Design Transfer, Design Change Controls, and Design History File

FDA Small Business
Regulatory Education for Industry (REdI)
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Learning Objectives

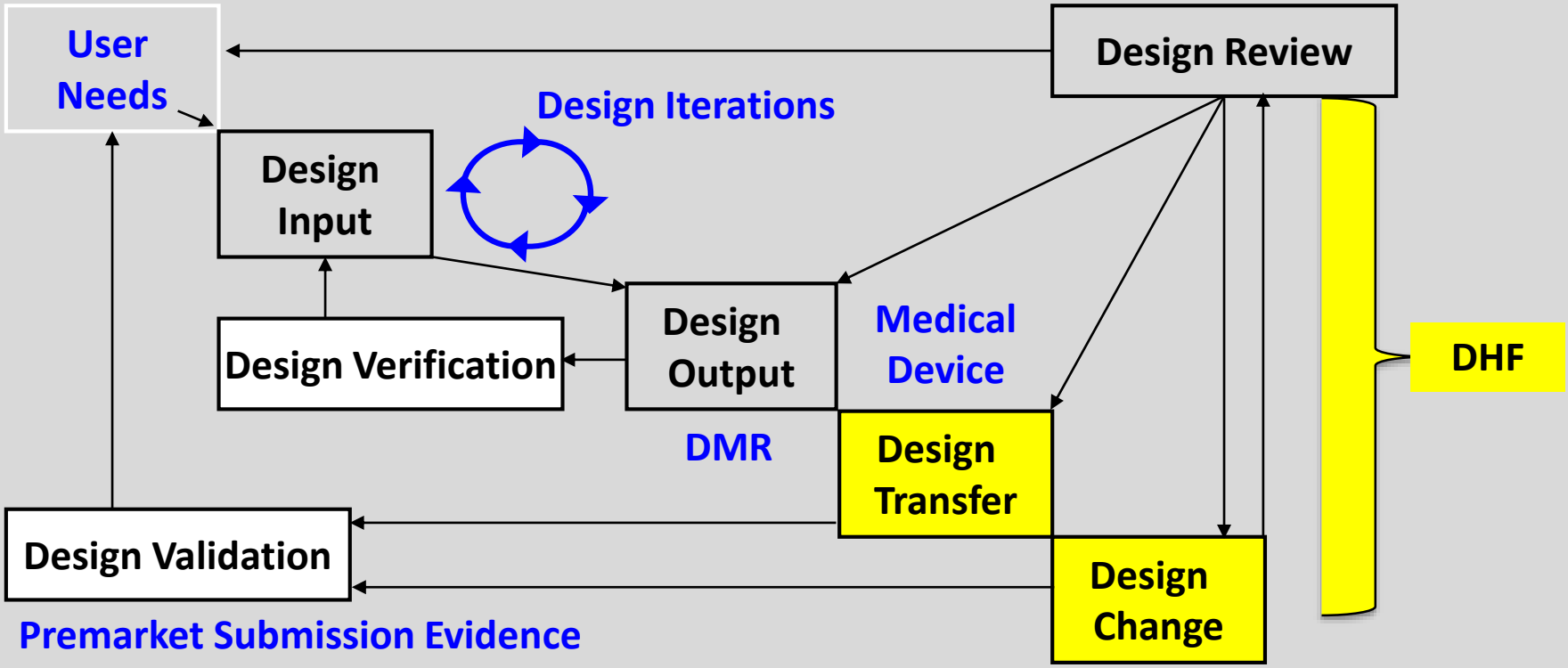
- Understand the requirements for design transfer, design change, and the design history file (DHF)
- Identify the linkages between design and other quality systems elements
- Learn the three steps to success
- Apply the three steps in real world examples

Why am I here?

