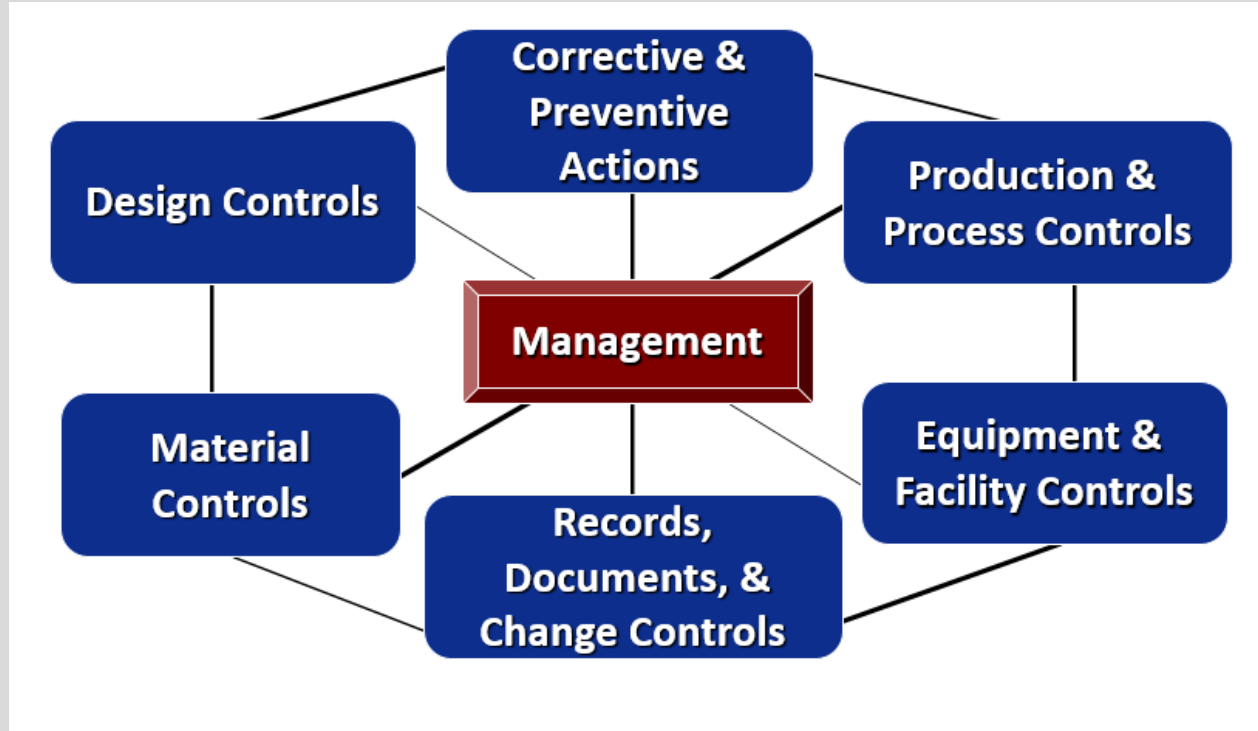
Bottom line: It's Your Quality System!

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

- Complexity of device
- Complexity of manufacturing processes
- Size and complexity of manufacturing facility

Quality System Regulation

7 Subsystems of a Quality System



Quality System

- Management is key to quality system and processes
 - can delegate performance of activity, but not responsibility
 - is ultimately responsible to ensure that QS is implemented and effective
- Subsystems are interrelated and linked

