Overview of the Quality System Regulation for Medical Devices

FDA Small Business

Regulatory Education for Industry (REdI)

Silver Spring, MD

September 30, 2015

Tonya A. Wilbon

Quality System Specialist

Office of the Director

Office of In Vitro Diagnostics and Radiological Health

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Online Poll #1

Learning Objectives

- Provide background information about the Quality System Regulation
- Indicate documents used to establish a quality system
- Review Definitions
- Explain the 7 Major Subsystems approach to a Quality System

Background

The Quality System Regulation

- Effective June 1, 1997
- Replaces the 1978 GMP Regulation for medical devices
- Preamble to the 1997 regulation - VERY Important

Background *cont.*

The 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

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
- Compliance Program (7382.845)

Definitions

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

Definitions *cont.*

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.

Definitions *cont.*

Quality System [21 CFR 820.3(v)]:

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

Definitions *cont.*

Quality Control:

Test/inspect components/finished products vs approved specifications

Quality Assurance:

Manufacture quality into product

Definitions *cont.*

Establish [21 CFR 820.3(k)]:

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

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

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 QS commensurate with:

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

7 Subsystems of a Quality System

4 Major Subsystems

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

Management Controls Subsystem

Purpose:

- Provide adequate resources
- Ensure the establishment and effective functioning of the quality system
- Monitor the quality system and make necessary adjustments

Management Controls Subsystem *cont.*

Requirements:

- Establish a quality policy, objectives, and organizational structure
- Establish appropriate responsibility and authority
- Appoint a management representative
- Provide adequate resources

Management Controls Subsystem *cont.*

Requirements:

- Conduct management reviews
- Establish a quality plan and quality system procedures
- Conduct quality audits
- Have sufficient personnel with necessary education, background, training and experience

Management Controls Subsystem *cont.*

"It is without question management's responsibility to undertake appropriate actions to ensure that employees understand management's policies and objectives."

(Preamble page 52612, response to comment #45)

Design Controls Subsystem

Purpose:

- Control the design process
- Assure the device design meets user needs, intended uses, and specified requirements

Design Controls Subsystem *cont.*

Requirements:

- Establish a plan that describe or reference design and development activities
- Identify design inputs
- Develop design outputs
- Verify that design outputs meets design inputs
- Validate the design (include software validation and risk analysis)

Design Controls Subsystem *cont.*

Requirements:

- Control design changes
- Review design results
- Transfer the design to production
- Compile a design history file

Design Controls Subsystem *cont.*

Apply to:

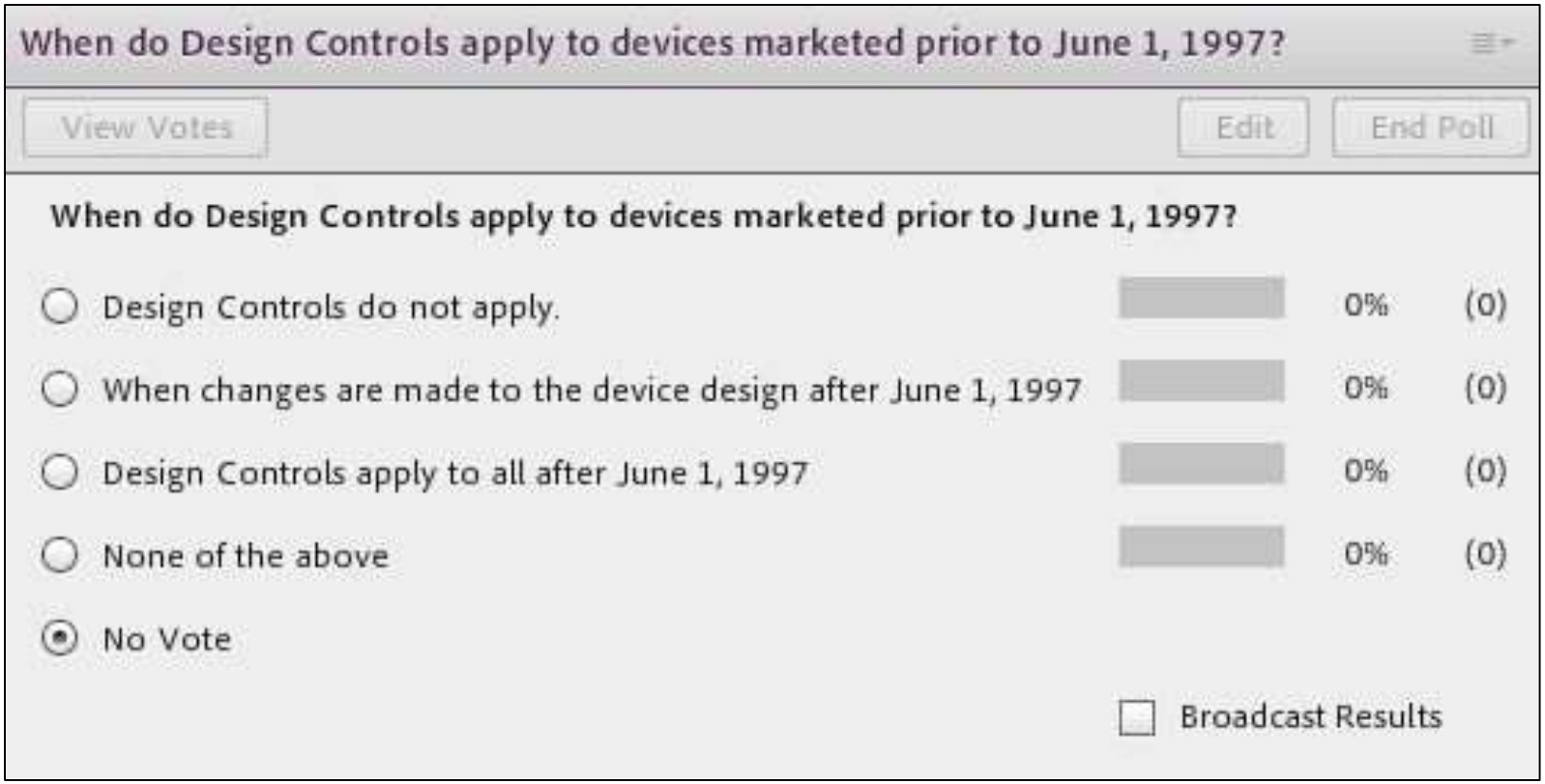
- Class II
- Class III
- Class I per 21 CFR 820.30(a)(2)

