



Overview of the Quality System Regulation for Medical Devices

Tara Goldman, M.Sc.

CSO

Office of In Vitro Diagnostic Device
Evaluation and Safety

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Outline

- Background
- Documents used
- Definitions
- 7 Major Subsystems approach to a Quality System

Background

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

Documents Used:

- Preamble to the final rule published 1996 in the Federal Register
- Title 21, Code of Federal Regulations, Part 820 (21CFR 820)
- “Quality System Information for Certain Premarket Application Reviews: Guidance for Industry and FDA Staff”: 2003
- QSIT Guide

Definition

- Quality System -
Design and manufacture quality into products and includes specific CAPA requirements

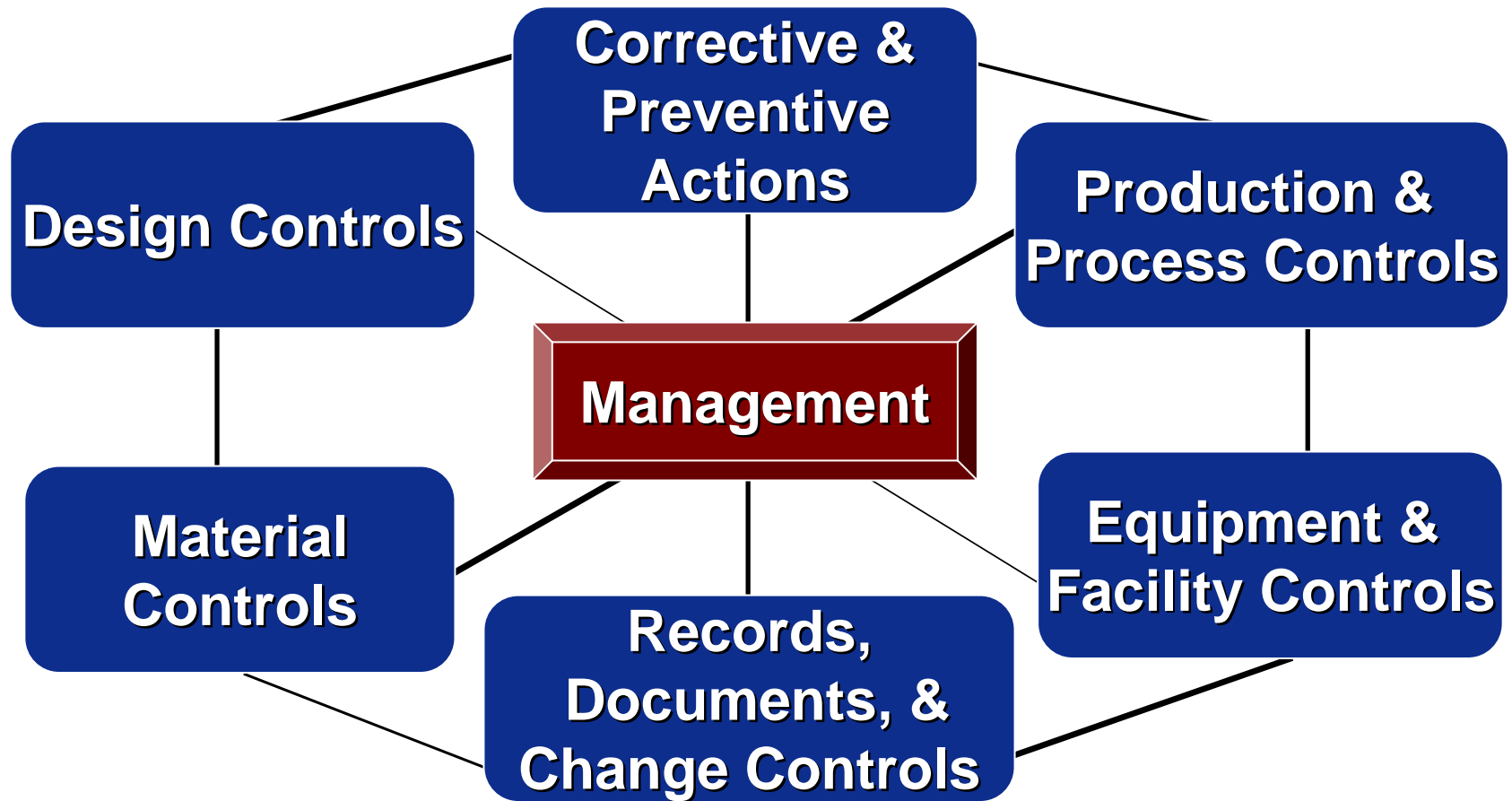


It's your Quality System!

