Introduction to the Quality System Regulation

FDA Small Business
Regulatory Education for Industry (REdI)
Rockville, MD
September 28, 2017

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Learning Objectives

- Introduce the Quality System (QS) Regulation and Background
- Review Definitions
- Introduce the 7 Major Subsystems Approach for QS
- Review Records, Documents and Change Controls Requirement, Including Required Records

Poll Question

For how many years have you been involved in the Quality System regulation (21 CFR 820) that applies to medical devices?

a) More than 15 years

b) Between 5-15 years

c) Less than 5 years

d) None

Quality System Background

The Quality System Regulation: 21 CFR 820

- **Safe Medical Device Act** (SMDA)
  - Effective June 1, 1997
  - Replaces the 1978 GMP Regulation for medical devices
- **Preamble to 1996 QS Regulation**
  - VERY Important
  - Medical Device Quality System Regulation and Preamble

Quality System Regulation

- Requirements are not prescriptive
- Provides framework of basic requirements for manufacturers
- Harmonized with ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- Regulation is flexible

Definition

Manufacturer

Any person who designs, manufactures, fabricates, assembles, or processes a finished device….. includes…. contract sterilization, installation, relabeling, remanufacturing, repackaging, or specification development, and initial distributors of foreign entities performing these functions.

§ 820.3 (o)

Definitions

Finished device

… *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

§ 820.3 (l)

Component

… *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.

§ 820.3 (c)

Quiz

This wheelchair tire is manufactured by a third party. Is it a finished device or a component?

a. Finished Device

b. Component

c. It depends

d. None of the above

Definitions Continued

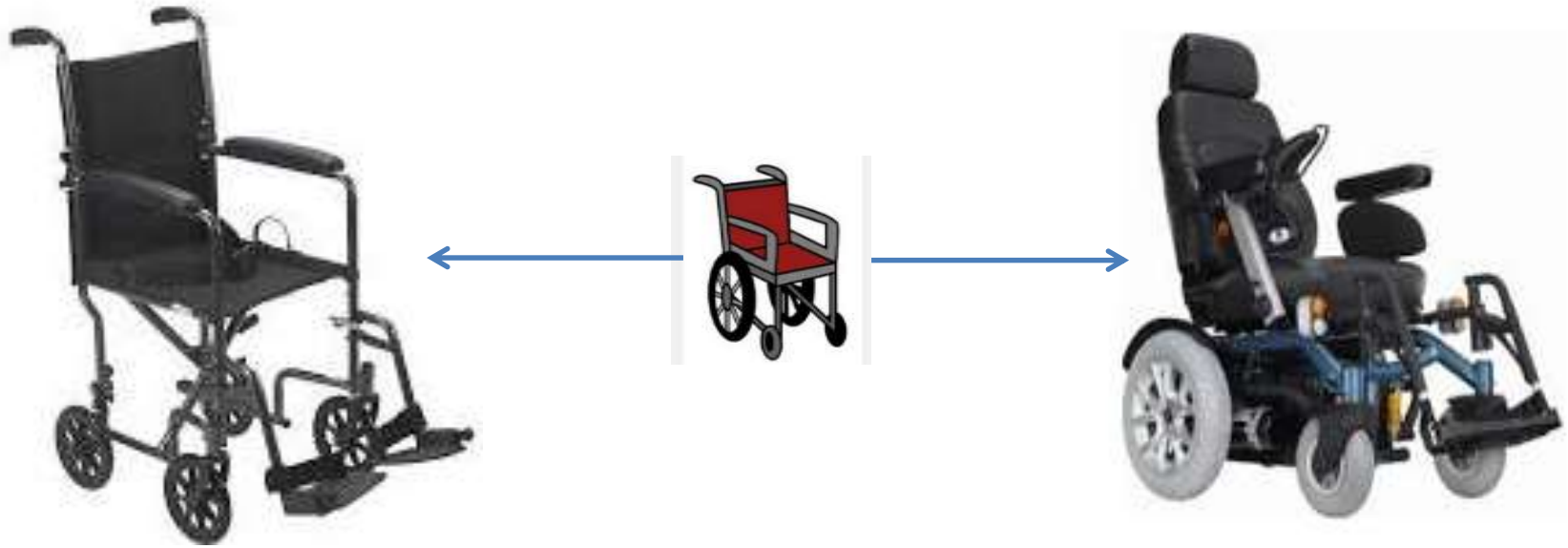
Quality

Totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance

Quality System

Design and manufacture quality into products

Quality is not a “one size fits all concept”



