Overview of the Quality System Regulation for Medical Devices

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Outline

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

Background

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- 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

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- 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:

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- **Quality Control:**

  Test/inspect components/finished products vs approved specifications

- **Quality Assurance:**

  Manufacture quality into product

Definitions *cont*.:

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

Bottom line …
It's your Quality System!

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

- risk presented by the device

Bottom line …
It's your Quality System!

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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:

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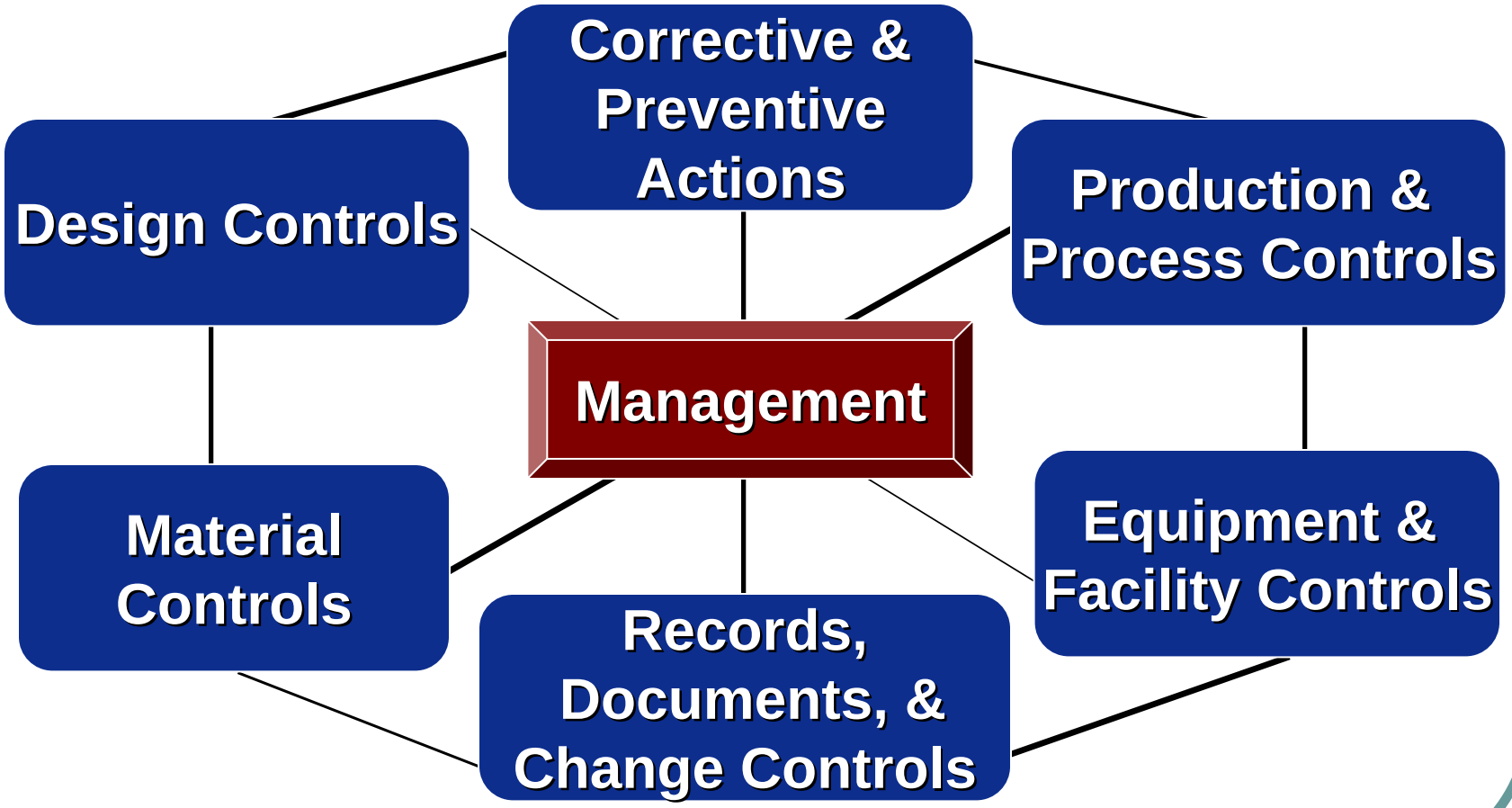