Design Controls Subsystem *cont.*

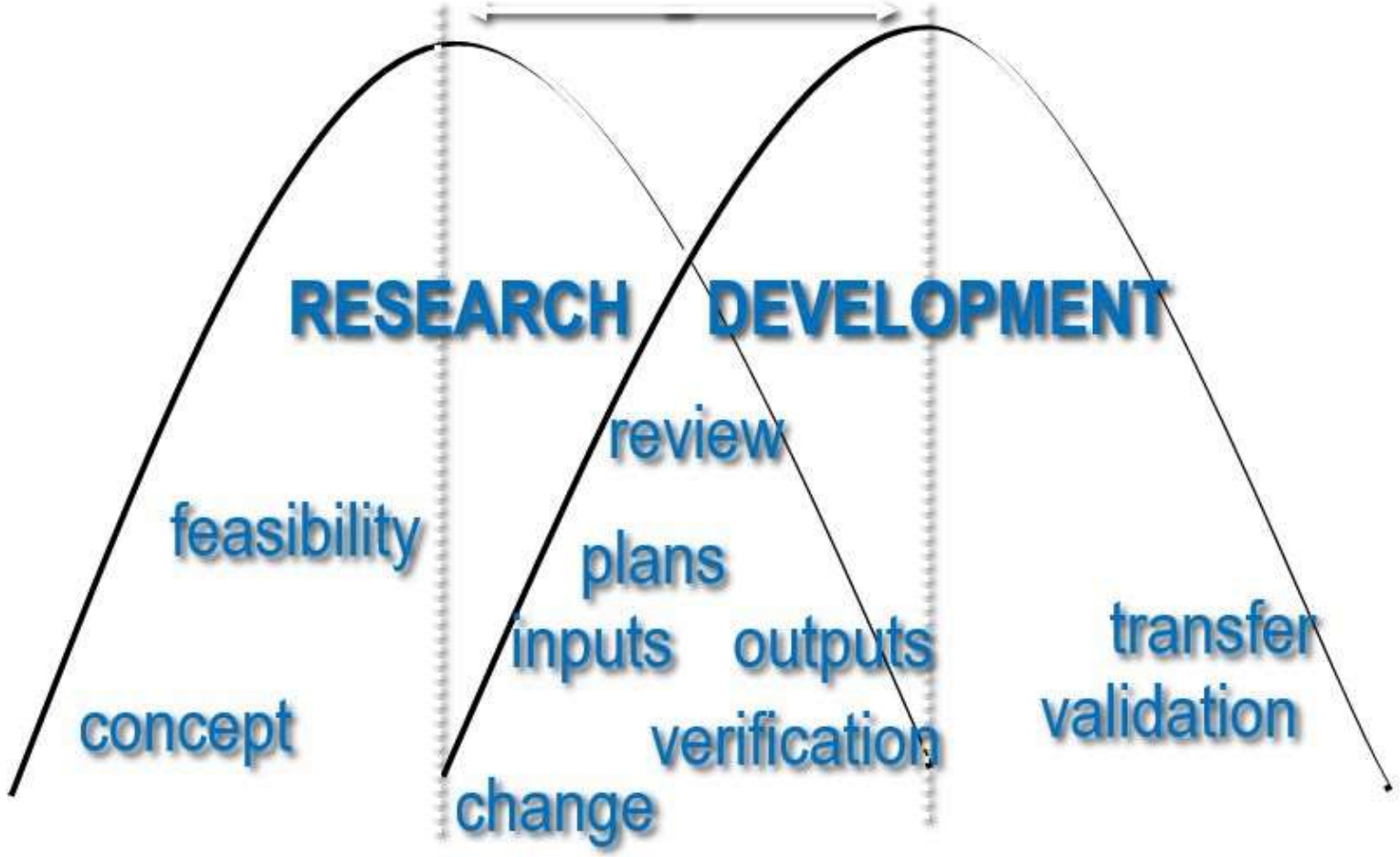
Design Controls DO apply to products being reused

- Must back engineer the devices' design
- Must design the process to meet device specifications