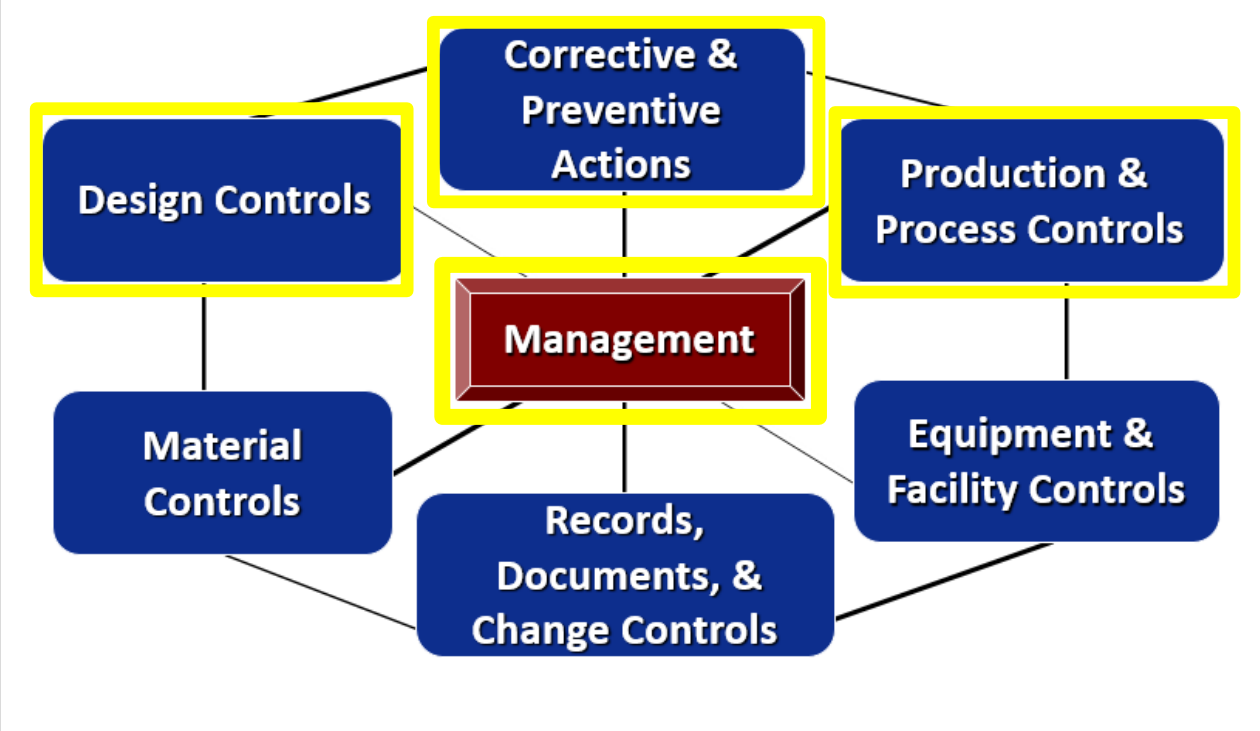
Continuous System: close the loop



Quality System

- Manufacturers should:
 - PLAN to define and implement effective procedures
 - DO what they say they are going to do
 - CHECK system and make necessary changes
 - corrections, corrective actions, and preventive actions
 - ACT upon changes and ensure they are implemented