“Establish” 21CFR 820.3(k)

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- Define
- Document
- Implement (Do)

Management Controls

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

Design Controls

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

(The Quality System Regulation became effective on June 1, 1997)

Design Controls *cont.*

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- Design Controls DO apply to products being reused
- Must back engineer the devices design
- Must design the process to meet device specifications

CHANGES…

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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?

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“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

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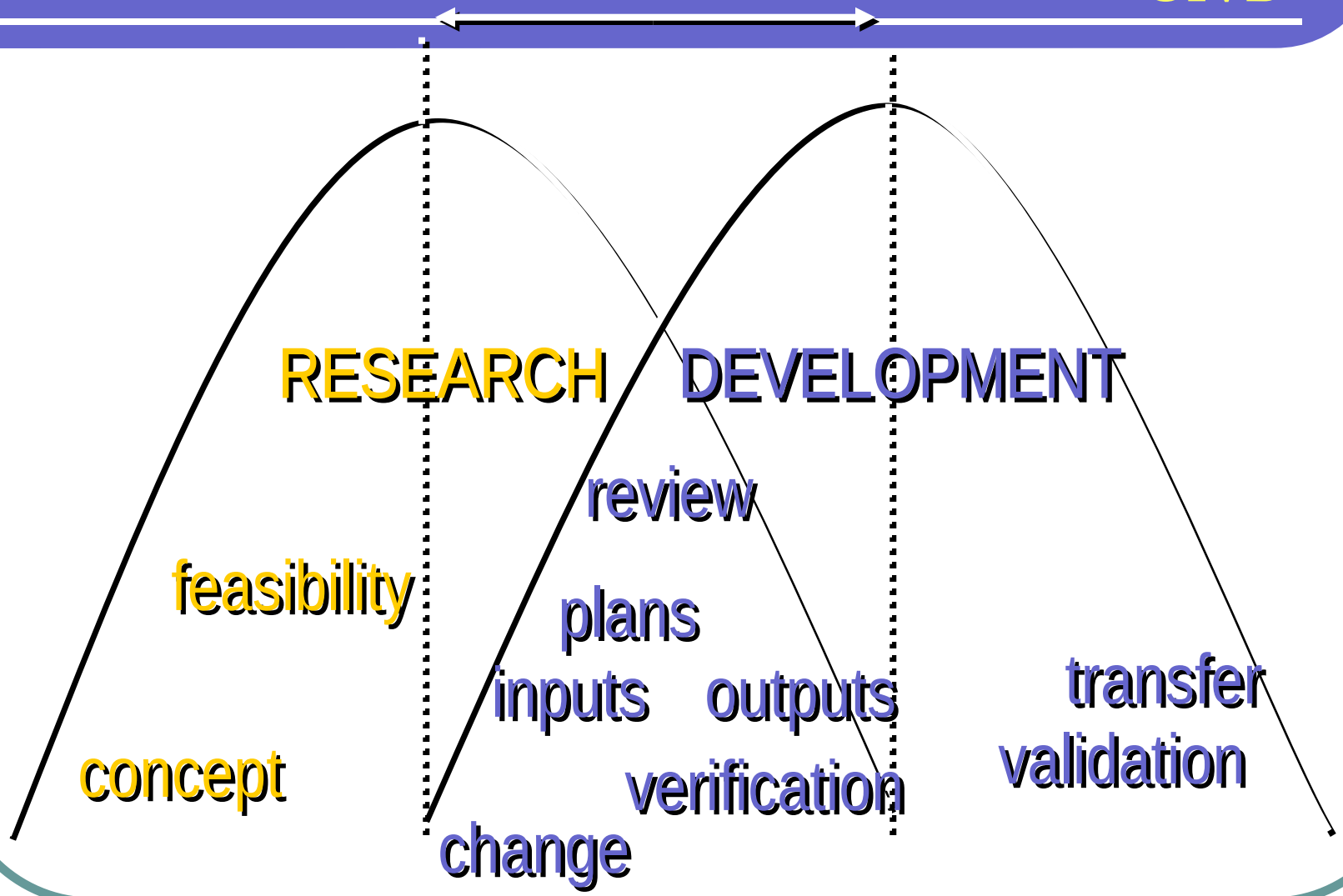