I am here to improve product quality

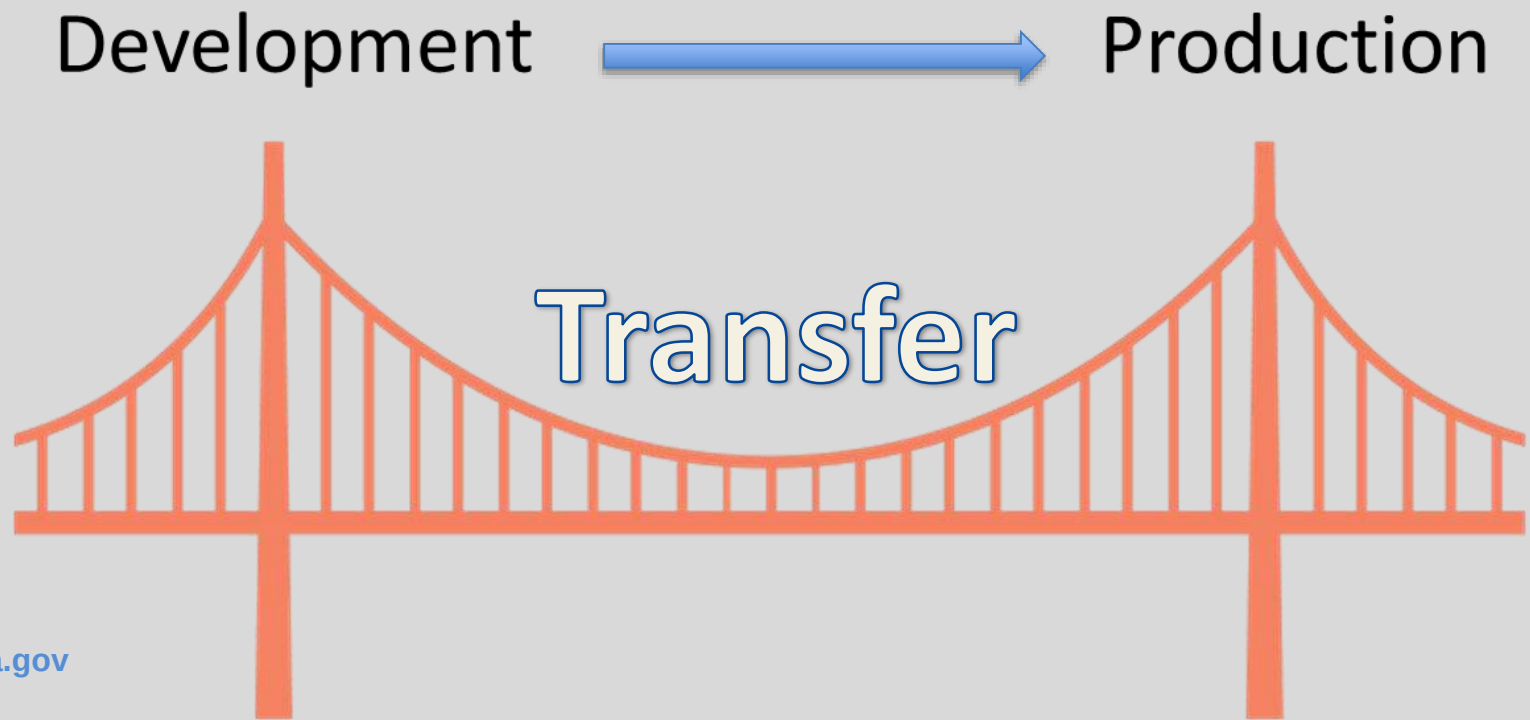
I am here because higher quality products, means less compliance

Design Controls Overview



Design Transfer 21 CFR 820.30(h)

