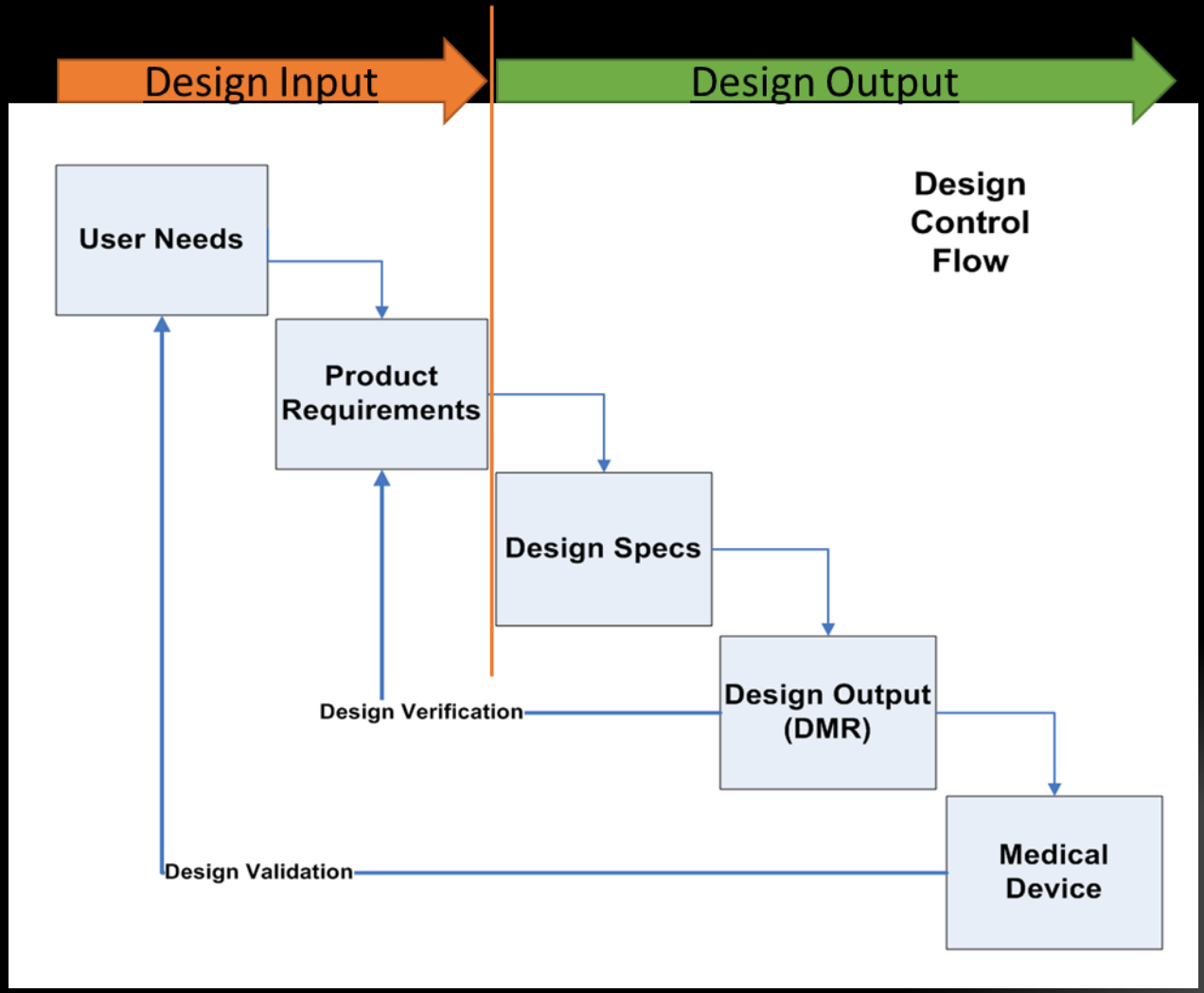
Design Outputs



Design Outputs

- **Examples of Design Output**
  - Medical Device Specifications
    - Dimensions
    - Assembly drawings
    - Materials
    - Testing specifications
  - Production Procedures