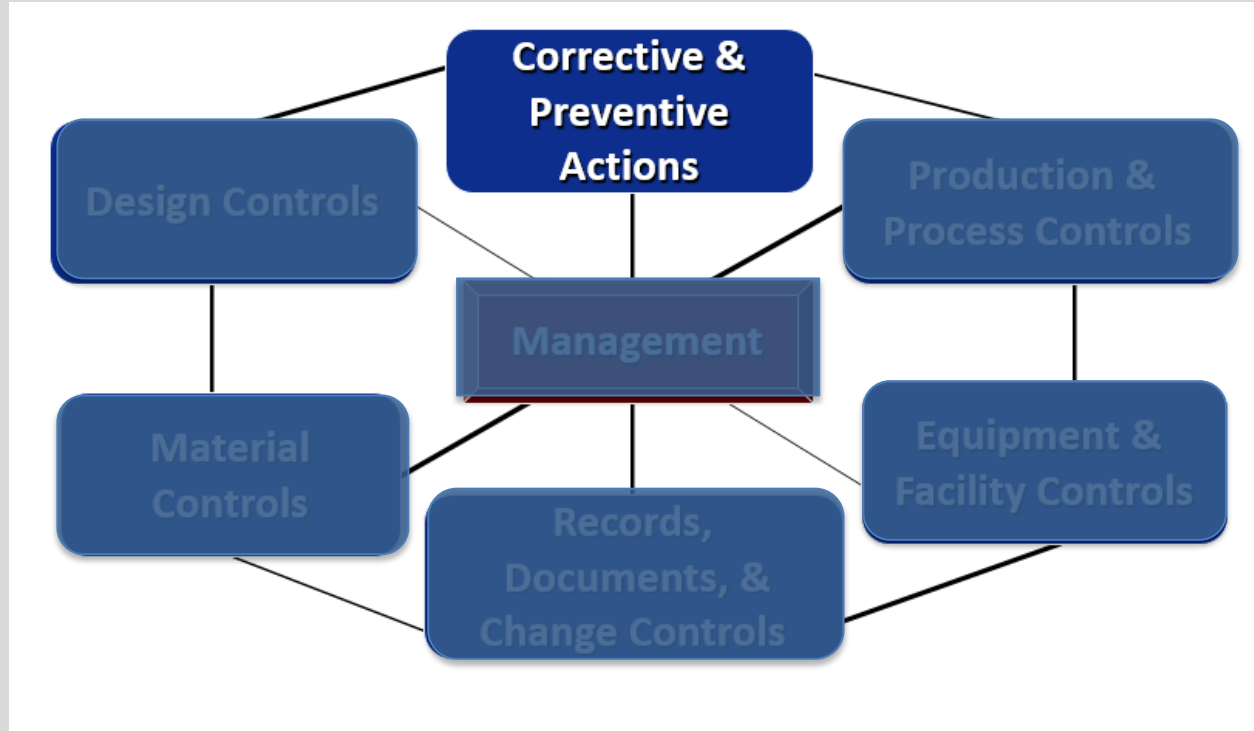
4 Major Subsystems of a Quality System



4 Major Subsystems

- Focus of FDA medical device inspection
- Considered key quality indicators
- Detailed information about major subsystems in [CDRH Learn](#) (see Postmarket Activities section)

7 Subsystems of a Quality System



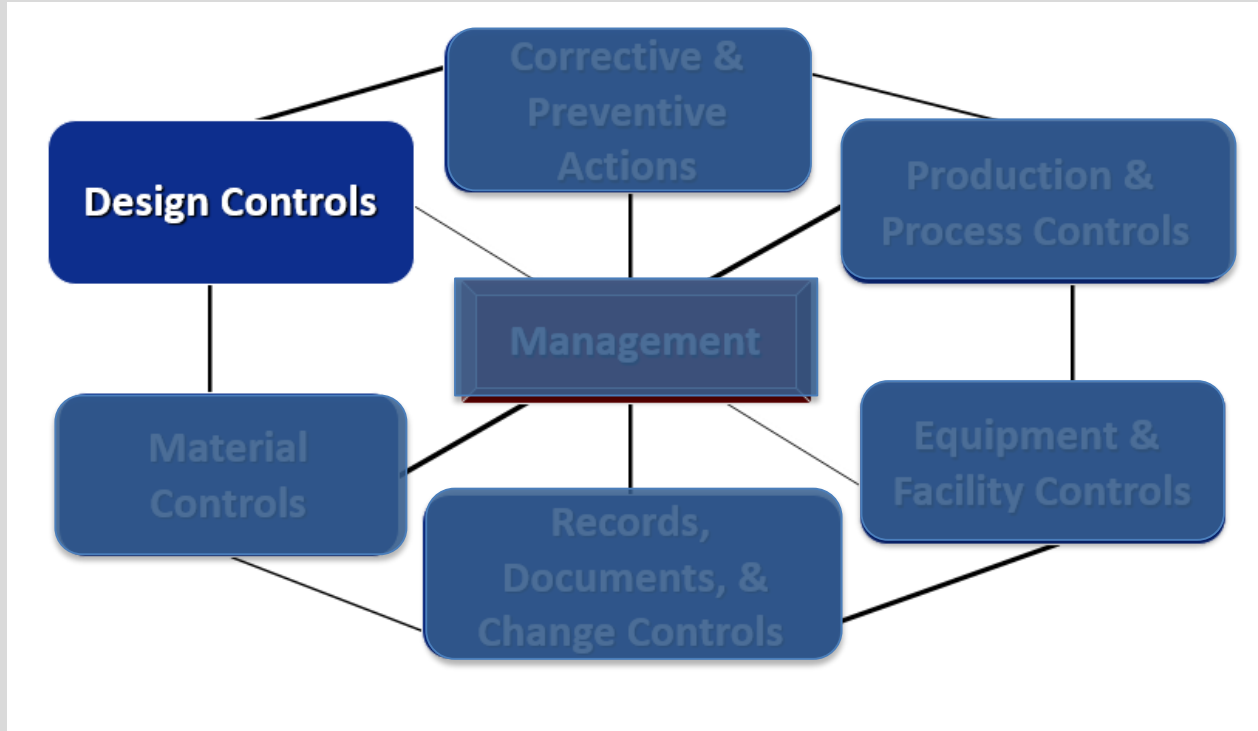
Corrective and Preventive Action (CAPA)