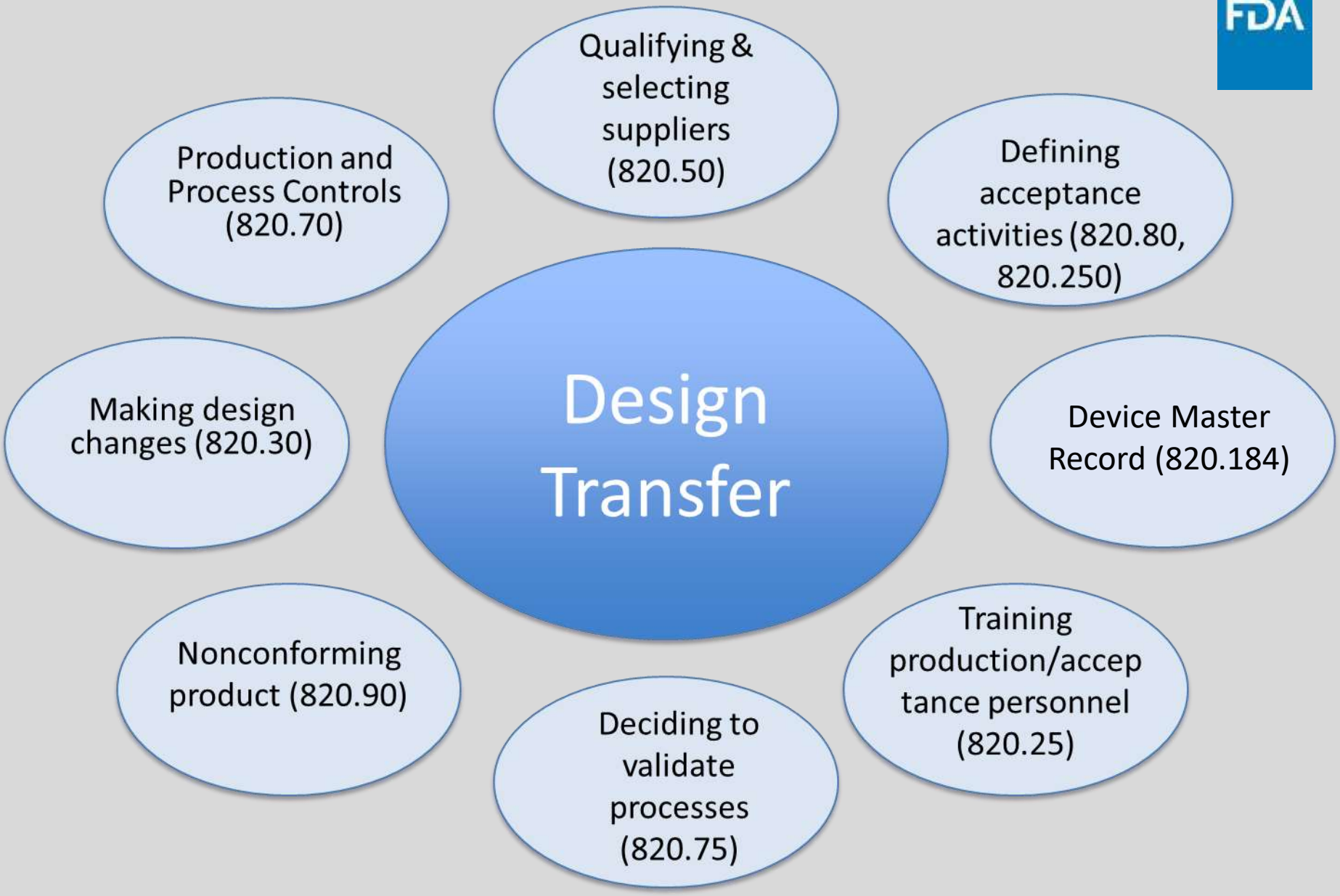
Device design is correctly translated into specs