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

7 Subsystems of a Quality System:





“Establish”

21CFR 820.3(k)

- Define

- Document

- Implement (Do)

Management Controls

- Appoint a management representative
- Conduct management reviews
- Ultimately responsible for the entire Quality System

Design Controls, 820.30

- Class II
- Class III
- Class I per 21CFR 820.30(a)(2)

(On June 1, 1997, the Quality System Regulation became effective)

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."

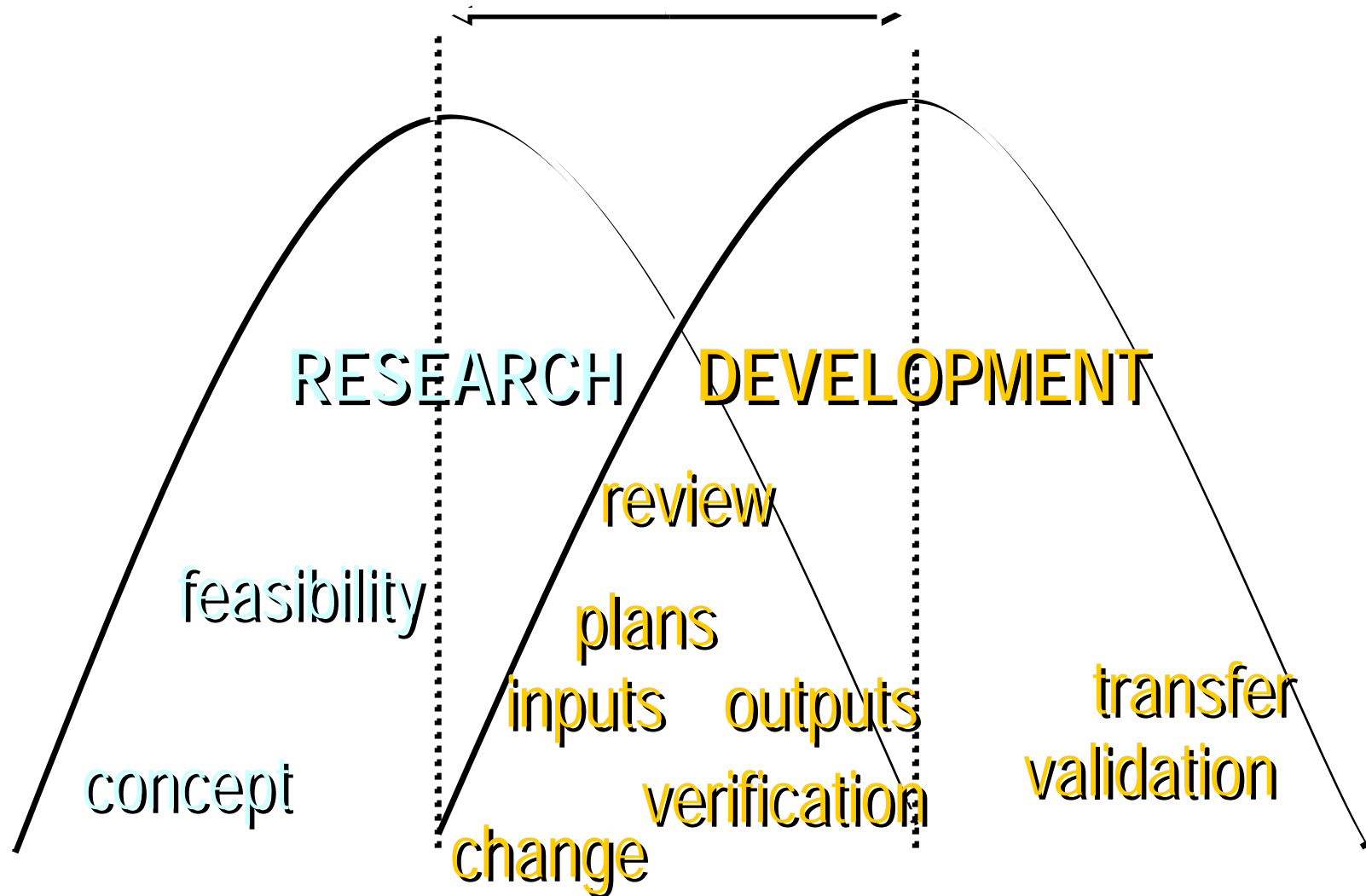
(Preamble p. 52616, response to comment #64)



Anything else?

