

# **Overview of the Quality System Regulation for Medical Devices**

**FDA Small Business  
Regulatory Education for Industry (REdI)**  
Silver Springs, MD  
September 28, 2016

**Aileen I. Velez Cabassa**  
Consumer Safety Officer  
Postmarket and Consumer Branch  
Division of Industry and Consumer Education  
Office of Communication Education  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

# Learning Objectives

- Learn the Quality System (QS) Regulation and Background
- Review Definitions
- Introduce the 7 Major Subsystems Approach for QS
- Elaborate on Records, Documents & Change; Controls, Production & Process Controls Subsystem; and Nonconforming Product

# Poll Question

D2S2-1

View Votes
Edit
End Poll

**D2S2-1: For how many years have you been involved in the Quality System regulation (21 CFR 820) that applies to medical devices?**

<input type="radio"/> More than 15 years (a lot)		0%	(0)
<input type="radio"/> Between 5-15 years (some)		0%	(0)
<input type="radio"/> Less than 5 years (a little)		0%	(0)
<input type="radio"/> None		0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

# 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 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
- Flexible regulation

# Definition

## Manufacturer

Means 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 Continued

## Finished device

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

[§ 820.3 \(I\)](#)



# Definitions Continued

## Component

Means 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

D2S2-2

View Votes
Edit
End Poll

**D2S2-2: Is the tire on a wheelchair an accessory (finished device) or a component?**

<input type="radio"/> Accessory		0%
<input type="radio"/> Component		0%
<input type="radio"/> Not sure		0%
<input checked="" type="radio"/> No Vote		