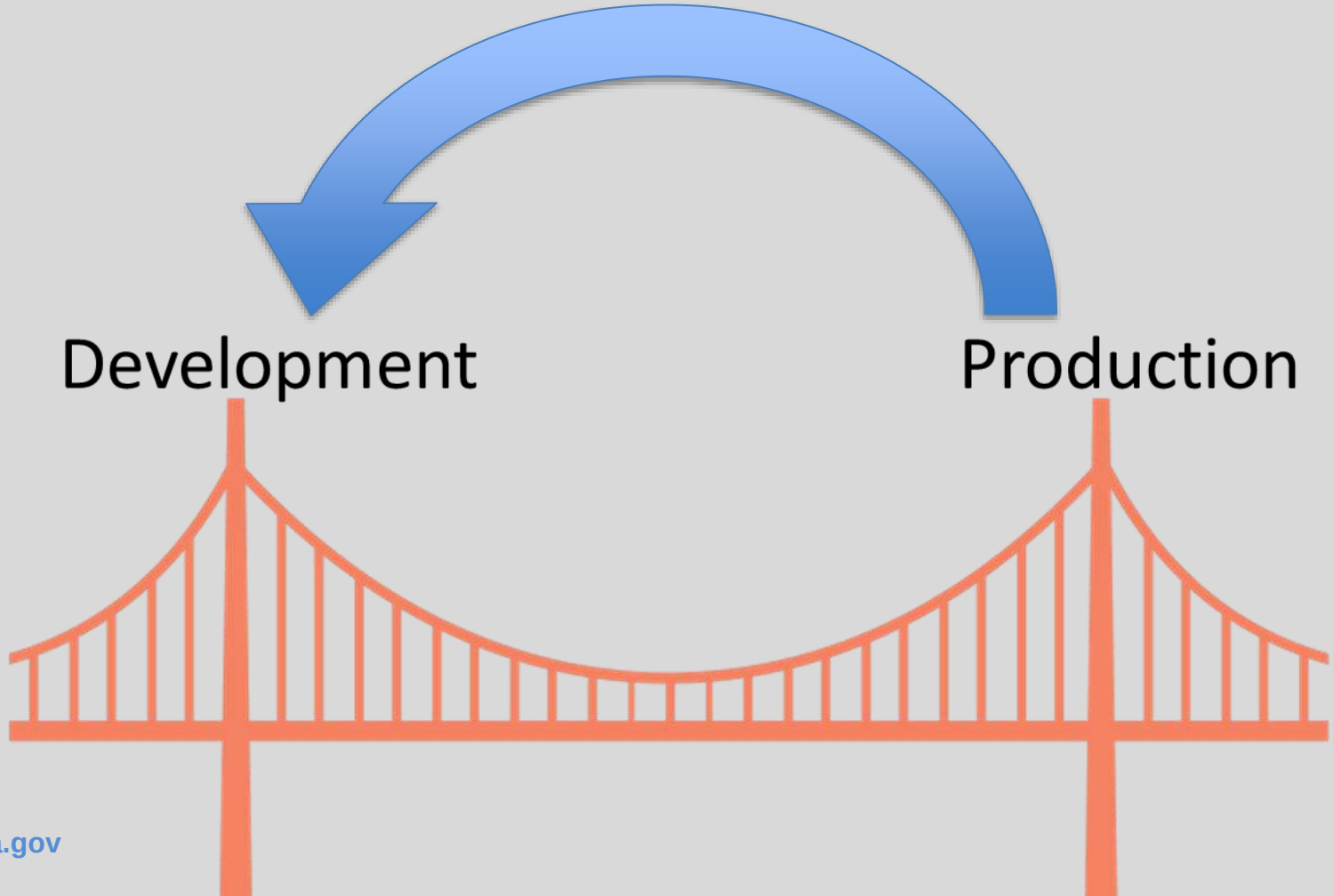
Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff

FDA expects design transfer to cover:

- Final review & approval for transfer
- Documents in the Device Master Record, DMR


Qualifying & selecting suppliers (820.50)
Production and Process Controls (820.70)
Defining acceptance activities (820.80, 820.250)
Design Transfer
Making design changes (820.30)
Device Master Record (820.184)
Nonconforming product (820.90)
Training production/acceptance personnel (820.25)
Deciding to validate processes (820.75)

Design Changes 21 CFR 820.30(i)



How to succeed at design changes?