- Purpose:
 - Collect and analyze information
 - Identify and investigate nonconforming products and quality problems
 - Identify cause(s) of nonconforming products
 - Take effective corrective and preventive action

CAPA

- Sources of quality problems:
 - Results of monitoring manufacturing processes
 - Inspection and testing of incoming product
 - Complaints

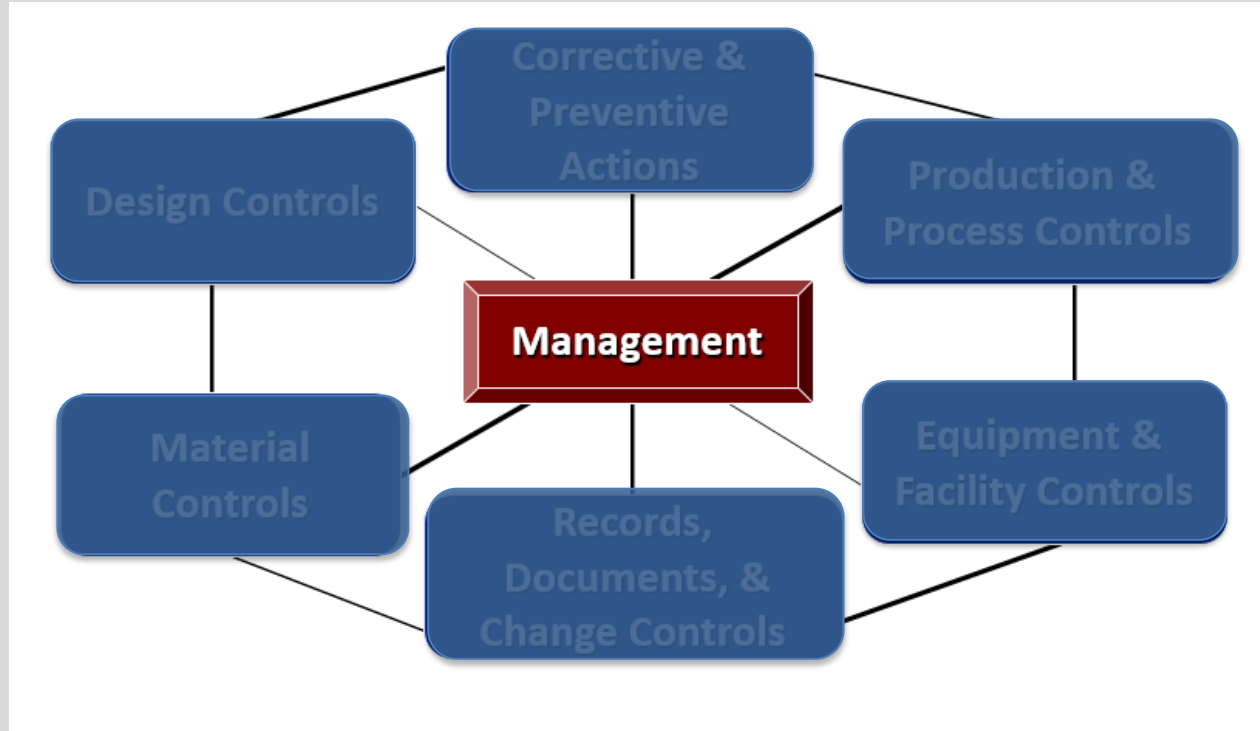
7 Subsystems of a Quality System



Design Controls

- Purpose:
 - To control design process to assure:
 - user needs and intended uses are met
 - design is adequately transferred into manufacturing
- Identify applicable conformance standards as design input

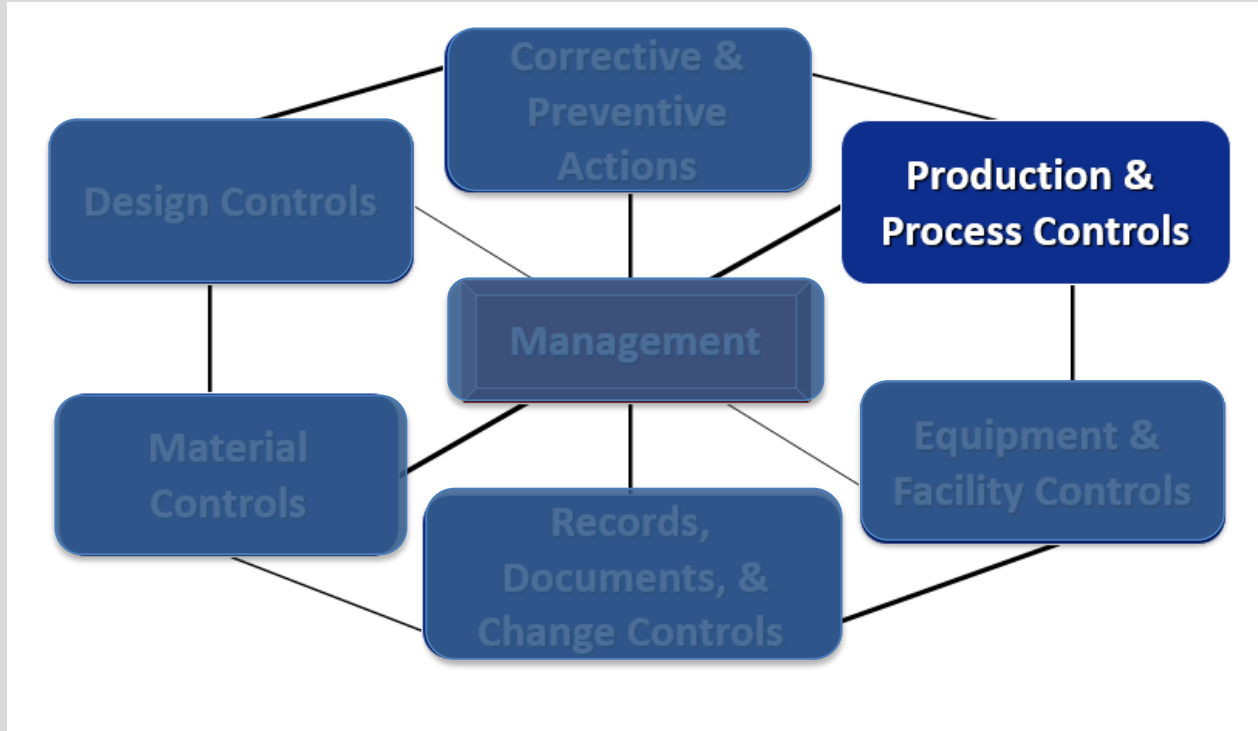
7 Subsystems of a Quality System



Management Controls

- Purpose:
 - Provide adequate resources for operations
 - Monitor quality system
 - Make necessary adjustments
 - Assure quality system is functioning properly
- Quality System monitored through periodic reviews