Online Question



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

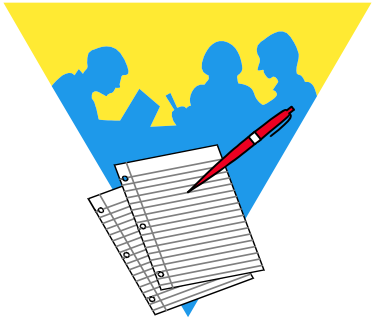
Design Output

- 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

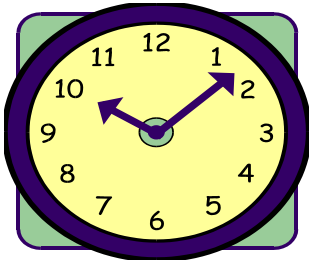
Design Reviews

- **Purpose**



- **Participants**

- **Timing**



Design Verification

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

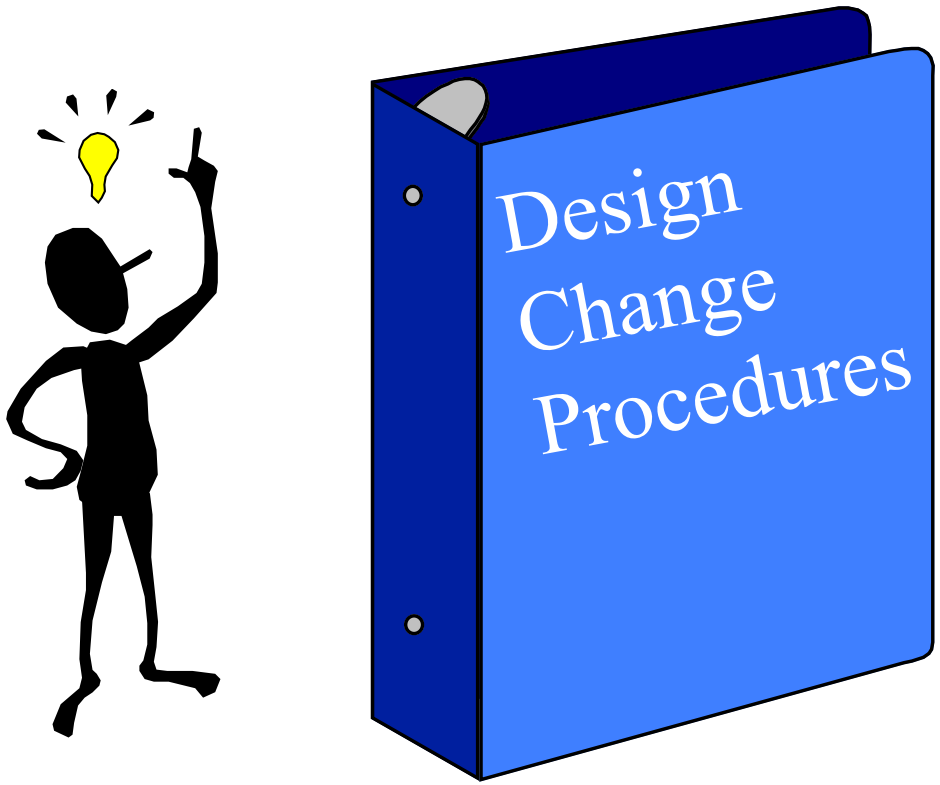
Process Validation…

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

Define and Document Design Change Procedures



Design Controls Helpful Hints...

- Understand the jargon
- Use the results of Risk Analysis and Risk Management tools throughout the design control process

Production and 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

Production and Process Controls Subsystem *cont.*

Requirements:

- Develop, conduct, control, and monitor production processes to ensure device conforms to its specifications

Production and Process Controls Subsystem *cont.*

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

Production and Process Controls Subsystem *cont.*

Requirements:

- 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

Production and Process Controls Subsystem *cont.*

Requirements:

- Validate processes where the results of the process cannot be fully verified by subsequent inspection and test
- Validate computer software for its intended use when used as part of production or the quality system