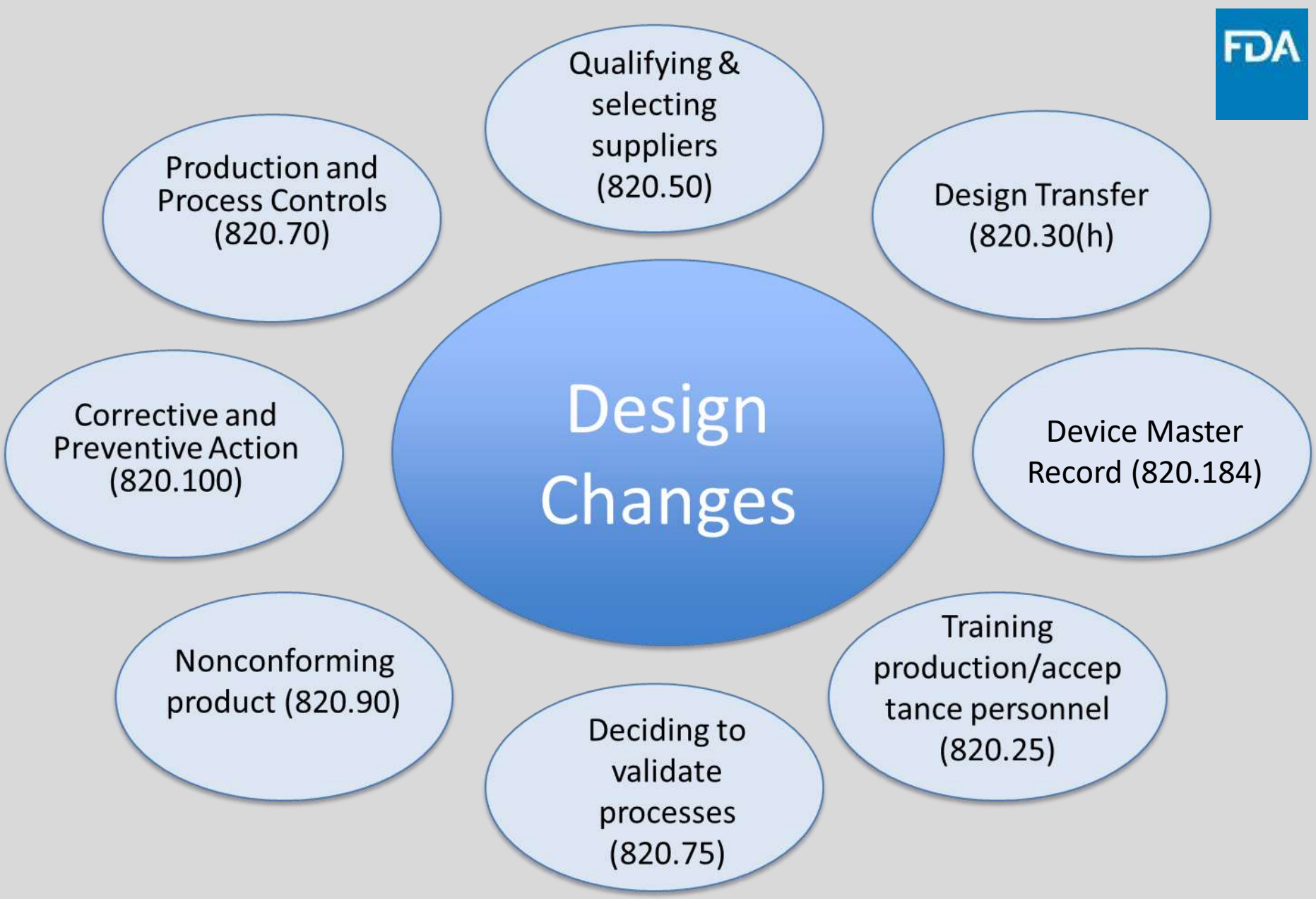
- Identify
- Document
- Validate / Verify
- Review
- Approve

Before you make the change!

Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff

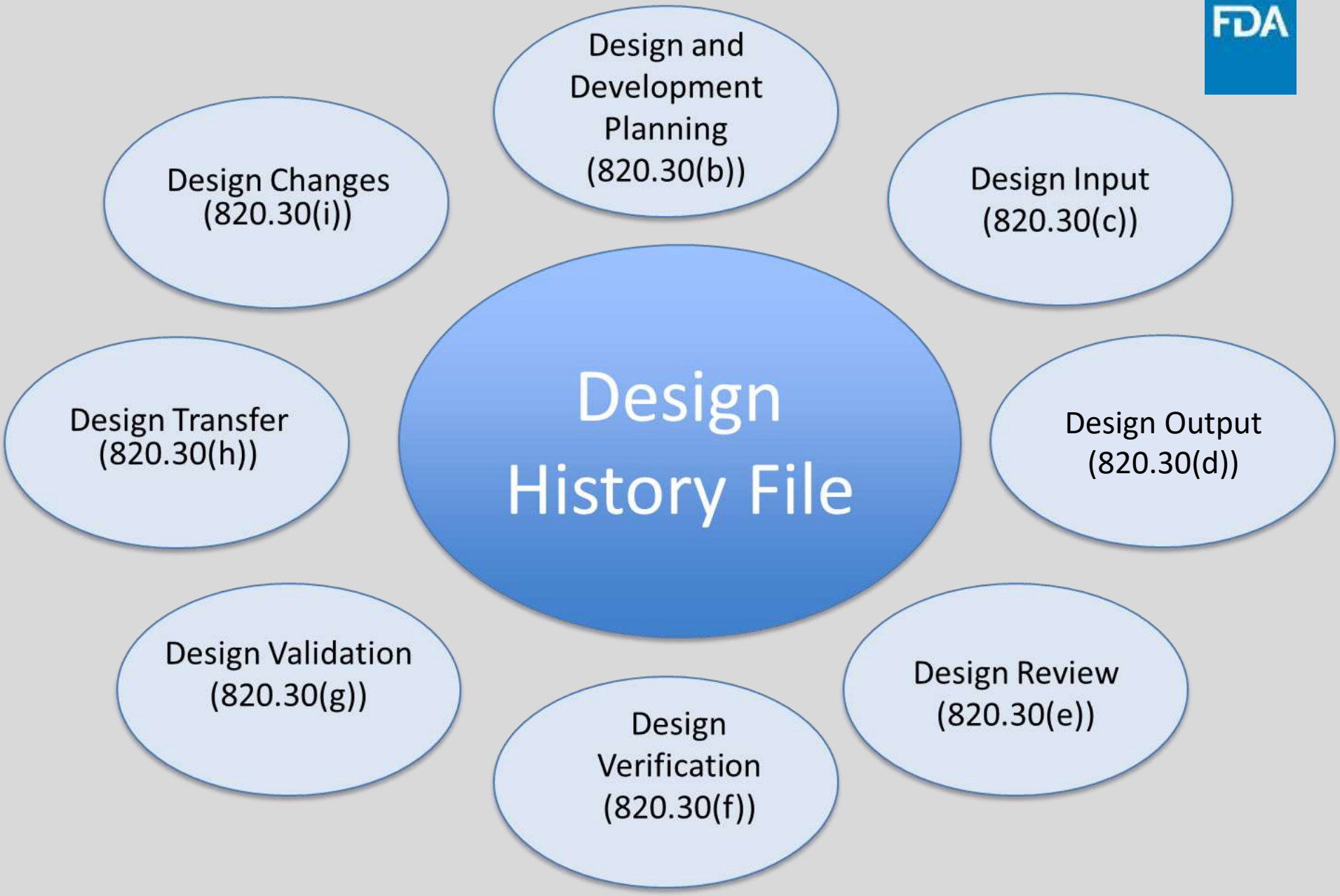
FDA expects design change procedures to cover:

- Verification vs. Validation
- Prevent implementation until approval
- Consider manufacturing process changes


Qualifying & selecting suppliers (820.50)
Production and Process Controls (820.70)
Design Transfer (820.30(h)
Design Changes
Corrective and Preventive Action (820.100)
Device Master Record (820.184)
Nonconforming product (820.90)
Training production/acceptance personnel (820.25)
Deciding to validate processes (820.75)

Design History File (DHF)
21 CFR 820.30(j)