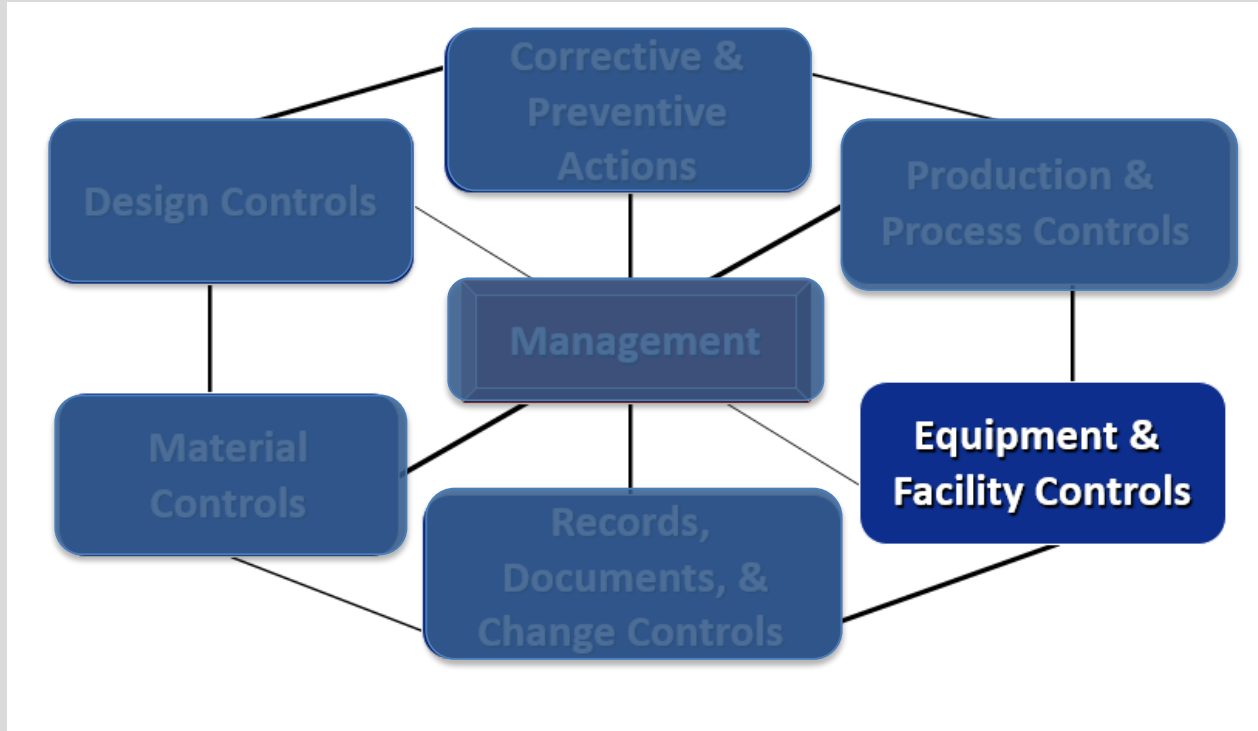
7 Subsystems of a Quality System



Production and Process Controls

- Purpose:
 - To manufacture devices that meet specifications
- Controlling and monitoring processes is essential