“Procedures must ensure that after the design requirements are established and approved, changes to the design, both pre-production and post-production are also reviewed, validated (or verified where appropriate), and approved.”

Application of Design Controls



Design Inputs

- Design Input means the physical and performance requirements of a device that are used as a basis for device design
- Ensure requirements are appropriate and address intended use of a device and the needs of the user

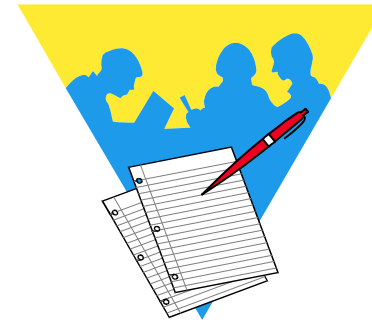
Design Output

- Design output means the results of a design effort at each phase and the end of the total design effort
- Consists of the device, its packaging and labeling, and the device master record

Design Reviews



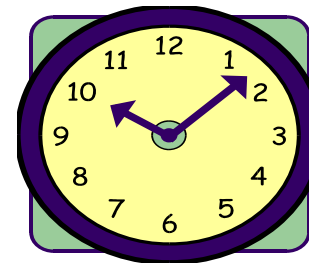
Purpose



Participants



Timing



Design Verification vs. Design Validation

■ Design *Verification*...

- Are the product specifications being met and can I prove it?

■ Design *Validation*...

- Is the product meeting user needs and intended uses for all specifications, even after remanufacturing, and can I prove it?

Design Validation vs. Process Validation

- *Process Validation...*
 - Does the process consistently produce a result or product meeting predetermined specifications and can I prove it?



Design Transfer

- Ensure the device design is correctly translated into production specifications

Design Changes

- Identify, document, validate or where appropriate verify, review and approve changes before implementation

Production and Process Controls 820.70

- Develop processes that are adequate to produce devices that meet specifications and validate those processes if results cannot be fully verified by subsequent inspection and test
- Monitor and control the manufacturing processes

Plus...

- Purchasing 820.50
- Acceptance 820.80
- Buildings & Equip.
- Calibration 820.72
- Personnel
- Statistical Techs 820.250
- Others

Purchasing Controls 820.50

- Establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements
- Evaluate suppliers, contractors and consultants

Purchasing Controls

- Establish and maintain purchasing data/documents that describe or reference specified requirements (including notification of change agreements)
- Approve purchasing data/documents

Purchasing Controls

- GHTF Draft Proposed Guidance: “Quality management system-Medical Devices-Guidance on the control of products and services obtained from suppliers”
 - A product or service is one which is purchased or otherwise received by the manufacturer
 - A supplier is anyone that is independent from the manufacturer’s quality management system.

Purchasing Controls

- An internal supplier:
 - Part of the manufacturer's organization
 - Operates under a separate quality management system
 - Not part of the manufacturer's internal audit scope (quality audit)
- Internal suppliers are to be controlled in a similar way as external suppliers

Corrective and Preventive Action 820.100

- Collect and analyze data to identify nonconforming product and other quality problems
- Investigate cause
- Identify and implement corrective and preventive action

Corrective and Preventive Action

- Verify or validate effectiveness
- Communicate information about quality problems to staff
- Forward information for management review

Who is responsible...

“FDA emphasizes that it is always **management’s** responsibility to ensure that all nonconformity issues are handled appropriately.”

Preamble, Comment #165


Correction vs. Corrective Action

“*Correction*” refers to repair, rework, or adjustment and relates to the disposition of an **existing** nonconformity

“*Corrective action*” relates to the elimination of the **causes** of an existing nonconformity

“Healthy” CAPA subsystem procedures include provisions to ...