- The DHF are records from design controls
- It shows design control activities were completed
- Can be actual records, or references to them


Design and Development Planning (820.30(b))
Design Changes (820.30(i))
Design Input (820.30(c))
Design Transfer (820.30(h))
Design History File
Design Output (820.30(d))
Design Validation (820.30(g))
Design Review (820.30(e))
Design Verification (820.30(f))

Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff

If multiple devices share a DHF:

Identify what parts are shared, and what are not

Steps to Succeed

1. Have a procedure – write it down!
2. Make sure it meets 21 CFR 820
3. Consistently follow your procedure

Following these steps, avoids most problems!

Successful Design Transfer

- Involve your manufacturing staff early
- Determine the process settings necessary to produce the device consistently
- **Example**: a checklist of activities for transfer

Successful Design Changes

- Design control activity commensurate to change
- **Example**: a form to document design change activities
- Other procedures will point to the form

Successful Design History File

- Plan your activities in Design Planning
- **Example**: records have a unique name or number
- Multiple products of the same type can share a DHF if each device is identified

Real World Examples

- I have five examples of Warning Letters

- Identify the problem
  - Lack of procedure
  - Procedure does not meet regulation
  - Failure to follow procedure

Warning Letter Example 1

Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications, as required by 21 CFR 820.30(h).

For example: Design Control Procedure, does not describe how design transfer will be controlled.

Warning Letter Example 1 - Poll

For example: Design Control Procedure, does not describe how design transfer will be controlled.

a. **Lack of a Procedure**

b. **Procedure does not meet regulation**

c. **Failure to follow procedure**

d. **a. or b.**

Warning Letter Example 2

Failure to adequately establish procedures for design transfer, as required by 21 CFR 820.30 (h).

For example, the production work instructions that were being used were obsolete.

Warning Letter Example 2 - Poll

For example, The production work instructions that were being used were obsolete.

a. **Lack of a Procedure**

b. **Procedure does not meet regulation**

c. **Failure to follow procedure**

Warning Letter Example 3

Failure to establish and maintain adequate procedures for the identification, documentation, validation, or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

For example: your firm has not validated or documented software changes for the device.

Warning Letter Example 3 - Poll

For example: your firm has not validated or documented software changes for the device.

a. **Lack of a Procedure**

b. **Procedure does not meet regulation**

c. **Failure to follow procedure**

d. **b. and c.**

Warning Letter Example 4

Failure to adequately establish procedures for design change, as required by 21 CFR 820.30(i).

For example, your firm implemented design changes to your devices. Your firm did not maintain documentation to demonstrate that the design changes were reviewed and approved before their implementation.

Warning Letter Example 4 - Poll

For example, your firm implemented design changes to your devices. Your firm did not maintain documentation to demonstrate that the design changes were reviewed and approved before their implementation.

a. **Lack of a Procedure**

b. **Procedure does not meet regulation**

c. **Failure to follow procedure**

Warning Letter Example 5

Failure to establish and maintain a design history file (DHF) for each type of device, as required by 21 CFR 820.30(j).

For example: the product does not have a DHF.

Warning Letter Example 5 - Poll

Failure to establish and maintain a design history file (DHF) for each type of device, as required by 21 CFR 820.30(j). For example: the product does not have a DHF.

a. **Lack of a Procedure**

b. **Procedure does not meet regulation**

c. **Failure to follow procedure**

Design Controls Resources

- Design Control Guidance For Medical Device Manufacturers
- Human Factors and Medical Devices
- CDRH Learn Module on design controls
- Implementation of risk management principles and activities within a Quality Management System GHTF 2005
- ISO 14971:2007/(R)2010 Medical Devices – Application of risk management to medical devices

Summary

- Design transfer is a bridge to production
- Design changes use the design controls after approval of design inputs
- Design history file is the compilation of the records created

Questions

Please evaluate this session:

surveymonkey.com/r/DEV-D2S05

Your Call to Action

Pathway to success is straightforward!

- Have a procedure
- Ensure it covers all required elements
- Follow the procedure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