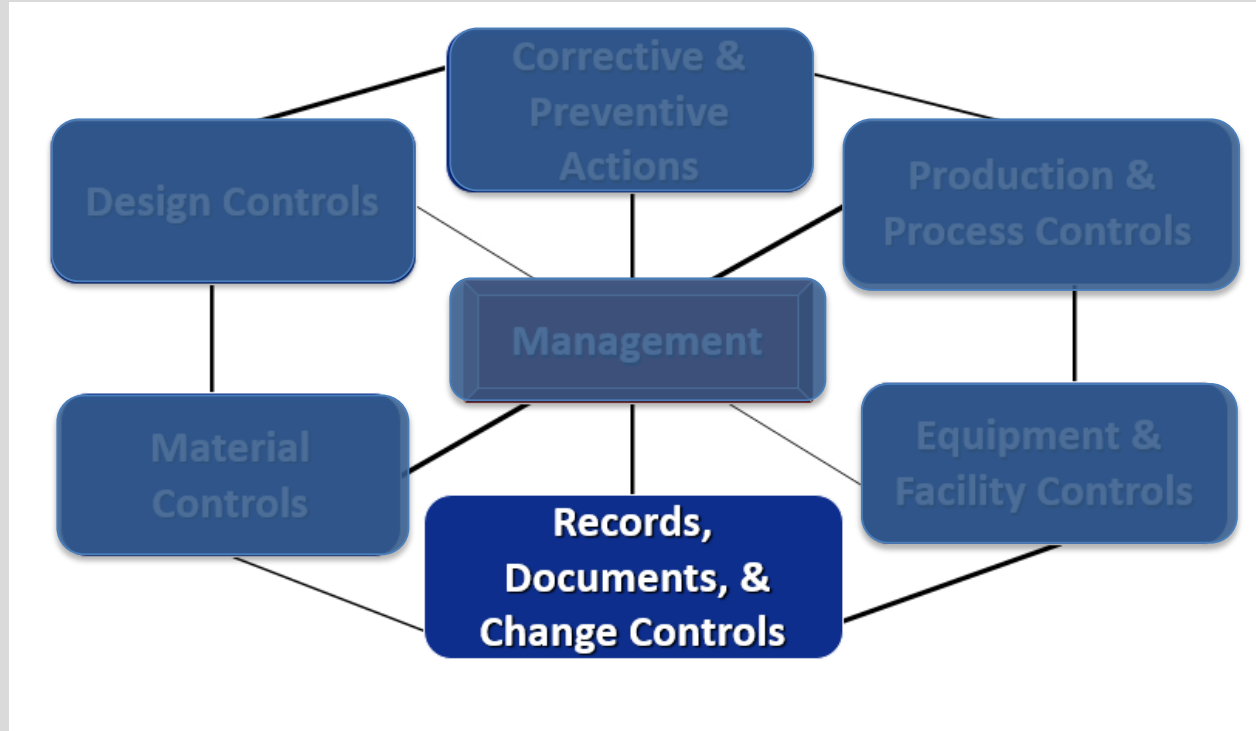
7 Subsystems of a Quality System



Equipment & Facility Controls

- Purpose:
 - Ensure devices are not adversely affected by manufacturing environment, buildings or equipment
- Make sure buildings are adequate for operation being conducted