☐ Broadcast Results



# Definitions Continued

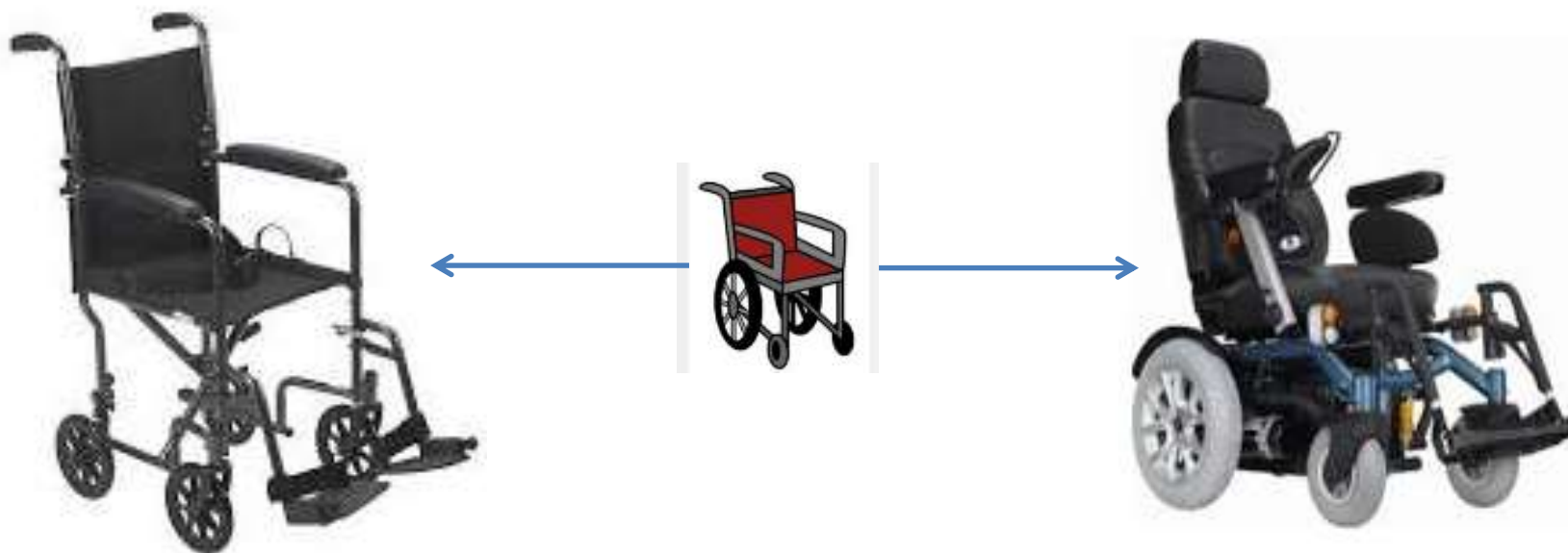
## Quality

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!**

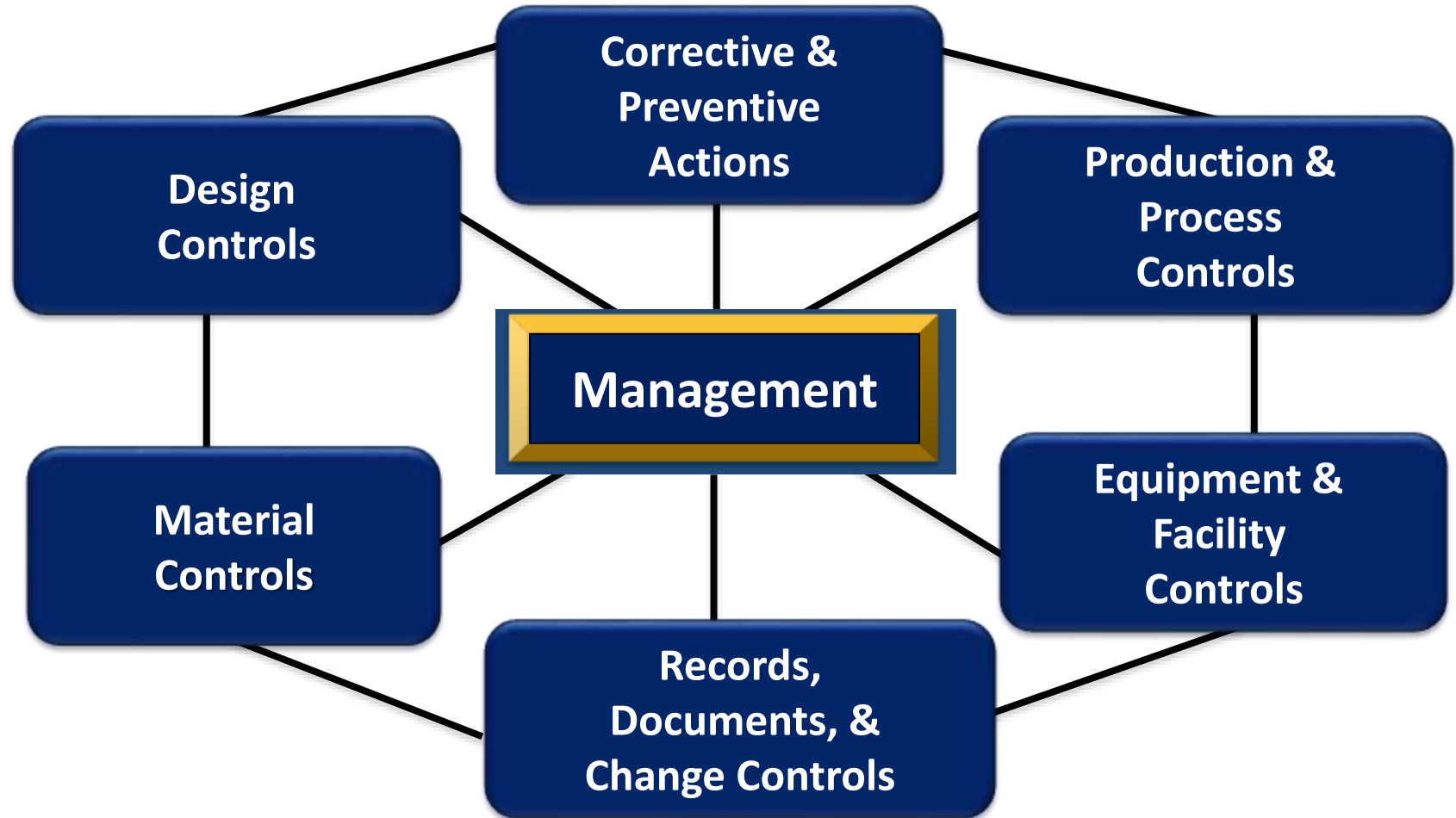
**A manufacturer must develop a Quality System (QS) commensurate with:**

- risk presented by the device
- complexity of device and manufacturing processes
- size and complexity of manufacturing facility

# The 7 Subsystems of a Quality System



# The 7 Subsystems of a Quality System



From [Quality System Inspection Technique](#)

# The 4 Major Subsystems of the Quality System

- Design Controls
- Management Controls
- Production & Process Controls
- Corrective & Preventive Action