Design Inputs

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- 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

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- 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

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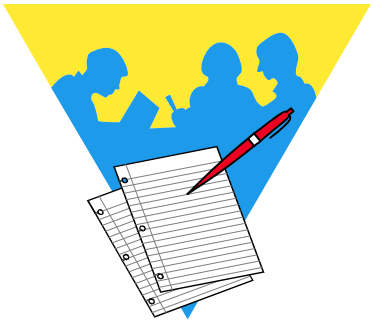
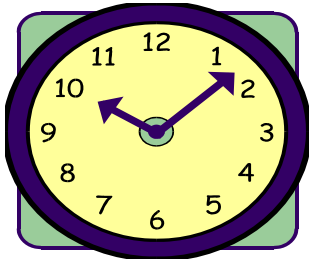
- **Purpose**



- **Participants**

- **Timing**



Design Verification

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Design *Verification*…

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

Design Validation

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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

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Ensure the device design is correctly translated into production specifications

Define and Document Design Change Procedures

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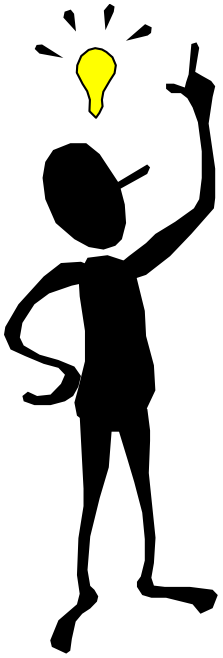

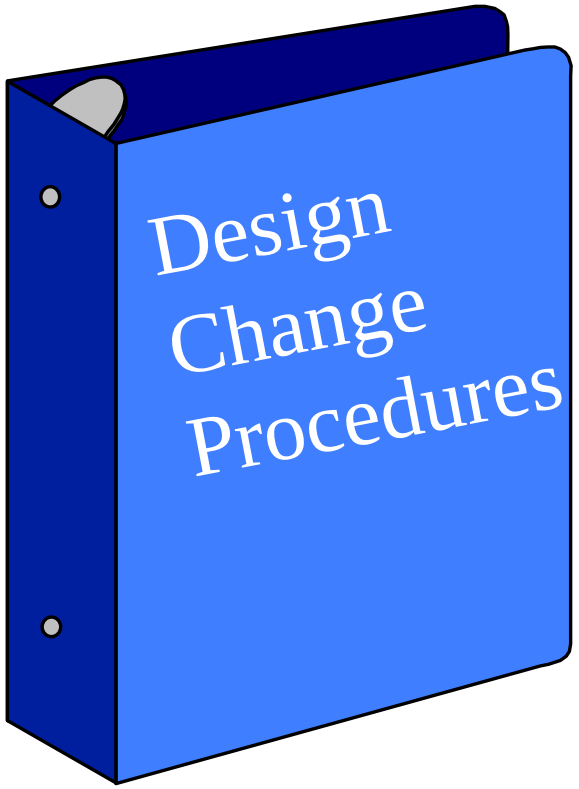

Design Controls Helpful Hints...

