

# Quality System Regulation 21 CFR 820 Basic Introduction

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# Overview

- Background
- Definitions
- Subsystems
  - Management
  - Design and Development Controls
  - Production and Process Controls
  - Corrective and Preventive Actions
- Resources

# 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

# Quality Management System

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

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

# Quality System Regulation

## **820.3 Definitions**

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

# Quality System Regulation

## **820.3 Definitions**

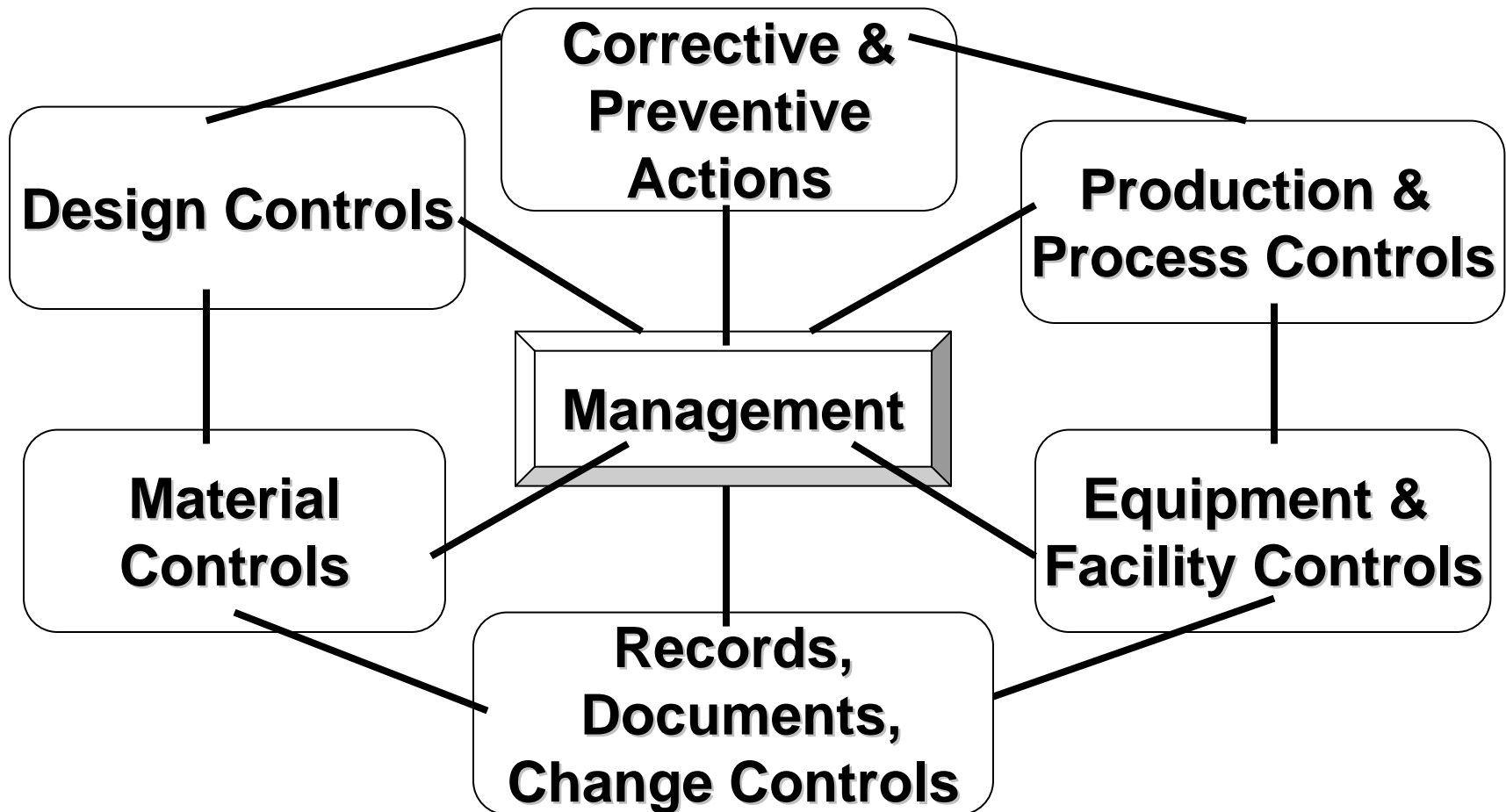
Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

# Quality System Regulation

## 820.3 Definitions

Manufacturer 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, repacking, or specification development, and initial distributors of foreign entities performing these functions.

# Quality Management Subsystems





# Management Subsystem

820.20 Management Responsibility

820.22 Quality Audits

820.25 Training

# 820.20 Management Responsibility

## Quality Policy.

- Must be established by management with executive responsibility.
- Must be understood, implemented, and maintained at all levels of the organization.

# 820.20 Management Responsibility

Must establish and maintain an adequate organizational structure, including

- Appropriate responsibility, authority, and interrelation of personnel
- Adequate resources
- Appointed management representative

# 820.20 Management Responsibility

## Management Review

Management with executive responsibility shall review the suitability and effectiveness of the quality system

- At defined intervals
- With sufficient frequency
- According to established procedures

# 820.20 Management Responsibility

## Management Representative

- Member of management.
- Responsible for ensuring establishment of quality system and reporting on quality system performance to management with executive responsibility.

# 820.22 Quality Audit

- Establish procedures for quality audits.
- Conduct audits to assure compliance by individuals not having direct responsibility for areas audited.

# 820.22 Quality Audit

- Perform corrective action(s), including reaudit of deficiencies.
- Generate a written report of audit results for management review.