# 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
  - The **expected life of the device or at least 2 years** from the date of release for commercial distribution

# Required QS Documents

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

# Definition

## Device master record (DMR):

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

[§ 820.3 \(j\)](#)



# The DMR Includes

1. Device specifications
2. Production process specifications
3. Quality assurance procedures and specifications
4. Packaging and labeling specifications
5. Installation, maintenance and servicing procedures and methods

[§ 820.181](#)

# Definition

## **Device history record (DHR):**

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

[§ 820.3 \(e\)](#)



# The DHR Includes

1. Dates of manufacture
2. Quantity manufactured
3. Quantity released for distribution
4. Acceptance records which demonstrate the device is manufactured in accordance with DMR

[§ 820.184](#)

# 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 that are not specific to a particular type of device
  - Records required by 21 CFR 820.20

[§ 820.186](#)

# Production & Process Controls Subsystem

Purpose: Manufacture products that meet specifications

- Develop processes that are adequate
- Validate (or fully verify the results) those processes
- Monitor and Control the manufacturing processes

[§ 820.70](#)

# Production & Process Controls

## Subsystem continued

- ✓ Purchasing
- ✓ Acceptance Activities
- ✓ Buildings & Equip.
- ✓ Calibration
- ✓ Personnel
- ✓ Identification
- ✓ Labeling
- ✓ Handling, Storage, & Distribution
- ✓ Installation & Servicing

# Production & Process Controls Subsystem - Process Validation

## When must you validate you process?

- Where the results of the process cannot be fully verified by subsequent inspection and test  
[§ 820.75](#)
- Computer software for its intended use when used as part of production or the quality system  
[§ 820.70\(i\)](#)

# Production & Process Controls

## Subsystem Process Validation continued

- Verify, or where appropriate validate, changes to a specification, method, process, or procedure before implementation
- Ensure all inspection, measuring , and test equipment is suitable for use

For more on Process Validation visit [CDRHLearn](#)

# Production & Process Controls Subsystem

## - Environmental Control

- Establish procedures to adequately control environmental conditions
- Inspect control system(s) to verify adequacy and proper functioning
- Document and review these activities

[§ 820.70\(c\)](#)

# Production & Process Controls Subsystem

## - Personnel

- Hire sufficient personnel with necessary education, background, training, and experience.
- Establish procedures for identifying training needs and to ensure personnel are adequately trained.
- Document training

[§ 820.25](#)





# **Production & Process Controls Subsystem – Personnel continued**

Make personnel aware of:

- Device defects that could occur from improper job performance and,
- Errors that could be encountered as part of their job.

# Production & Process Control

## Subsystem - Statistical Techniques

- Identify statistical techniques required for the acceptability of processes capability
- Base sampling plans on a valid statistical rationale
- Ensure sampling methods are adequate

[§ 820.250](#)

# Nonconformance Definition

## Nonconformity (820.3(q))

means the nonfulfillment of a specified requirement.

Nonconforming product is product that does not meet specifications

[§ 820.90](#)



# Nonconforming Product

Establish and maintain procedures, including:

- Identification
- Documentation
- Evaluation
- Segregation
- Disposition

Document the evaluation and any investigation

# Nonconforming Product Continued

## Review & Disposition

Document disposition of nonconforming product, including the justification for use and the signature of individual(s) authorizing use, as per your established procedure.

# Nonconforming Product continued

## Review and disposition - Rework

- Establish and maintain procedures for rework, including retesting and reevaluation.
- Document rework and reevaluation activities in the DHR

# **Additional QS requirements not discussed at 2016 REdI**

- Corrective and Preventive Action
- Identification and Traceability
- Acceptance Activities
- Labeling and Packaging Control
- Handling, Storage, Distribution & Installation
- Purchasing Controls
- Servicing

# Summary

- We reviewed the background about the Quality System (QS) Regulation, including some definitions.
- The Quality System has 7 Major Subsystems.
- The Quality System Regulation elaborates on key tasks, such as Records, Documents & Change Controls, Production & Process Controls Subsystem & Nonconforming Product.



# Questions

Please complete the session survey:

[surveymonkey.com/r/DEV-D2S2](https://surveymonkey.com/r/DEV-D2S2)

# Call to Action

- It is your Quality System, own it!
- Have established procedures for all of your QS processes.
- Ensure all documents required by Part 820 are maintained.
- Make use of our educational resources;
  - Review the Quality System training modules in CDRH Learn

