Design Control

Introduction and Design Inputs for Medical Devices and Combination Products

Overview of Seminar

- Overview of Design Control for Medical Devices
- Overview of design inputs (requirements)
- Boring regulatory stuff
- A look at Design Inputs
  - Where do they come from
  - Flow
  - Traceability

Quick Overview of Design Control

- In simple terms, it is the complete control over the design development of your product

- Design Controls designates the application of a formal methodology to the conduct of product development activities.

What Design Control is NOT

- Control over R&D activities
- Something the FDA made up because they had nothing better to do
- Bad for business
- Something only medical device companies do
- Many other industries use design control
- Properly applied, the use of design control will increase the quality of your products!

Need For Design Controls

- Many people (and companies) see design control as just more paperwork and stress
- But…a robust design control process will eliminate lots of stress during development and post market

Need For Design Controls

- Business Need
  - Failure to establish a robust design control system, can:
  - Lead to the development of product which is not “suitable for use”
  - Inability to be able to correct issues once a product is on market
  - Open you up to audit observations for violations of CFR’s and ISO standards

Need For Design Controls

- Design control and the documentation which is required:
  - It makes it much easier to fix any issues which may crop up after product launch.
    - Need to be able to trace design decisions
    - Formulation changes
    - Vendor changes
    - Manufacturing changes

Need For Design Controls

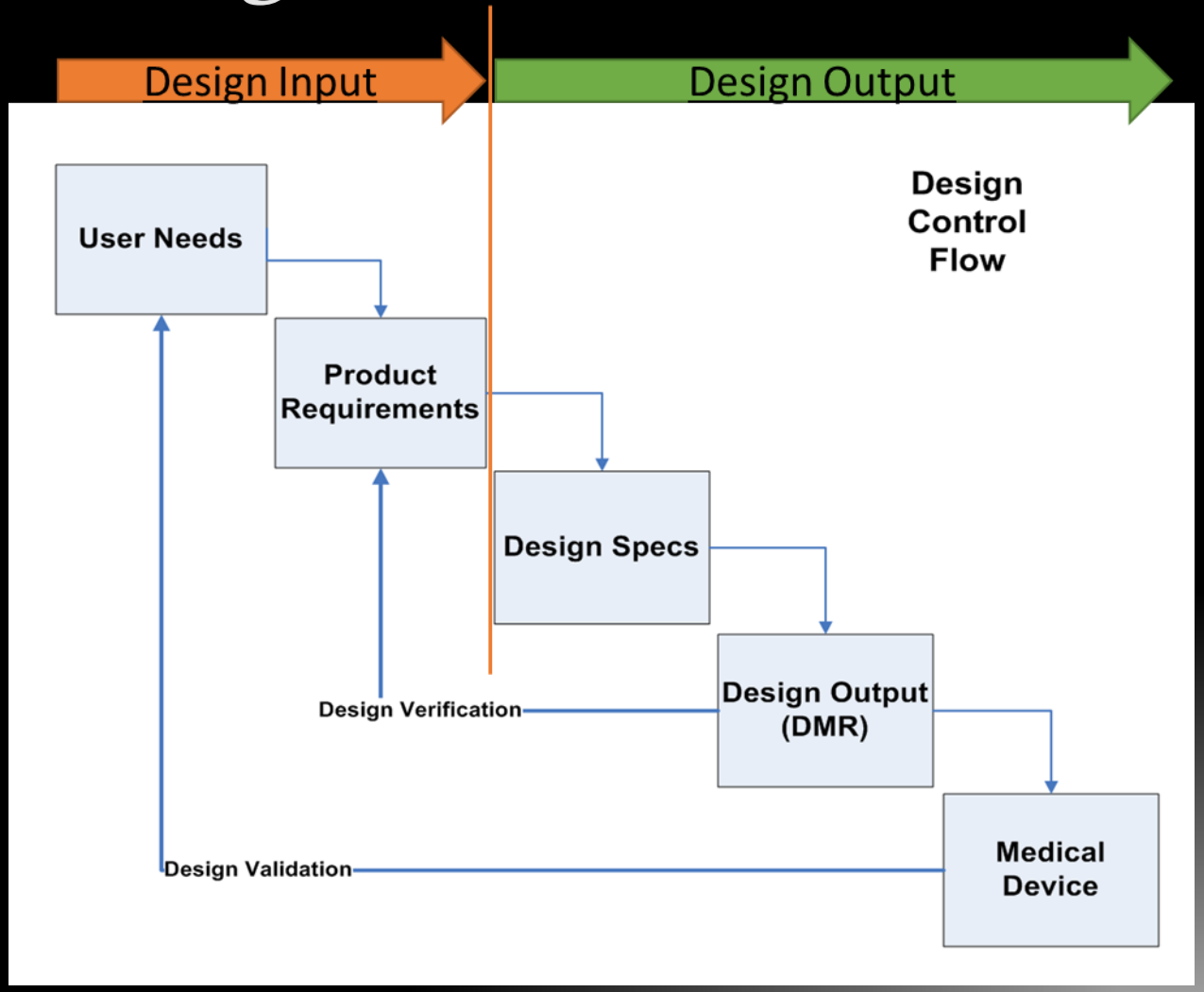
- Regulatory Requirements
  - The Quality System regulation includes Design Controls
  - Quality System regulation was first major revision to medical device GMPs since Final Rule in 1978
  - Quality System regulation published in October 1996; effective June 1997
  - Medical device manufacturers required to comply with regulation
  - Design Controls actively enforced starting June 1998

Overview of Design Control

Design Controls (21CFR820)	ISO 13485:2016
(a) General	7.3.1 General
(b) Design and Development Planning	7.3.2 Design and Development Planning
(c) Design Input	7.3.3 Design and Development Inputs
(d) Design Output	7.3.4 Design and Development Outputs
(e) Design Reviews	7.3.5 Design and Development Review
(f) Design Verification	7.3.6 Design and Development Verification
(g) Design Validation	7.3.7 Design and Development Verification
(h) Design Transfer	7.3.8 Design and Development Transfer
(i) Design Changes	7.3.9 Control of Design and Development Changes
(j) Design History File	7.3.10 Design and Development Files

Overview of Design Control

- The Design Control Waterfall:
- Inputs
  - Am I making the right product
- Verification
  - Did I make what I said I was going to make
- Validation
  - Did I make what my customer(s) want



Design Inputs

- Possibly the most important part(s) of Design Control
- If you get this part wrong you are designing the wrong product!

Design Inputs: Boring Regulatory Part

- General Quality System Requirements
  - There must be established procedures to determine design inputs
  - Design inputs must be appropriate and address the intended use of the device
  - Incomplete, ambiguous or conflicting inputs must be resolved
  - Must be documented, reviewed and approved

Design Inputs: Boring Regulatory Part

- 21 CFR Part 820: Quality System Regulations
  - Subpart C – Design Controls
    - (c) Design input. Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

Design Inputs: Boring Regulatory Part

- ISO 13485: 2016
  - 7.3.3 Design and development inputs
- Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include:
- a) functional, performance, usability and safety requirements, according to the intended use;
- b) applicable regulatory requirements and standards;
- c) applicable output(s) of risk management;
- d) as appropriate, information derived from previous similar designs;
- e) other requirements essential for design and development of the product and processes.
- These inputs shall be reviewed for adequacy and approved.
- Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other

Design Inputs: User Needs

- Defining, approving and documentation of user needs is (in my opinion) the most critical aspect of design control
  - If you get this wrong, you are designing the wrong product for the right customer or the right product for the wrong customer (or both).