# 820.25 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 Personnel

- Make personnel aware of device defects that could occur from improper job performance.
- Make personnel aware of defects and errors that could be encountered as part of their job.

# Design and Development Subsystem

- 820.30 Design Controls
- 820.70(b) Production and Process Changes
- 820.181 Device Master Record
- 820.250 Statistical Techniques

# 820.30 Design Controls

- Since 1984, the FDA has identified lack of design controls as one of the major causes of device recalls.
- The SMDA provided the FDA with the authority to add preproduction design controls to the device GMP regulation.

# 820.30 Design Controls

- The design control requirements are not intended to apply to development of concepts and feasibility studies.

*Preamble #62*

- FDA will evaluate the process, the methods, and the procedures that a manufacturer has established to implement the requirements for design controls.

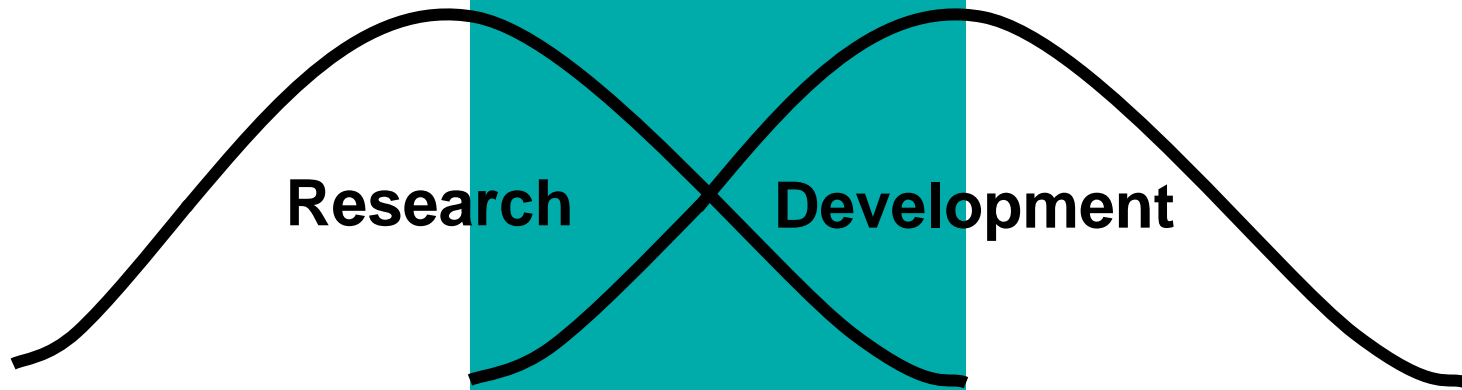
# 820.30 Design Controls

- The FDA has amended the IDE regulation, reaffirming that an IDE device is exempted from complying with the GMP's ... with the exception of Sec. 820.30 "Design Controls."
- FDA will not inspect design controls during bioresearch monitoring inspections.

# 820.30 Design Controls

Applicable to all class II and III and the following class I devices

- Devices automated with computer software
- Tracheobronchial suction catheters
- Surgeon's gloves
- Protective restraints
- System, radionuclide applicator, manual
- Source, radionuclide teletherapy