- **Examples of Design Output**
  - Software code
  - QC Specifications
  - Installation/Service Manuals
  - Packaging and Labeling Specifications
  - Storage Specifications

Note: a specification is a requirement that the product, process, service or Other activity has to conform to ensure proper function of the product

Design Outputs

- Design Output is Translated to the Product Device Master Record (DMR)
  - After all specifications are approved, they are the basis for the product's Device Master Record
    - The DMR is the collection of documents needed to:
      - Source materials
      - Manufacture
      - Test
      - Assemble
      - Label
      - Store
      - Ship

Design Outputs

- Examples of User Needs – Product Requirements – Design Output Trace

User Need	Product Requirement	Design Output
Instrument must be portable	Dimensions no greater than 20cm X 10cm X 6cm	Drawing # DR12345
	Weight < 10kg	Materials list #ML12345
	Padded Carry Handle	Drawing # DR12345 Materials list #ML12345

Design Outputs

- Design Output Checklist
  - Is there an SOP to address:
    - Identification and definition of design outputs
    - Documentation of acceptance criteria
    - How essential design outputs are identified and documented
      - Normally traced through Risk Documentation
    - Who has authority to approve design outputs
  - Are acceptance criteria clearly defined
  - Are essential design outputs clearly defined
  - Are all design outputs approved
  - Do design outputs address all aspects of the DMR
    - The device, production, testing, labeling, packaging, storage, shipping

Design Outputs

- Design Outputs – Summary
  - Require established procedures
  - Design outputs must be defined and documented
  - Reference acceptance criteria
  - Identify essential design outputs
  - Document – Review – Approve
  - Consist of
    - The device, and the instructions to manufacture, test, assemble, package, label, store, ship and service
  - Design Inputs (requirements) are translated to specifications (Design Output)
  - Design Output becomes product Device Master Record (DMR)

Design Verification

- Verification – Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled
  - Did I make what I said I was going to make?