Definitions Continued

Establish

- ✓**D**efine
- ✓**D**ocument (in writing or electronically)
- ✓Implement **(Do)**

§ 820.3 (o)

Bottom line:
It's Your Quality System!

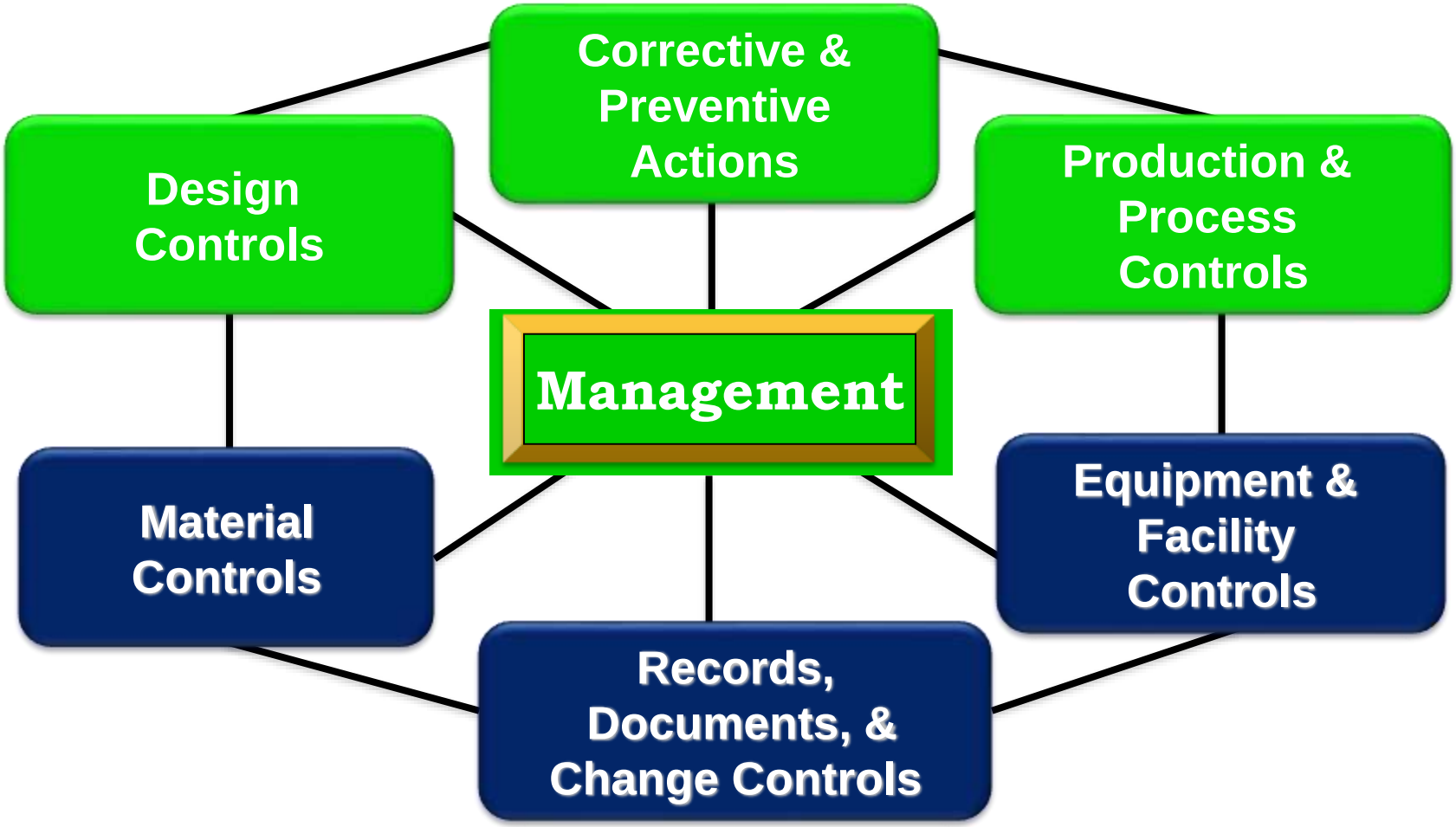
A manufacturer must develop a Quality System (QS) consistent with:

- Risk presented by the device
- Complexity of device and manufacturing processes
- Size and complexity of manufacturing facility

The 7 Subsystems of a Quality System

Guide to Inspections of QS: Quality System Inspection Technique

The 4 Major Subsystems



Guide to Inspections of QS: Quality System Inspection Technique

Documents, Records & Change Controls

Purpose - to assure:

- Only current documents used
- Changes are reviewed, approved and incorporated

§ 820.40

Documents, Records & Change Controls continued

Establish and maintain procedures to control all documents required by Part 820

Procedures shall provide for:

1. ***Document approval and distribution***
2. ***Document changes***

§ 820.40 (b)

Documents, Records & Change Controls continued

- Distribution: Documents shall be available at all locations for which they are designated, used, or otherwise necessary.

- Remove all obsolete documents promptly or otherwise prevent their unintended use!

§ 820.40(a)

Documents, Records & Change Controls continued

- Make required records readily available for review and copying
- Records shall be legible and stored to prevent loss
- Maintain for the required length of time

  = **Expected life of the device or at least 2 years** from the date of release for commercial distribution

Required QS Records

- Design History File (DHF)
- Device Master Record (DMR)
- Device History Record (DHR)
- Quality System Record (QSR)

Design History File (DHF)

A compilation of records which describe the design history of a finished device.

- Establish and maintain a DHF for each type of device
- Include or reference records information

§ 820.30 (J)

Device Master Record (DMR)

A compilation of records containing the procedures and specifications for a finished device.

Includes:

- ❑ Device specifications
- ❑ Production process specifications
- ❑ Quality assurance procedures and specifications
- ❑ Packaging and labeling specifications
- ❑ Installation, maintenance and servicing procedures and methods

§ 820.3 (j)

Device History Record (DHR)

A compilation of records containing the production history of a finished device.

Includes:

- ❑ Dates of manufacture
- ❑ Quantity manufactured
- ❑ Quantity released for distribution
- ❑ Acceptance records which demonstrate the device is manufactured in accordance with DMR

§ 820.3 (e)

Quality System Record (QSR)

- Maintain QSR
- Prepare and approve per 21 CFR 820.40
- Includes or refers to location of:
  - Procedures and documentation of activities
    - required by Part 820
    - not specific to a particular type of device
  - Records required by 21 CFR 820.20

§ 820.186

Resources

- Medical Device Quality System Regulation and Preamble (**Device Advice**)
  - www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm
- Quality System Website (**Device Advice**)
  - www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm
- Guide to Inspections of QS: QS Inspection Technique/QSIT.
  - www.fda.gov/downloads/ICECI/Inspections/UCM142981.pdf
- **CDRH Learn** training modules under the Postmarket Activities section
  - www.fda.gov/Training/CDRHLearn

Summary

- Introduced the QS Regulation, including background and definitions
- Discussed the Quality System 7 Major Subsystems Approach
- Reviewed requirements for Records, Documents and Change Controls

Questions

Please complete the session survey:

surveymonkey.com/r/DEV-D2S02

Call to Action

- It’s your Quality System: Own it!
- Have established procedures and documentation for all of your QS processes.
- Account for all documents and records required by 21 CFR Part 820.
- Use FDA resources for additional QS training.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