Design Verification

- All Product Requirements Must be Successfully Verified
  - If not, a deviation must be written and the failure investigated
    - May require an update to product requirements (design change control)

Design Verification

- If you have done a good job of writing product requirements and characterization of your system, this should be a very rare event
- You should have procedures as part of your quality system to follow
- Investigate, investigate, investigate
  - The reason might not be related to your system
- If after a thorough investigation
  - You determine that you really can’t verify a product requirement
  - You need to take a good look at that product requirement
  - It might not be achievable with your product as designed
  - Can the product requirement be updated and re-verified?
  - Without impact to the user need it is traced to
  - Can you make a design change and re-verify?

Design Verification

- You Pass the Protocol
  - You have successfully verified/validated the stated product requirement
  - You have proven by objective evidence that your product meets it's design requirements
  - You have built what you said you were going to

Design Verification

- Design Verification Summary
  - Trace matrix
    - Shows the relationship from design inputs (product requirements) to the design verification protocol reference to the design verification record reference to the final result of the study

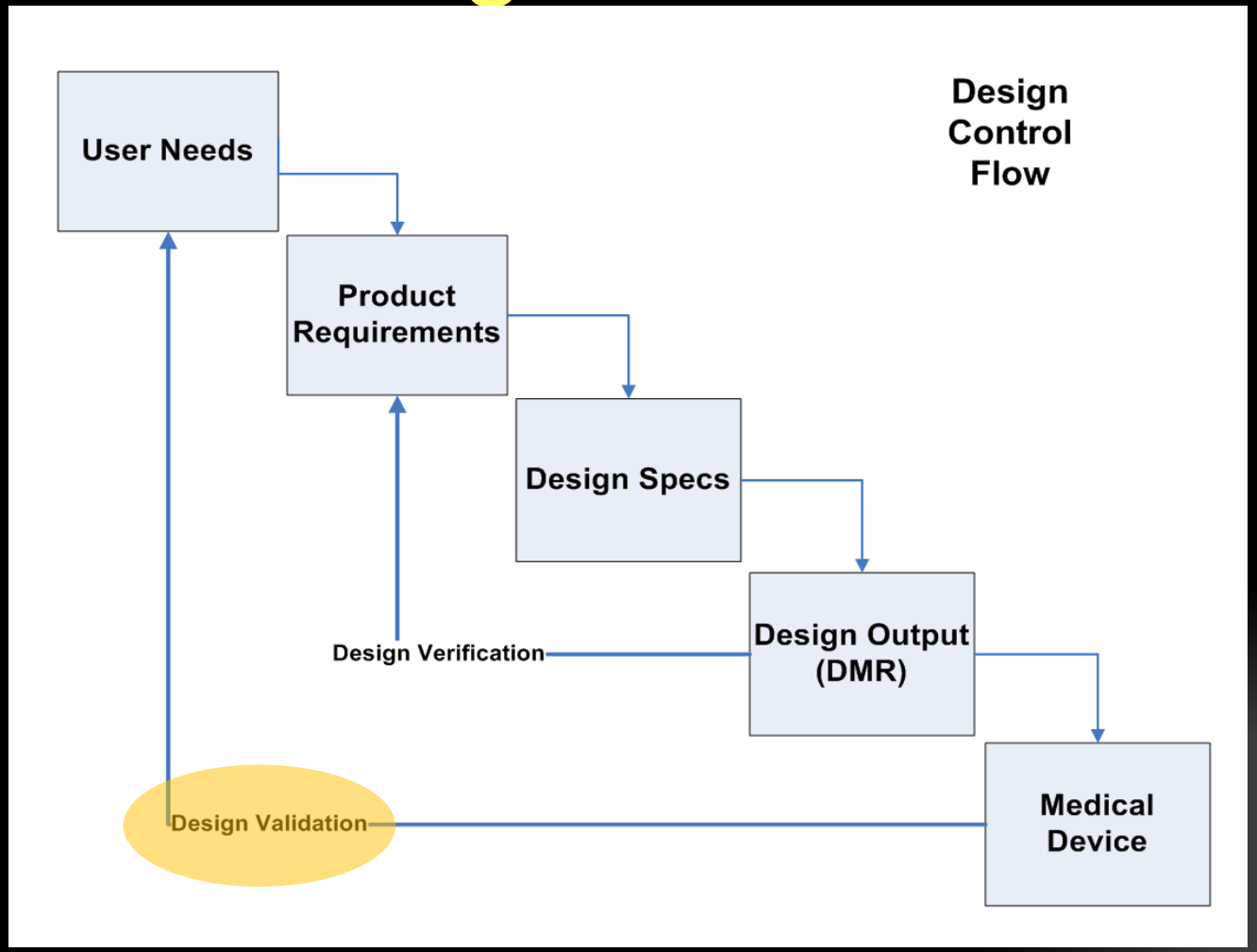
Product Requirement	Protocol	Record	Result	Deviations
Limit of Detection ≤ 0.5 mg/ml	Protocol 12345_v1	Record 12345_v1	Pass	None

Design Validation

- Validation
  - Means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

- Design Validation – Confirmation that the device specifications conform with the user needs and intended use(s).
  - Did I make what the customer (end user) wanted?

Design Validation



Design Validation

- 21 CFR 820.30
  - (g) *Design validation.* Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

Design Validation

- ISO 13485:2016
- 7.3.7 Design and development validation
  - Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.
  - The organization shall document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.
  - Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded.