**Research**

**Development**

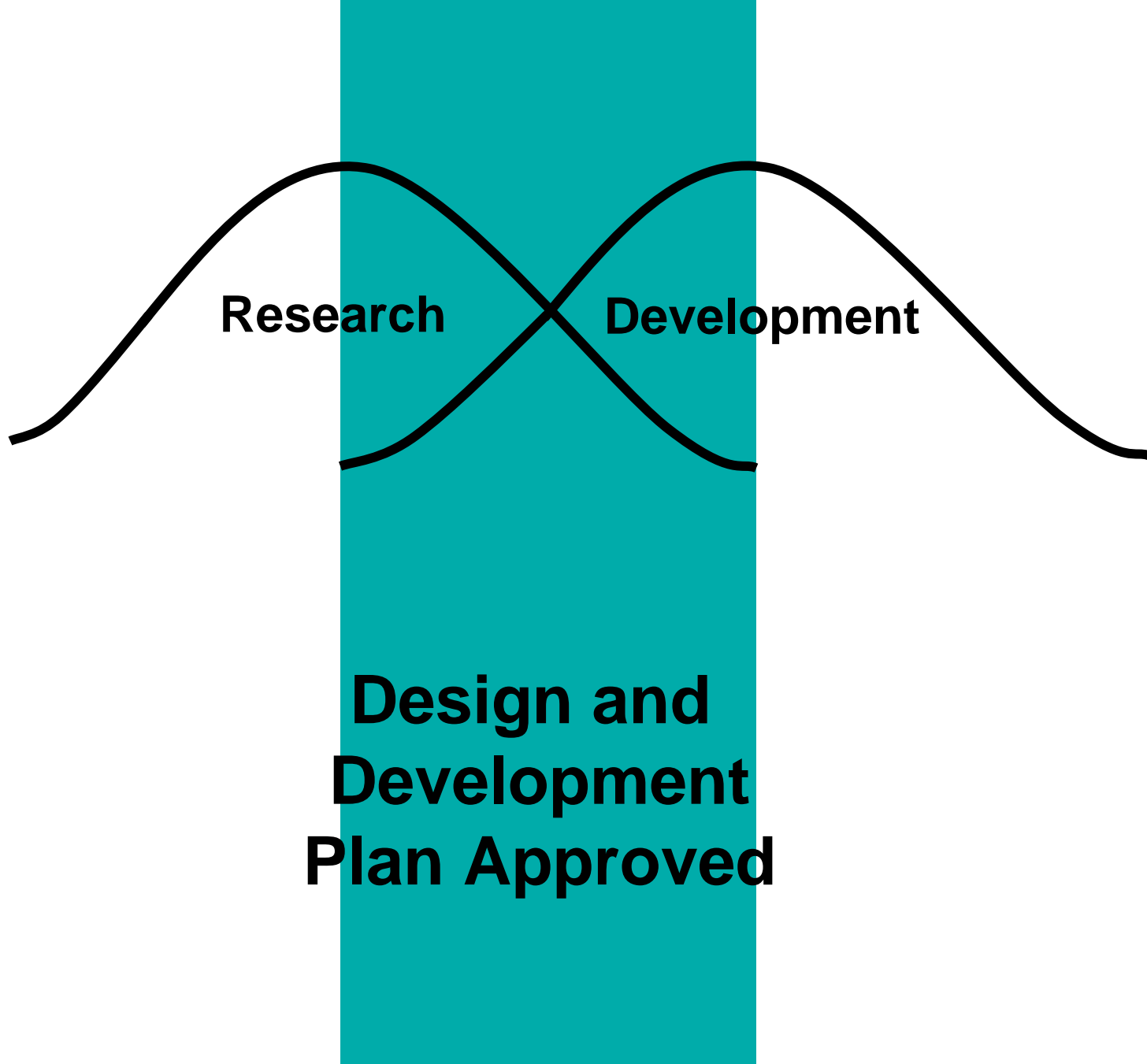
**Formal Design  
Controls Begin**

# Design and Development Planning

Describe design and development activities.

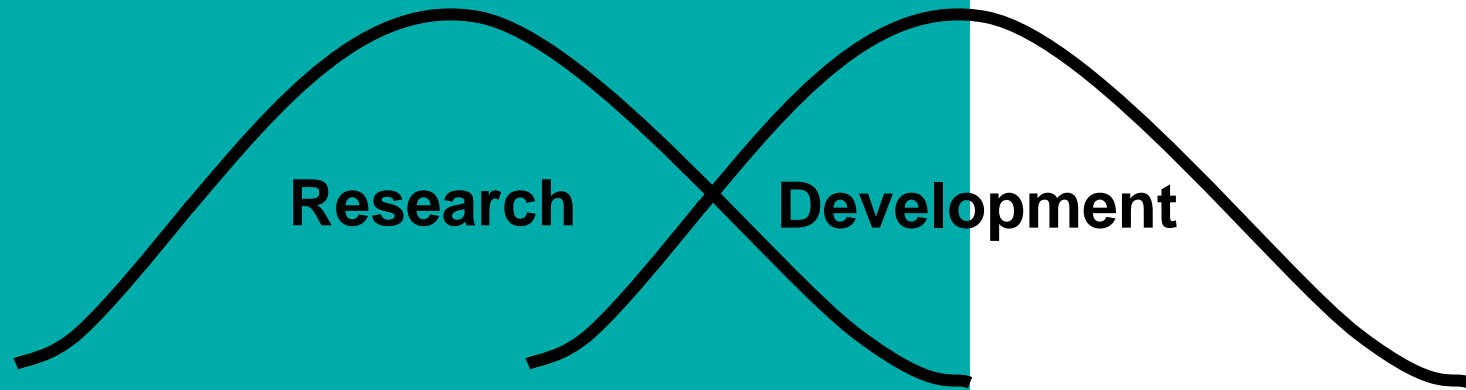
- Define responsibility for implementation.
- Identify and describe interfaces between different groups or activities.
- Review, update, and approve plans as design and development evolves.





# Design Input

- Ensure requirements are appropriate and address intended use of device.
- Address incomplete, ambiguous, or conflicting requirements.
- Document, review, and approve input requirements.



**Design Inputs  
Initially Developed  
and Approved**

# Design Output

- Define and document design output in terms that allow evaluation to design input.
- Reference acceptance criteria.
- Identify design outputs essential for the proper functioning of device.
- Document, review, and approve design outputs before release.

# Design Output

## Design output.

- Results of design effort at each phase and the end of the total design effort.
- Finished design output is basis for the DMR.

**Design Output**

**Research**

**Development**

**Design Verification**  
**Design Output = Design Input**

# Design Review

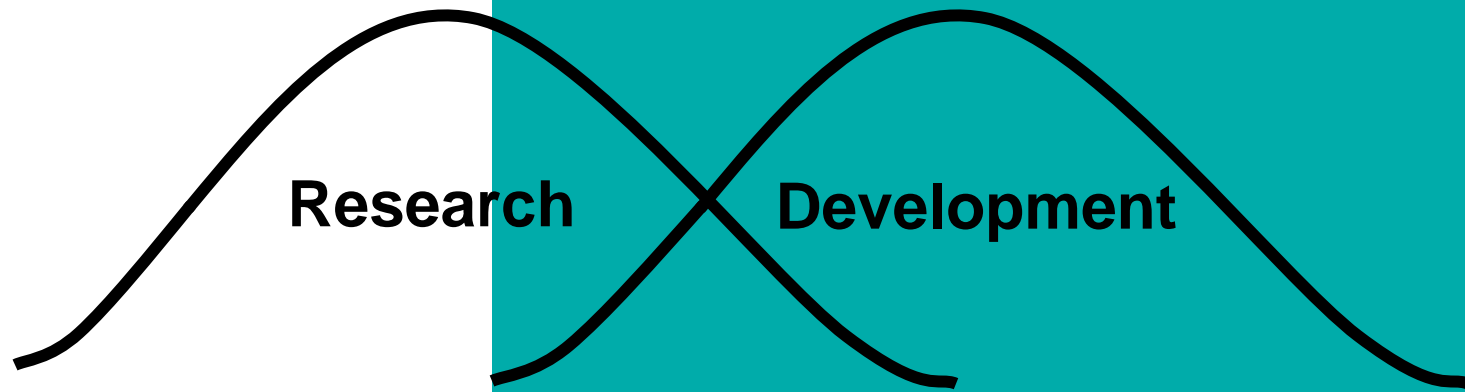
- A documented, comprehensive, systematic examination to
  - Evaluate adequacy of the design requirements
  - Evaluate capability of the design to meet requirements
  - Identify problems
- Ensure that formal reviews of design results are planned and conducted at appropriate stages.