Automated Processes

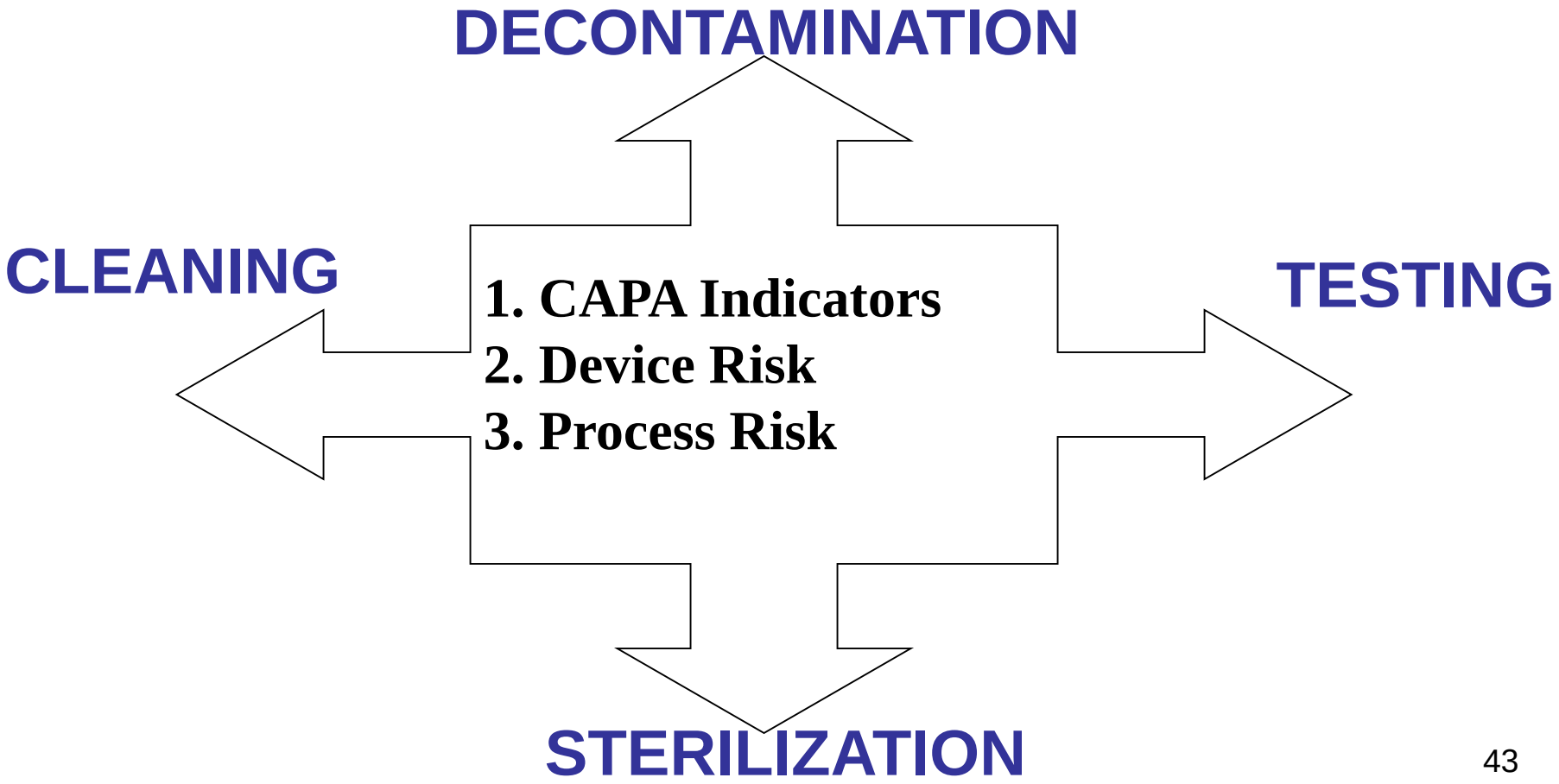
- ✓ Requirements
- ✓ Validation Protocol
- ✓ Validation Activities
- ✓ Validation Results
- ✓ Change Controls

Production and Process Controls Subsystem *cont.*

Requirements:

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

Production and Process Controls Subsystems *cont.*



Corrective and Preventive Action Subsystem

Purpose:

- Collect and analyze information/data
- Identify and investigate product and quality problems
- Identify and implement effective corrective and preventive action

Corrective and Preventive Action Subsystem *cont.*

Purpose:

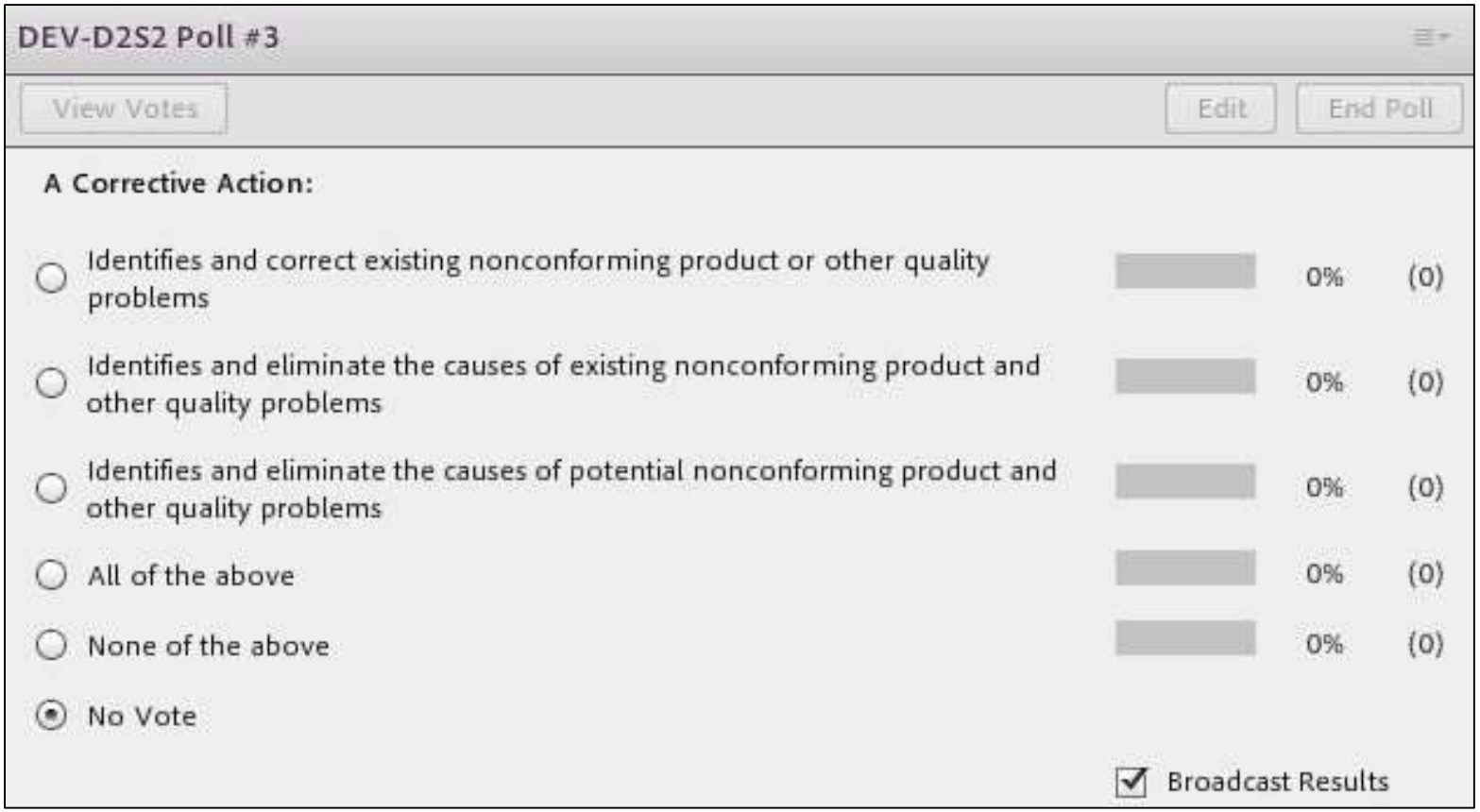
- Verify or validate corrective and preventive actions
- Communicate corrective and preventive actions to appropriate personnel
- Provide information for management review
- Document these activities

Have the CAPA requirements been "established"?