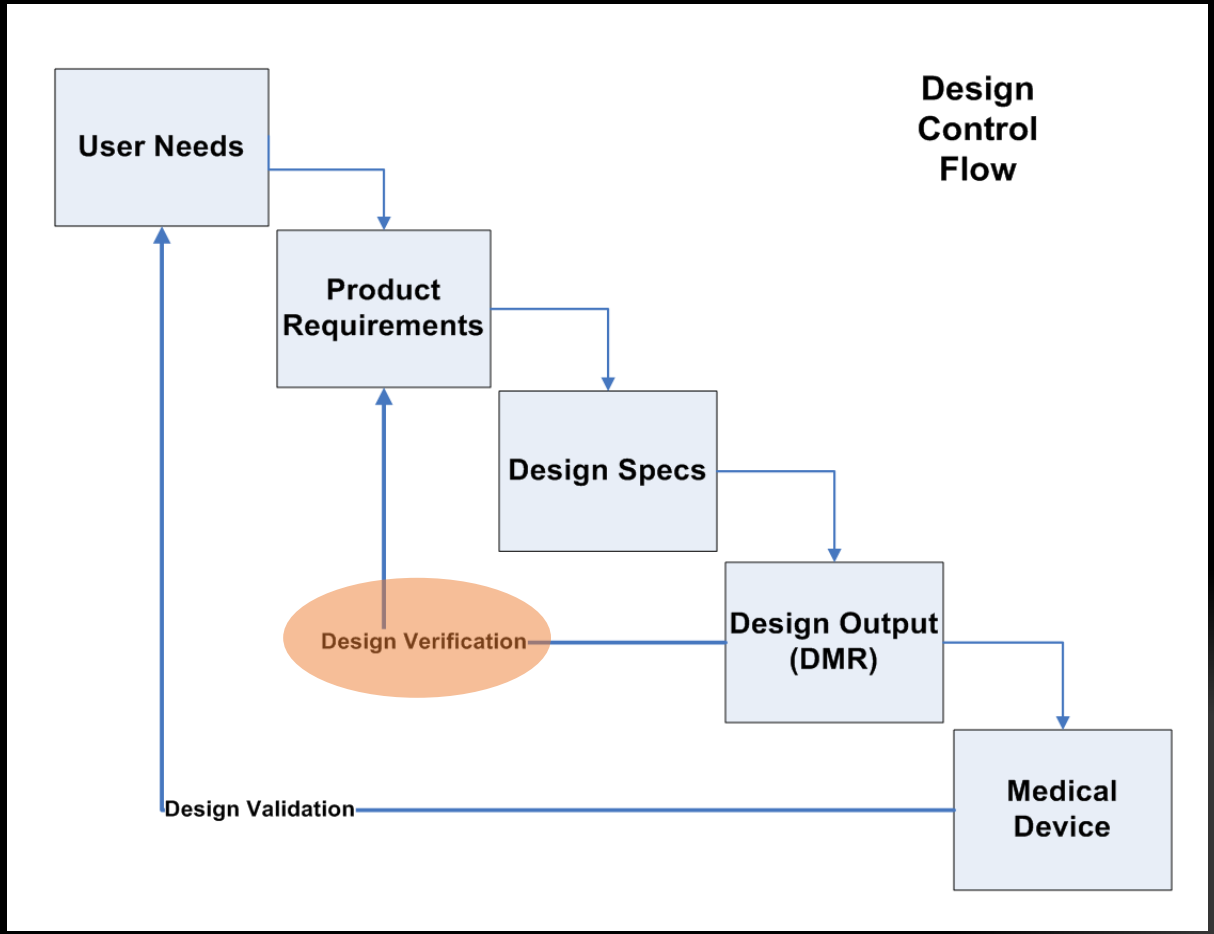
Design Verification

- 820.30 Design controls
  - (f) *Design verification.* Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

Design Verification

- ISO 13485:2016
  - 7.3.6 Design and development verification
    - Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements.
    - The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.
    - If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced.
    - Records of the results and conclusions of the verification and necessary actions shall be maintained

Design Verification



Design Verification

- Quality System Requirements
  - Must have approved, SOPs governing design verification
  - Activities must verify the device design
    - Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled
  - Confirm that design inputs (product requirements) meet design outputs (DMR)
  - **Protocols must be pre-approved with set acceptance criteria**
  - All results are documented in the Design History File (DHF)

Design Verification

- Example Verification Methods
  - Testing
    - Safety
    - Performance
    - Package Integrity
  - Inspection
    - Visual review
    - Measurements
    - Label review
  - Analysis
    - Worst case
    - Calculations

Design Verification

- Know the answer before you start!!
- Verification is not an experiment!
- Starts with clear, well defined User Need/Product Requirements
- Product requirements MUST be measurable
  - ⟐ Otherwise they can't be verified

Design Verification

- Formal Protocol
  - Link directly to an approved product requirement
  - Contain full methodology or reference to standard methodology
  - Statistical justification for number of samples, runs, etc.
  - Statistical plan for data analysis
  - Clear acceptance criteria
  - Procedure for what to do if verification fails
  - Pre-approved

Design Verification

- Formal Report
  - Reference to the protocol
  - Who performed the work
  - Where work was performed
  - Summary of Data
  - Can reference location of original data as long as it is in a controlled location
    - Or it can be part of the report
  - Summary of any deviations, exceptions or invalid results
    - And why they are acceptable
  - Significant deviations to the protocol must be pre-approved!
  - Clear statement of pass/fail
  - Reference to what you are going to do if the protocol fails
    - Should be an SOP for deviations or failures