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

Production and Process Controls

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- 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

Production and Process Controls

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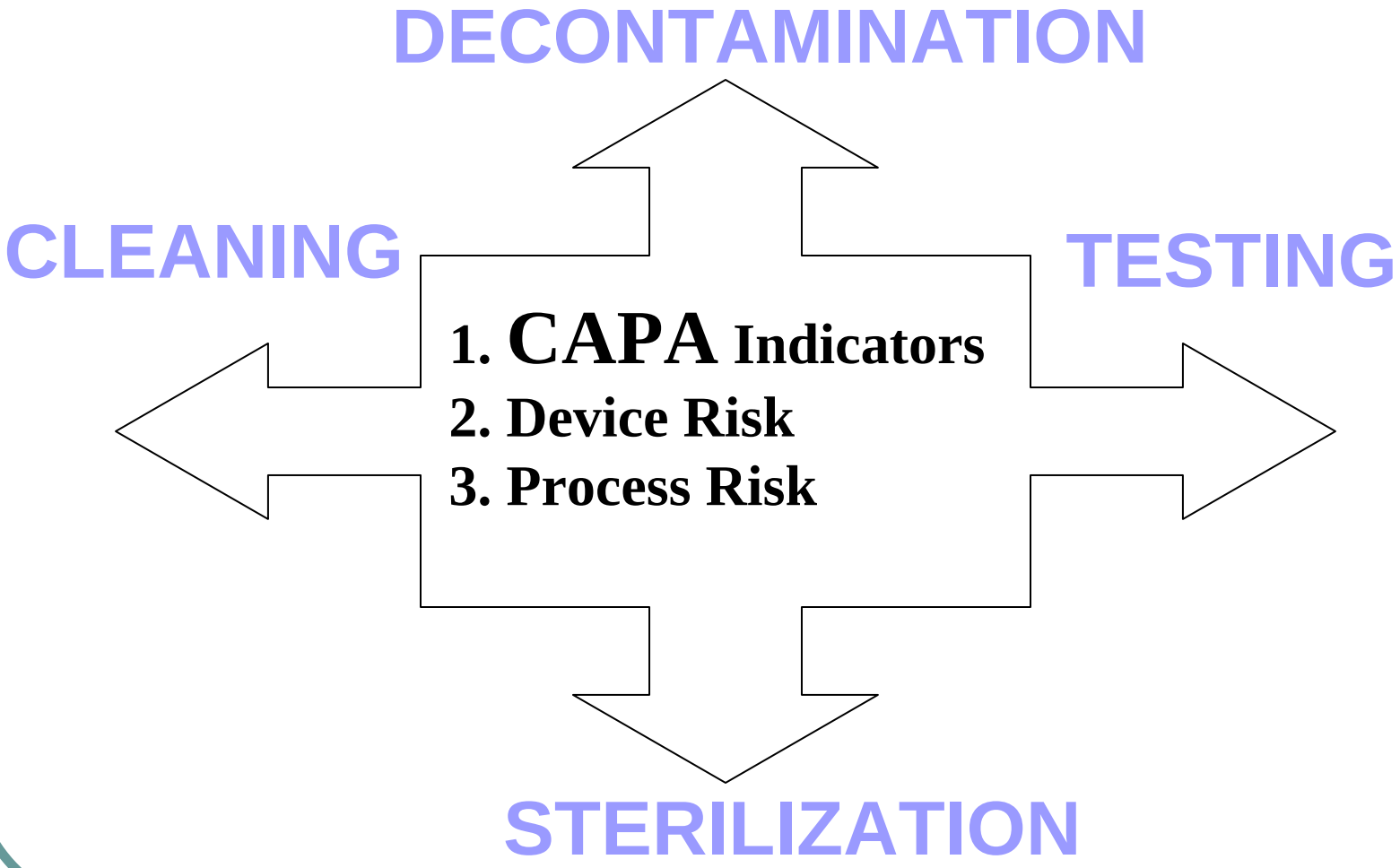

Plus...

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- Purchasing
- Acceptance
- Buildings & Equip.
- Calibration
- Personnel
- Statistical Tech.’s
- Others

Automated Processes

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

Purchasing Controls

- 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

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

Purchasing Controls

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GHTF Draft Proposed Guidance: “Quality management system-Medical Devices-Guidance on the control of products and services obtained from suppliers”

Purchasing Controls *cont.*

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- For GHTF document, 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 *cont.*

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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)

Purchasing Controls *cont.*

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Internal suppliers are to be controlled in a similar way as external suppliers

Corrective and Preventive Action

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- 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 *cont.*

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

Have the CAPA requirements been "established"?