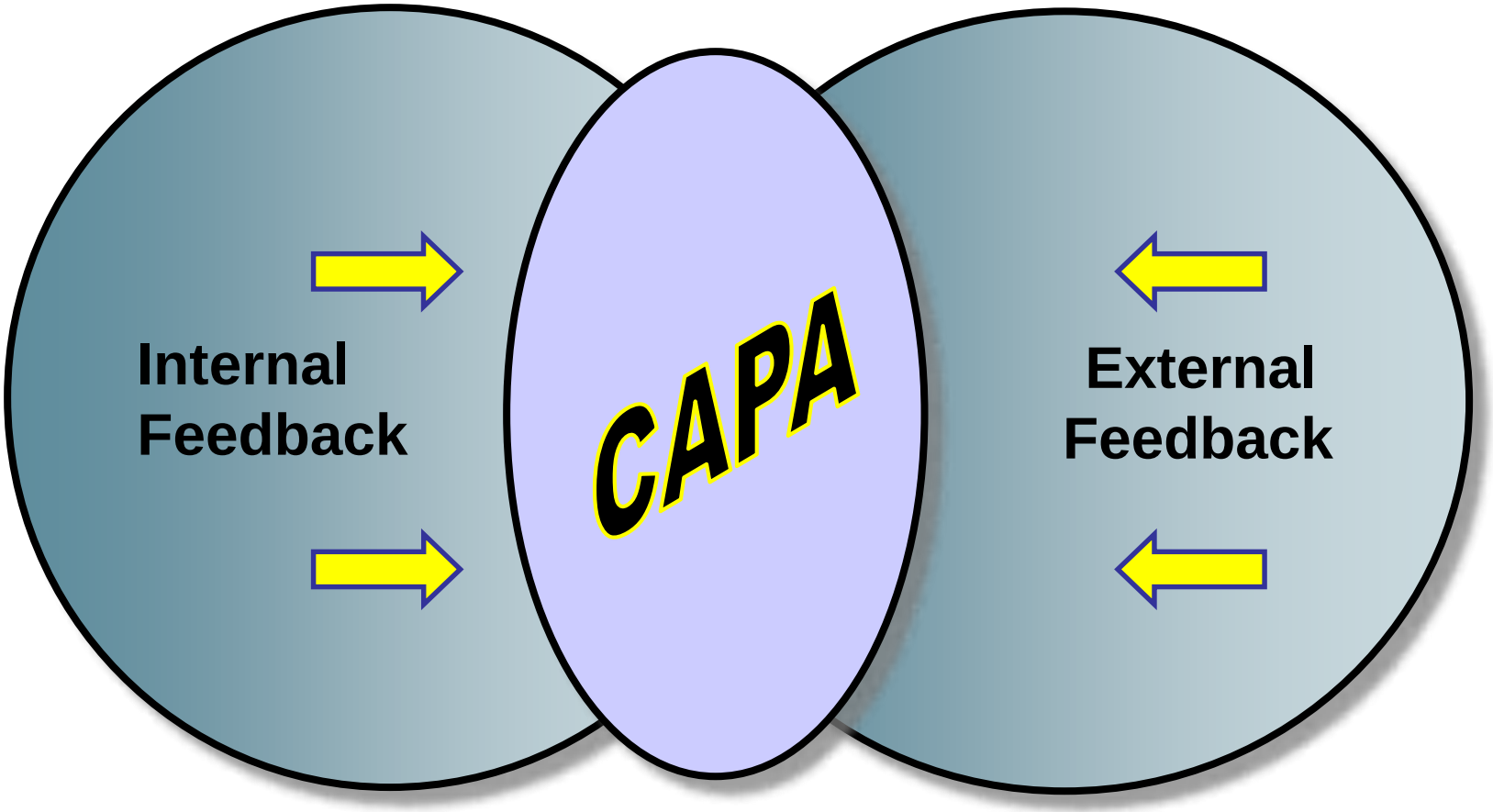
- ✓ Defined
- ✓ Documented
- ✓ Implemented

§820.3(k)

Online Question



Quality Data Sources



Internal Data Sources

- Acceptance Activities
- (Inspection and Test Data)
  - ***component, in-process and final test***
- Nonconforming product
  - ***scrap, rework, UAI***
- Process monitoring
  - ***process control data, control charts, SPC***