Design Validation

- 7.3.7 Design and development validation
  - As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements.
  - A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.
  - If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.
  - Validation shall be completed prior to release for use of the product to the customer.
  - Records of the results and conclusion of validation and necessary actions shall be maintained

Design Validation

- Quality System Requirement
  - Must validate the device design
  - Design validation is performed under defined operating conditions on initial production units or equivalents.
    - This ensures the final device conforms to defined user needs and intended use
  - Testing of production units must be under actual or simulated use conditions.
  - Software validation and risk analysis must be performed where appropriate

Design Validation

- Design Validation and Planning
  - Design Validation plan should be developed and approved early in the development process
  - Performance characteristics needing validation come from User Needs and Intended Use
  - Must establish acceptance criteria
- Establish Procedures (SOPs)
- If Equivalent (not final prototype) devices are used
  - Must establish equivalency to final device
  - Fully justified

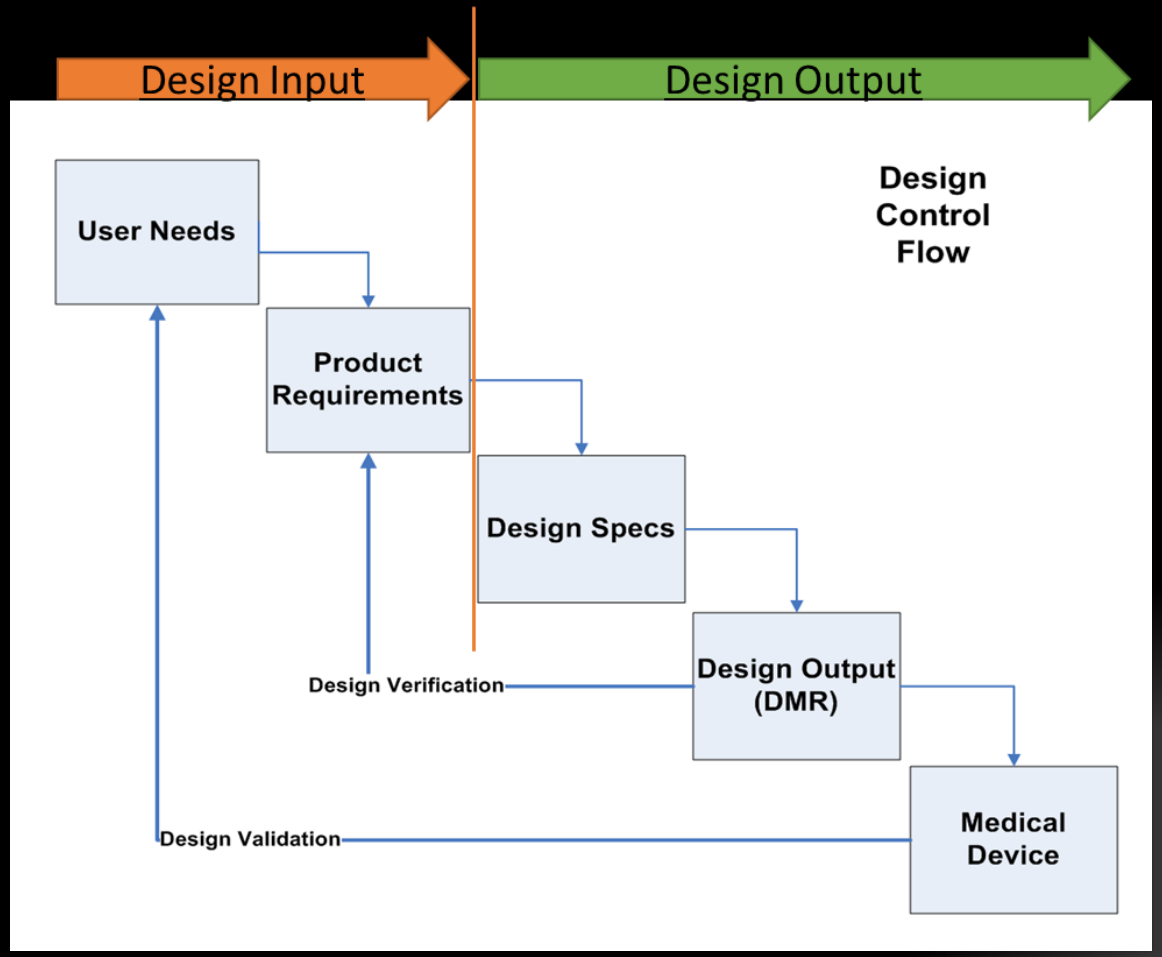
Design Validation

- Validation devices must be manufactured using product DMR
  - Documents can be “developmental” in nature and converted to full production after validation
    - Any changes to manufacturing procedures after validation of the device must be justified and could trigger re-validation if changes are too extensive
  - Production and testing of devices used for design validation using methods and procedures which will be used in routine production will help prevent distribution of unacceptable product.

Design Validation

- Clinical Studies vs. Clinical Evaluation
  - Clinical Studies
    - Not needed for all devices
    - Must be done in “actual use” conditions
    - May require an Investigational Device Exemption (IDE) from the FDA if results of clinical studies are used for actual patient management.
  - Clinical Evaluation
    - Done in some way for all devices
    - May include relevant scientific literature, historic evidence of similar designs and or material that can be shown to be clinically safe and effective and to show that the device would perform as intended

Summary



Thank You For Your Attention

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