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- ☑ **Defined**
- ☑ **Documented**
- ☑ **Implemented**

§820.3(k)

Who is responsible...

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"FDA emphasizes that it is always **management's** responsibility to ensure that all nonconformity issues are handled appropriately."

Preamble, Comment #165

Correction **vs.** Correction Action

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- ***"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 …

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1. **Identify and correct existing nonconforming product or other quality problems (“Correction”);**

2. **Identify and eliminate the causes of existing nonconforming product and other quality problems (“Corrective Action”); and**

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

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

Quality Data Sources

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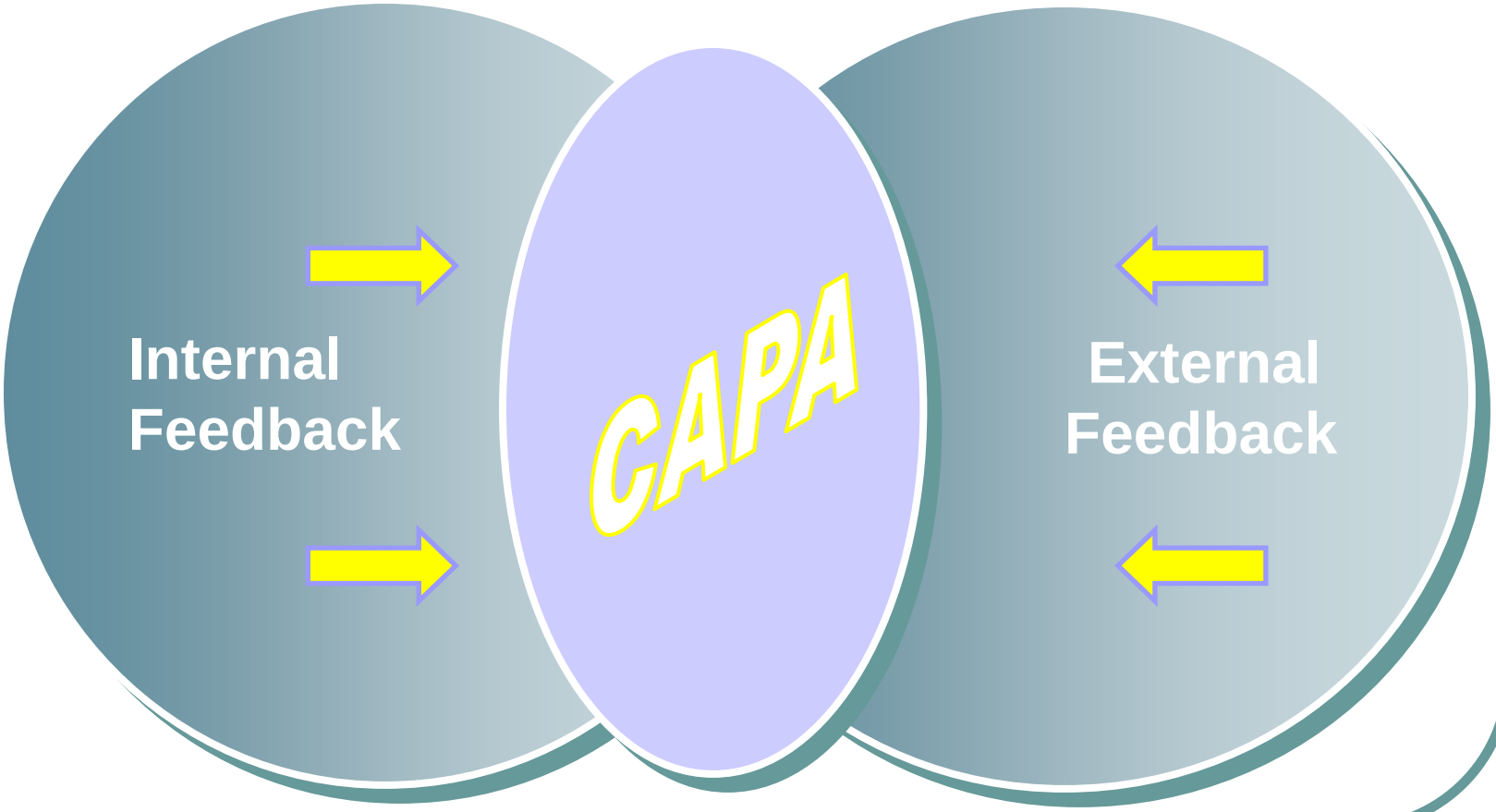