# Design Review

- Ensure participants include representatives of all functions concerned with design stage being reviewed.
- Document results in the Design History File (DHF).



# Design Reviews



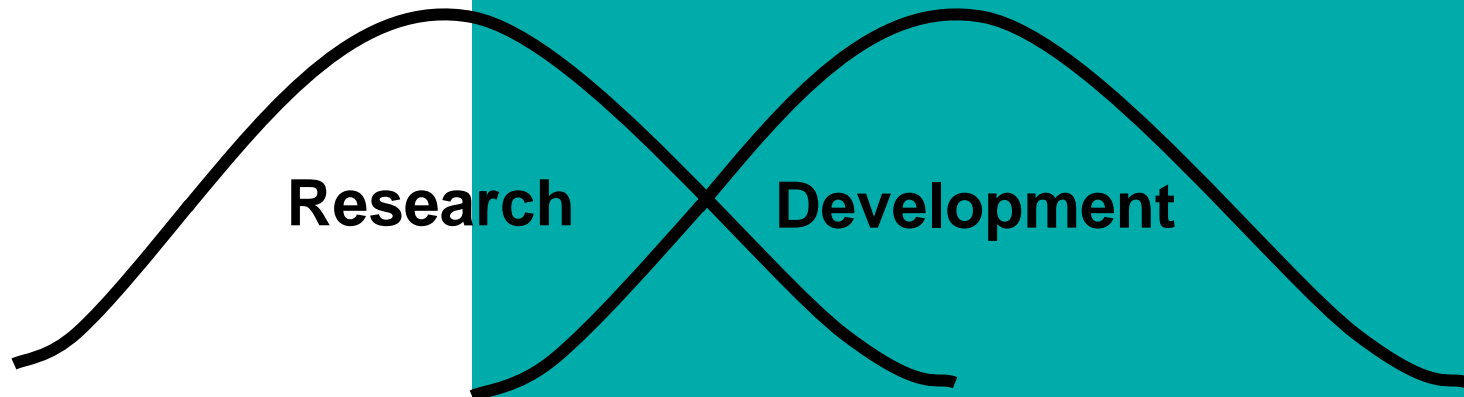
**Research**

**Development**

# Design Verification

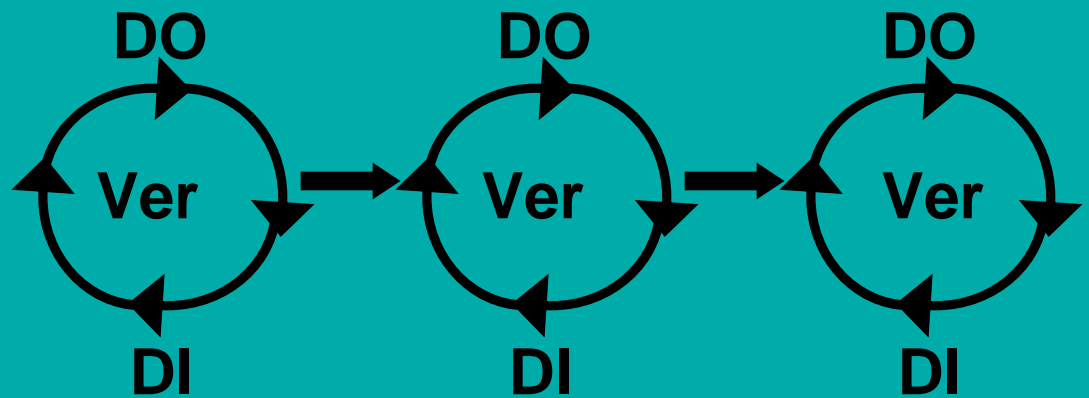
- Verify the device design.
- Confirm that design output meets design input requirements.
- Document results in the DHF.

# Design Verification



Research

Development



# Design Validation

## **820.3 Definitions – Design Validation**

Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s).

# Design Validation

- Validate the device design.
- Perform under defined operating conditions on initial production units or equivalent.
- Ensure devices conform to defined user needs and intended uses.