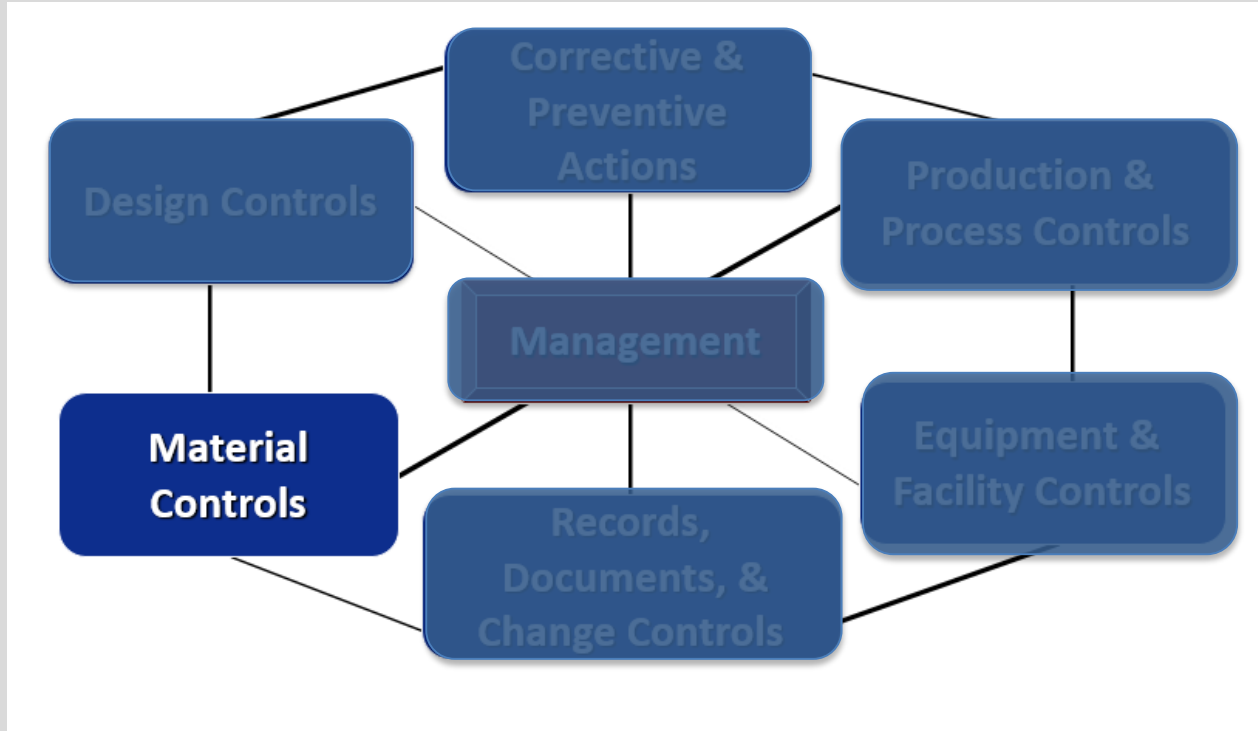
7 Subsystems of a Quality System



Record, Documents, and Change Controls

- Purpose:
 - specifications and procedures are adequate
 - only current documents are used
 - changes are reviewed, approved and incorporated into documents
 - documents are maintained for required length of time
- System to control documents - manual or electronic

7 Subsystems of a Quality System



Material Controls

- Purpose:
 - To ensure that all products that are accepted, used, and distributed meet specification
- Includes identification and traceability requirements

Identification

21 CFR 820.60

- Establish and maintain procedures for identifying product during all stages:
 - of receipt, production, distribution, and installation
 - to prevent mix-ups

Identification

21 CFR 820.60

Examples:

- Electronic systems: using bar codes
- Part Number
- Describe the product, material, finished device
- Revision number

Traceability

21 CFR 820.65

- Establish and maintain procedures to identify finished devices
- Identify with control number
- Required for devices intended for surgical implant or to support or sustain life
- Procedures must facilitate corrective action

Summary

- Medical device manufacturers must comply with the Quality System Regulation
- The Quality System Regulation is grouped into 7 interrelated subsystems
- Quality System is a continuous system

Your Call to Action

- Review quality system regulation and ensure you implement applicable requirements
- Demonstrate interfaces between subsystems
- Close the loop when establishing your quality system

Industry Education: Three Resources for You

1. CDRH Learn: Multi-Media Industry Education

- over 125 modules
- videos, audio recordings, power point presentations, software-based “how to” modules
- mobile-friendly: access CDRH Learn on your portable devices

www.fda.gov/Training/CDRHLearn

2. Device Advice: Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics

www.fda.gov/MedicalDevices/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