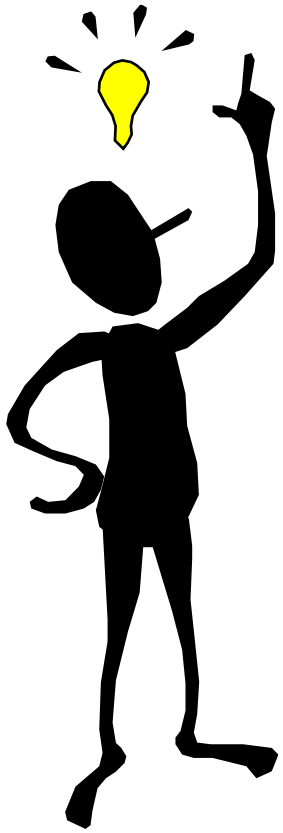
External Data Sources

- Complaints & MDRs
- Servicing
  - ***warranty, non-warranty***
  - ***field service reports***
  - ***returns***
- Recalls
- Legal Claims

Seeking Quality Data

Solicit feedback to support continuous improvement

- ***Customer Feedback***
- ***Employee Feedback***
- ***ISO 9001:2007***
- ***Principles of Quality Management***

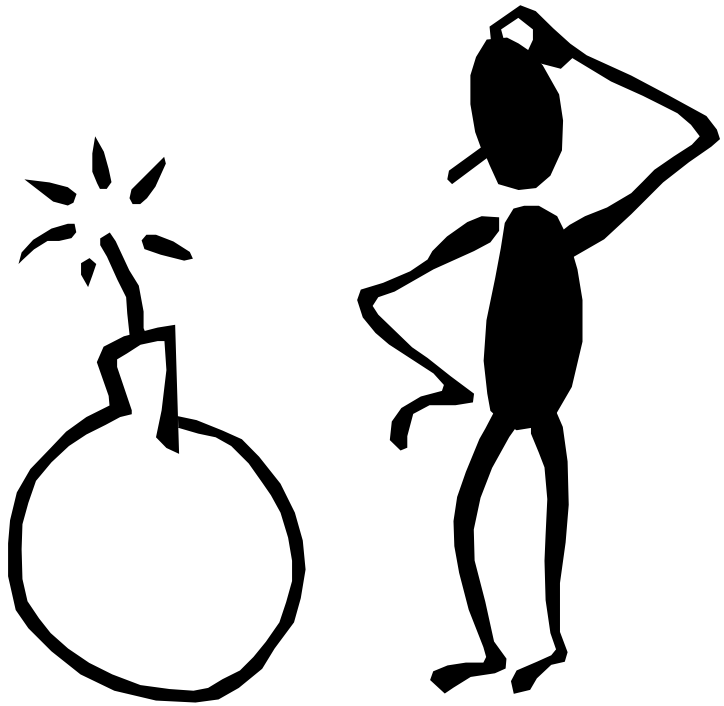


CAPA Program

- ***PRO*** active

  vs.

- ***RE*** active



CAPA Program *cont.*

- 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 *cont.*

- Analyze the problem
  - ***root cause analysis***
- Develop an action plan
  - ***consider impact and need for action***
  - ***immediate action (correction)***
  - ***short term corrective action***
  - ***long term corrective action***

CAPA Program *cont.*

- 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 *cont.*

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

Close the loop...

Summary

- Medical device manufacturers must comply with Quality System Regulation
- Several documents available as a resource
- Understand the terminology being used
- Basic foundation of a firm's quality system:
  - Management Controls
  - Design Controls
  - Production and Preventive Action
  - CAPA are

Industry Education Resources

1. **CDRH Learn – Multi-Media Industry Education**
   - over 80 modules
   - videos, audio recordings, power point presentations, software-based "how to" modules
   - mobile-friendly: access CDRH Learn on your portable devices

   http://www.fda.gov/Training/CDRHLearn

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2014 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm

Questions?

Please complete the session survey:

surveymonkey.com/r/DEV-D2S2