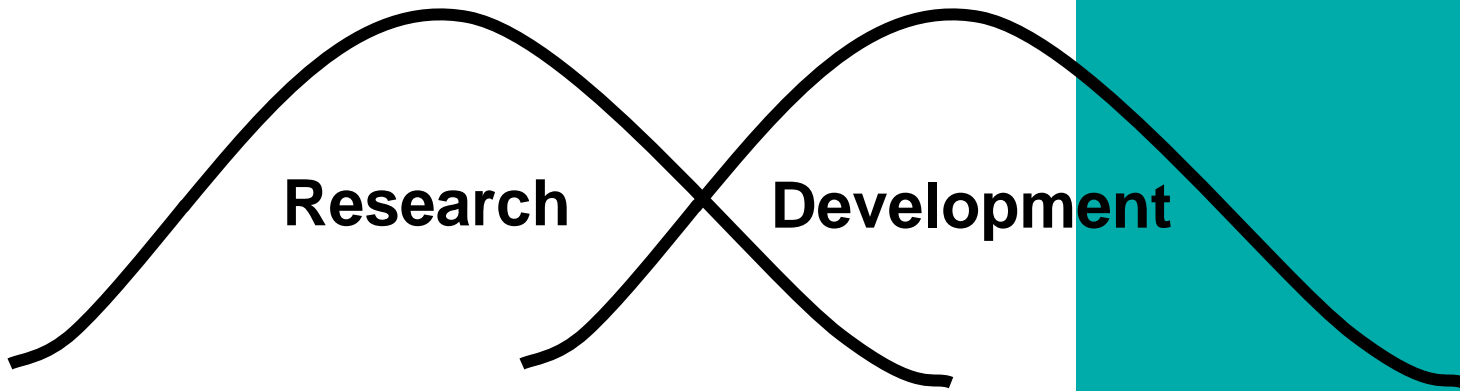
# Design Validation

- Test of production units under actual or simulated use conditions.
- Perform software validation and risk analysis, where appropriate.
- Document results in the DHF.