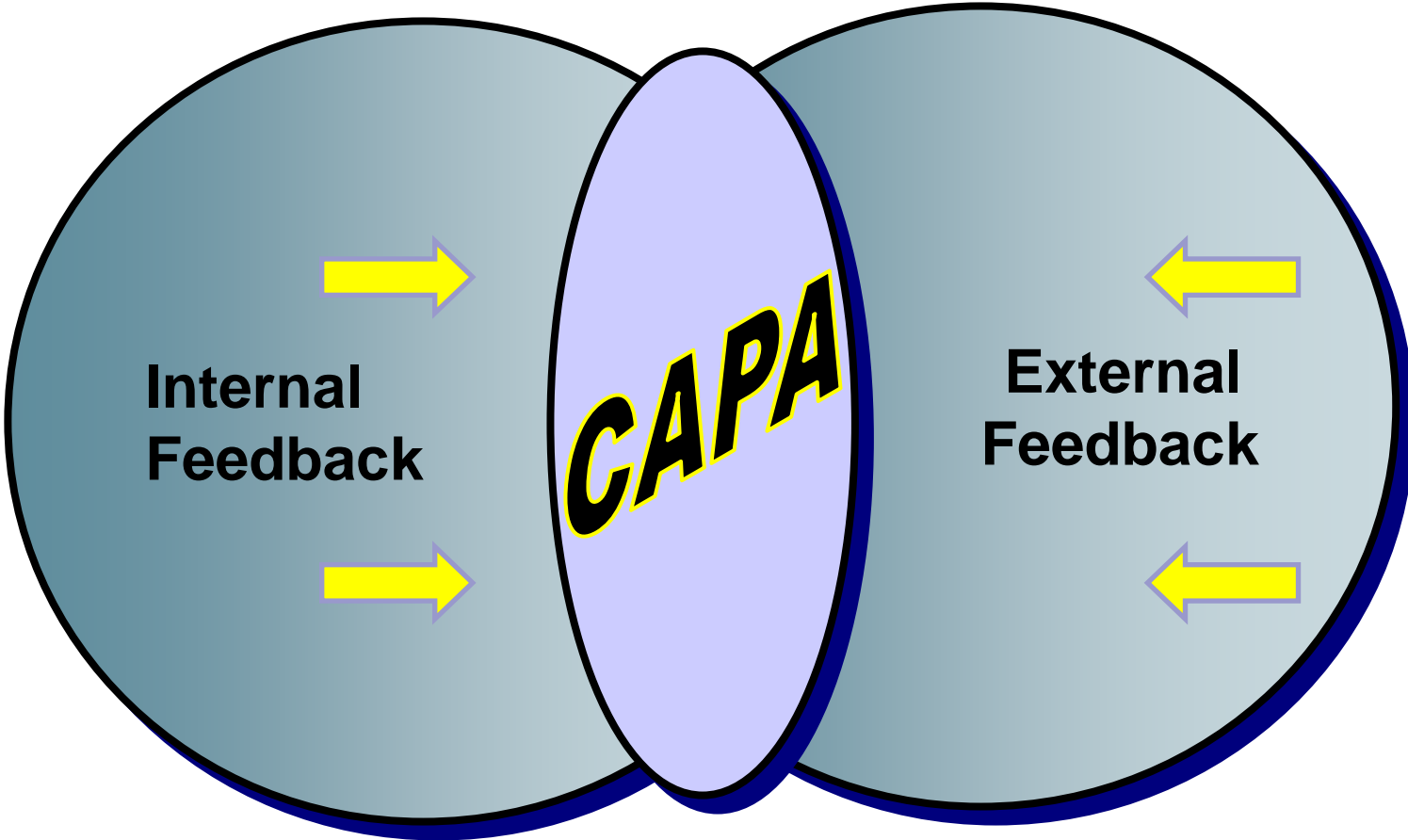
- Identify and correct existing nonconforming product or other quality problems (“Correction”);
- Identify and eliminate the causes of existing nonconforming product and other quality problems (“Corrective Action”); and



“Healthy” CAPA subsystem
procedures include provisions to ...

- Identify and eliminate the causes of **potential** nonconforming product and other quality problems (“Preventive Action”)

Quality Data Sources



Seeking Quality Data

- Solicit feedback to support continuous improvement
 - *Customer Feedback*
 - *Employee Feedback*



CAPA Program

- Identify data sources
- Document the problem
- Establish a priority system
 - ***consider impact / risks and select items with major impact***
 - ***proceed to items with less impact***

CAPA Program

- Verification and Validation
 - ***analysis of data may lead to more than one solution, assure solution is appropriate***
- Implementation
 - ***tracking for on-time completion***

CAPA Program

- Documentation and follow-up
 - *corrective action effective*
 - *adverse effect on product*
 - *records*
- Communicate changes
 - *to those directly responsible*
 - *management review*

For Further Information

- General

- www.fda.gov/cdrh/index.html

- Quality System Regulation

- www.fda.gov/cdrh/fr1007ap.pdf

- QSIT Guide

- www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.pdf



Thank you.....

Kimberly Trautman

FDA's Medical Device Quality Systems Expert,
Office of Compliance
kimberly.trautman@fda.hhs.gov

Jan Welch

QS/GMP Expert, Office of Compliance
jan.welch@fda.hhs.gov