Internal Data Sources

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- 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***

Internal Data Sources *cont.*

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- Equipment monitoring
  - ***calibration, maintenance***
- Device History Records
- Change Control Records
- Quality Audit Reports
  - ***Internal Audits***
  - ***3rd Party Audits (ISO, FDA)***
  - ***Management Review Results***
  - ***Supplier Audits***

External Data Sources

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

Seeking Quality Data

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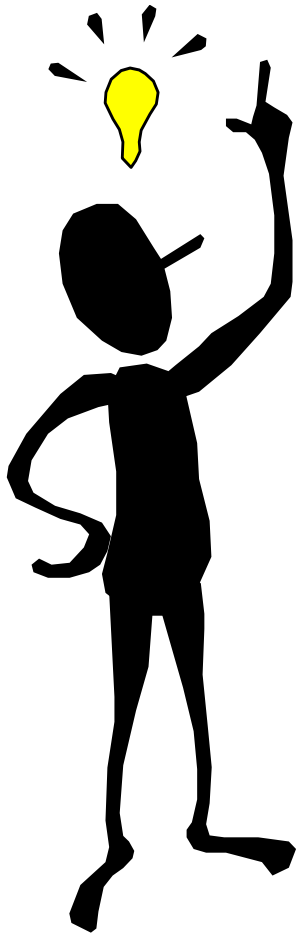
- Solicit feedback to support continuous improvement
  - ***Customer Feedback***
  - ***Employee Feedback***
  - ***ISO 9001:2007***
  - ***Principles of Quality Management***



CAPA Program

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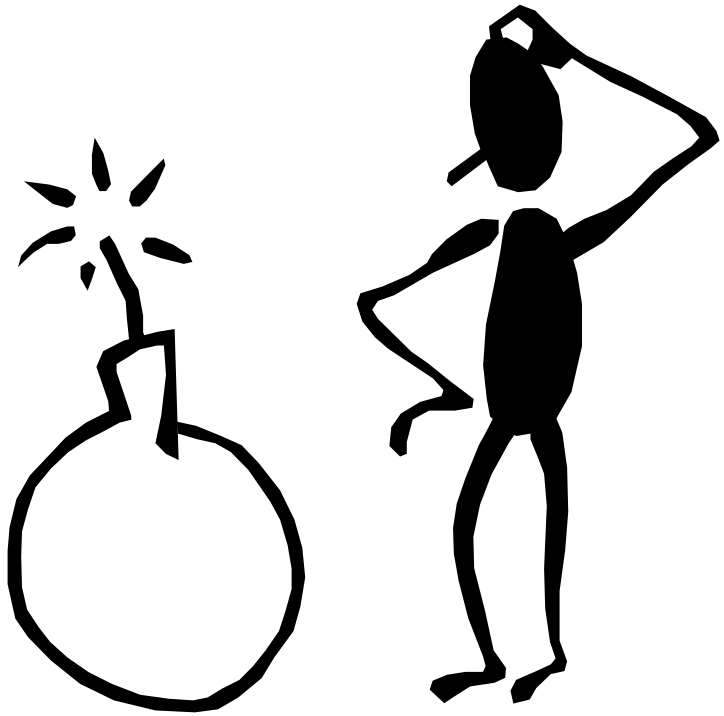
- ***PRO*** active

  vs.

- ***RE*** active



CAPA Program *cont.*

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- 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.*

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

CAPA Program *cont.*

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- 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...

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References

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- 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…….

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