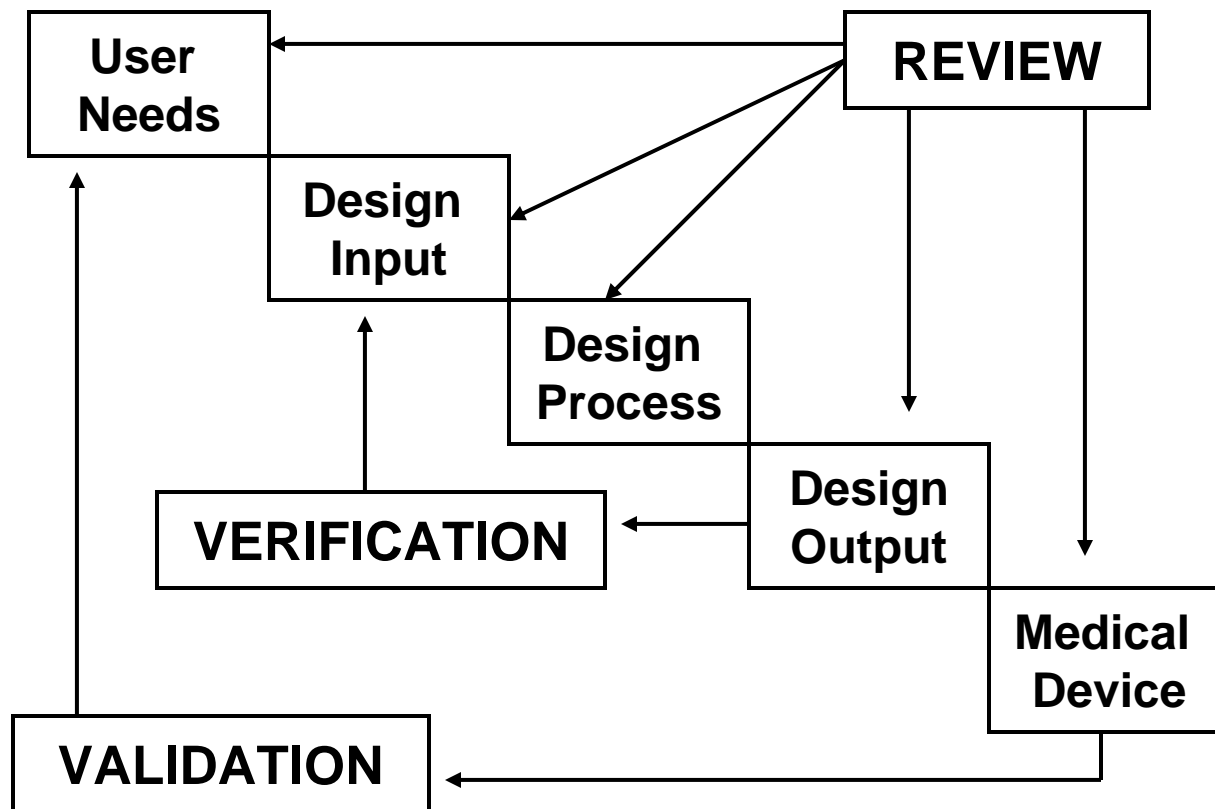
**Design  
Validation**

**Research**

**Development**



# Design and Development

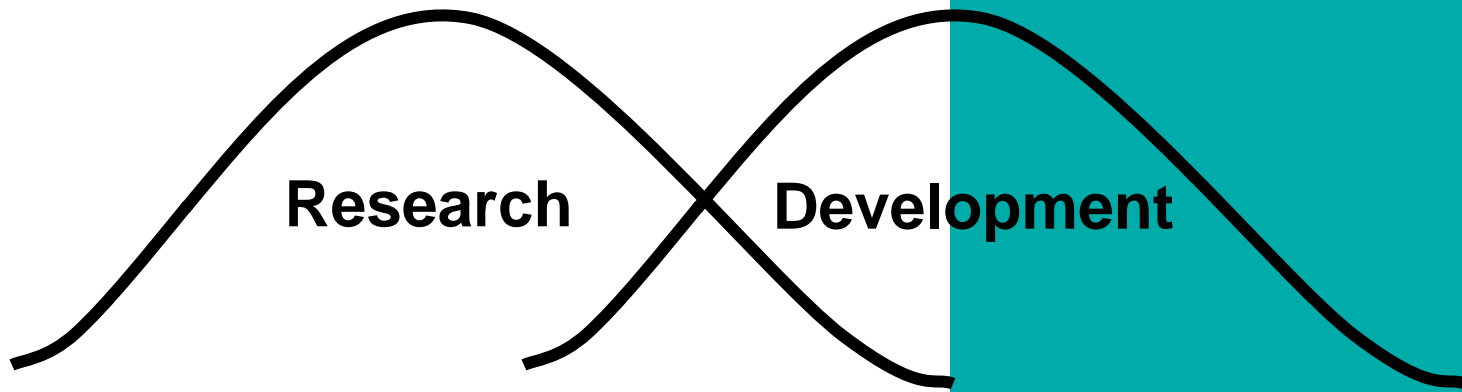




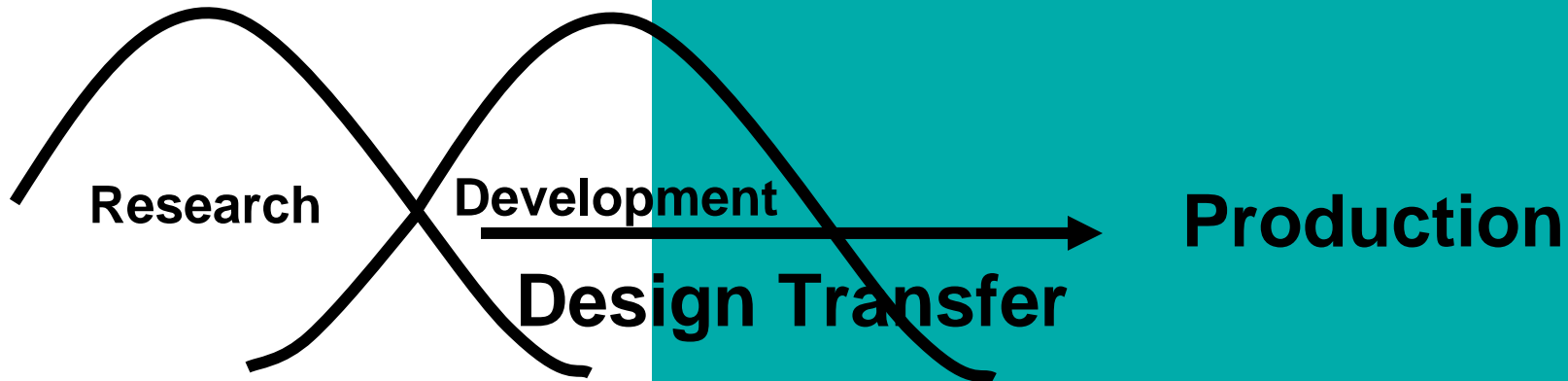
# Design Transfer

- Ensure the device design is correctly translated into production specifications.

# Design Transfer



## Design Validation

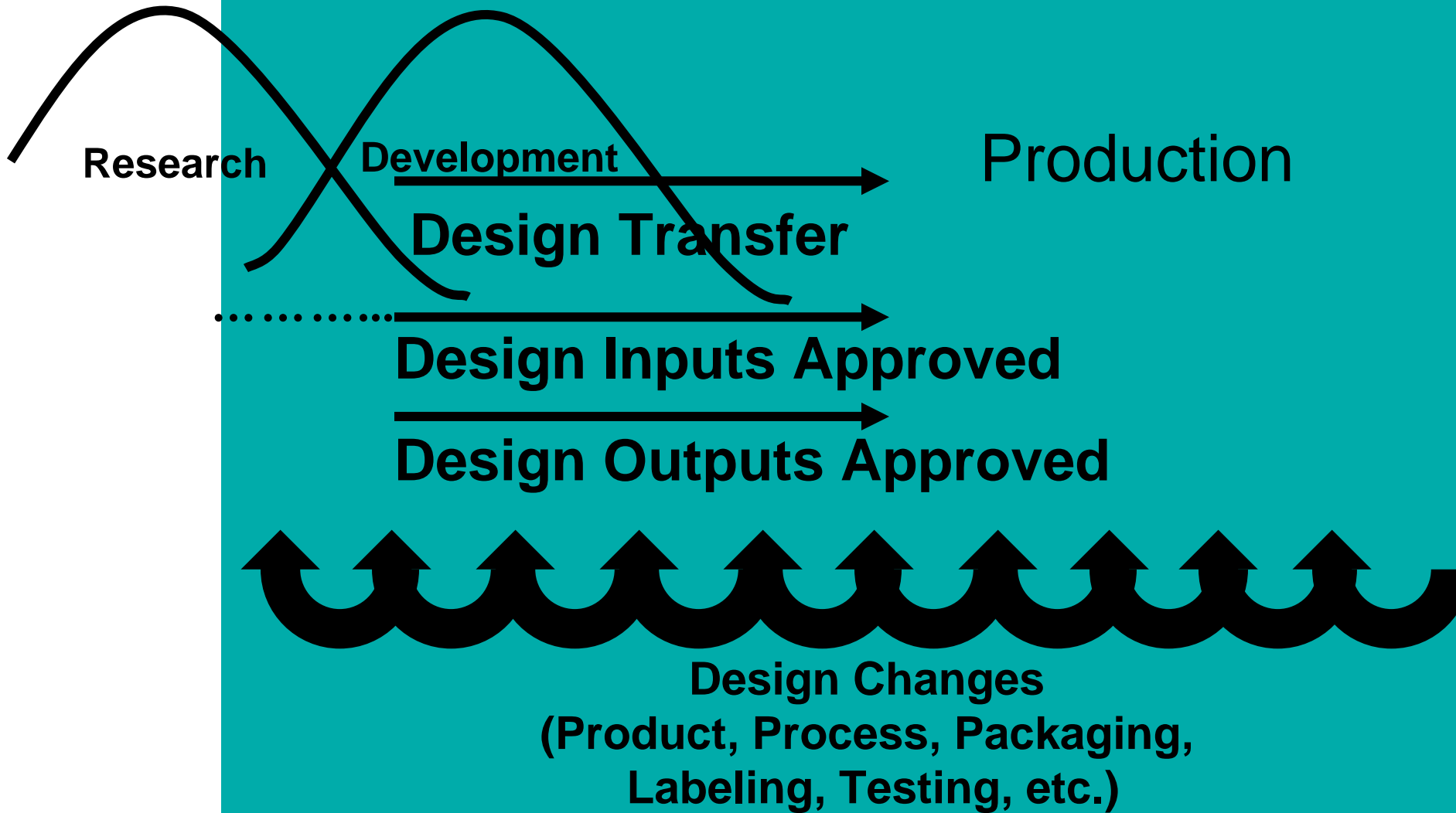


**Does the design meet  
user needs and intended  
use?**

# Design Changes

- Identify, document, validate or verify, review, and approve design changes before implementation.

# Design Changes



# Design History File

## **820.3 Definitions – Design History File**

Design history file (DHF) means a compilation of records which describes the design history of a finished device.

# Design History File

- Establish and maintain a DHF for each type of device.
- Maintain records to demonstrate development was in accordance with design plan and requirements of 820.30.
- Forms the Device Master Record (DMR)

# Production and Process Controls Subsystem

- 820.50 Purchasing Controls
- 820.60 Identification
- 820.65 Traceability
- 820.70 Production and Process Controls
- 820.72 Inspection, measuring, and test equipment
- 820.75 Process Validation



# Production and Process Controls Subsystem

- 820.80 Receiving, in-process, and finished device acceptance
- 820.86 Acceptance Status
- 820.120 Device labeling
- 820.140 Handling
- 820.150 Storage
- 820.160 Distribution
- 820.170 Installation

# 820.50 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

# 820.50 Purchasing Controls

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

Approve purchasing data/documents

# 820.50 Purchasing Controls

GHTF Guidance Document:

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

# 820.50 Purchasing Controls

A supplier is anyone that is independent from the manufacturer's quality management system and not apart of their Quality Audit.

- Internal Supplier
- External Supplier

# 820.50 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)

# 820.50 Purchasing Controls

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

Both internal and external suppliers are required to be controlled under 21 CFR 820.50.

# 820.70 Production and Process Controls

Develop, conduct, control, and monitor production processes to ensure devices conform to specifications.



# 820.70 Production and Process Controls

## Production and process changes.

- Establish procedures for changes to a specification, method, process, or procedure according to §820.30 Design Controls
- Verify/ validate according to §820.75.
- Approve in accordance with §820.40.

# 820.70 Production and Process Controls

## 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 Production and Process Controls

## Automated processes.

- Validate computer software used as part of production or the quality system for its intended use.
- Validate according to an established protocol.
- Validate all software changes before approval.
- Document validation activities and results.

# 820.75 Process Validation

Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

# 820.75 Process Validation

## Process Validation

- Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures.

# 820.75 Process Validation

## Control of Validated Processes.

- Monitoring and control methods and data
- Date performed
- Individual(s) performing the process, where appropriate
- Major equipment used, where appropriate

# 820.75 Process Validation

## Revalidation.

- When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate.

# 820.80 Receiving, In-Process, & Finished Device Acceptance

Receiving acceptance activities.

- Establish procedures for acceptance
- Inspect, test, or otherwise verify as conforming
- Document acceptance or rejection



# 820.80 Receiving, In-Process, & Finished Device Acceptance

## In-process acceptance activities.

- Establish acceptance procedures to ensure specified product requirements are met.
- Control in-process product until appropriate acceptance activities are completed and documented.

# 820.80 Receiving, In-Process, & Finished Device Acceptance

## Final acceptance activities.

- Establish and maintain procedures for finished device acceptance to ensure each production run, lot, or batch meets acceptance criteria.
- Control finished devices until appropriate activities required for release are completed.

# Corrective and Preventive Actions (CAPA) Subsystem

- 820.100 CAPA
- 820.90 Nonconforming Product
- 820.198 Complaints
- 820.200 Servicing
- 820.250 Statistical Techniques

# 820.100 Corrective and Preventive Action

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

# 820.100 Corrective and Preventive Action

- Verify and validate actions and effectiveness
- Communicate information on the quality problems and the necessary actions to appropriate staff
- Forward information to management review

# 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

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”)



# 820.90 Non-Conforming Product

- Establish and maintain procedures, including
  - Identification
  - Documentation
  - Evaluation
  - Segregation
  - Disposition
- Document the evaluation and any investigation

# 820.90 Non-Conforming Product

Nonconformity review and disposition.

- Establish and maintain procedures defining the responsibility for review and the authority for the disposition, including the review and disposition process.
- Document disposition of nonconforming product, including the justification for use and the signature of individual(s) authorizing use.

# 820.90 Non-Conforming Product

Nonconformity review and disposition.

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

# 820.198 Complaint Files

All manufacturers must

- Maintain complaint files.
- Designate a formal complaint handling unit.
- Establish and maintain procedures for receiving, reviewing, and evaluating complaints.

# 820.198 Complaint Files

Procedures must ensure that

- All complaints are processed in a uniform and timely manner.
- Oral complaints are documented upon receipt.
- Complaints are evaluated to determine whether the complaint represents an Medical Device Report.

# 820.198 Complaint Files

## Investigations.

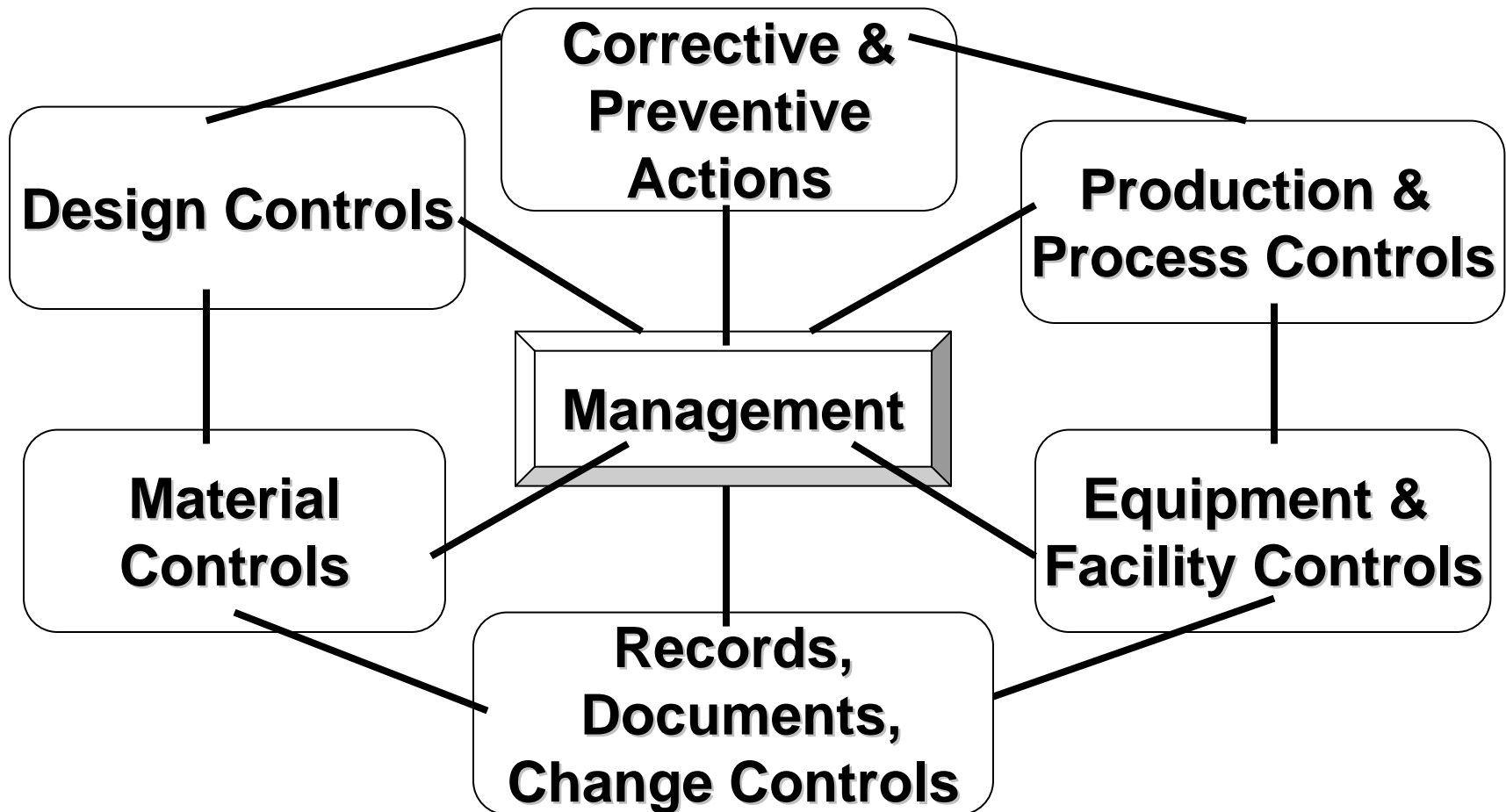
- Review and evaluate all complaints to determine whether an investigation is necessary.
- Records of investigation shall be maintain with certain specified information as required

# 820.198 Complaint Files

## Investigations.

- When no investigation is made, maintain a record that includes the
  - Reason no investigation was made and name of the individual responsible for the decision.

# Quality Management Subsystems





# Close the loop...



# Additional Resources

- FDA Compliance Program 7382.845  
Inspection of Medical Device Manufacturers  
implemented October 1, 2000  
[www.fda.gov/ora/cpgm/default.htm#devices](http://www.fda.gov/ora/cpgm/default.htm#devices)
- Guide to Inspections of Quality Systems,  
August 1999  
[www.fda.gov/ora/inspect\\_ref/igs/qsit/qsitguide.  
htm](http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm)

# Additional Resources

“Quality System Information for Certain  
Premarket Application Reviews:  
Guidance for Industry and FDA Staff”:  
2003

[http://www.fda.gov/cdrh/comp/guidance/  
1140.pdf](http://www.fda.gov/cdrh/comp/guidance/1140.pdf)

# Additional Resources

Global Harmonization Task Force Quality Management System Guidance Documents

<http://www.ghtf.org/sg3/sg3-final.html>

- “Implementation of Risk Management Principles and Activities Within a Quality Management System”: GHTF 2005
- “Quality Management Systems - Process Validation Guidance”: GHTF 2004