

# Design Controls

**FDA Small Business  
Regulatory Education for Industry (REdI)  
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# Challenge: Infusion Pump

Must be designed to work both **safely** and **effectively**  
in a modern operating room



By Norbert Kaiser - Self-photographed, CC BY-SA 2.5,  
<https://commons.wikimedia.org/w/index.php?curid=1955393>

# Learning Objectives

- Understand the ***context*** of Design Controls within the Quality System
- Understand the ***mechanisms*** and continual role of Design Controls in device development (both Premarket and Postmarket)
- Understand how effective ***use*** can contribute to quality and safety, thereby reducing cost

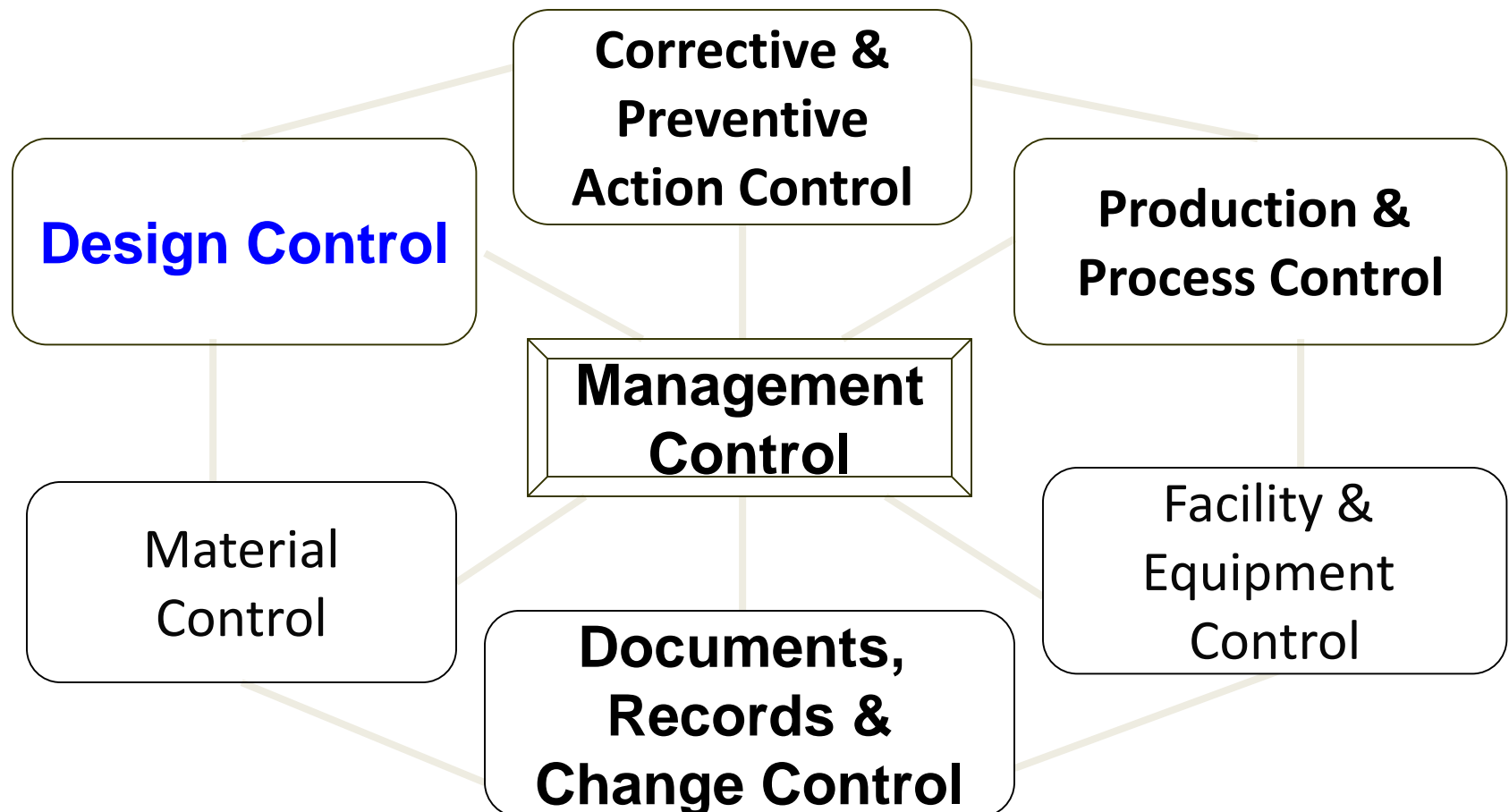
# Quality System

- **Medical Device Amendments of May 28, 1976**
  - authorized FDA to regulate medical devices.
- **Safe Medical Device Act of 1990**
  - added **Design Controls** (effective **June 1, 1997**) to the current Good Manufacturing Practices (cGMPs).

## **GMPs → Quality System Regulation**

- Quality System (21 CFR 820) - govern the design, manufacture, packaging/labeling, distribution, and installation/servicing of safe medical devices for the U.S..

# 7 Subsystems of the Quality System



# Design Controls (21 CFR 820.30)

- a) General requirements
- b) Design and development planning
- c) Design input
- d) Design output
- e) Design review
- f) Design verification
- g) Design validation
- h) Design transfer
- i) Design changes
- j) Design history file

# Design Controls – What are they?

- A set/framework of quality practices and procedures incorporated into the design and development process.
- Control the design process – Premarket and Postmarket - to assure that device specifications meet *user needs* and *intended use(s)*.
- They set medical device Quality System apart from Good Manufacturing Practices.

**cGMPs → Quality System Regulation**

# Poll Question

D1S3-1

View Votes Edit End Poll

What is your knowledge of Design Control requirements?

<input type="radio"/> Expert	<div></div>	0%	(0)
<input type="radio"/> Familiar	<div></div>	0%	(0)
<input type="radio"/> Basic	<div></div>	0%	(0)
<input type="radio"/> Unfamiliar - that's why I'm here	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results



# Design Controls – Scope

- Design controls apply to:
  - All **Class II** and **III** devices
  - Several **Class I** devices types:
    1. Devices automated with computer software
    2. Tracheobronchial suction catheters
    3. Surgeon's gloves
    4. Protective restraints
    5. Manual radionuclide applicator system
    6. Radionuclide teletherapy source

# Design Controls – Scope (continued)

- When do Design Controls Apply/Begin?
  - **Premarket**
    - *After* Feasibility/“Proof of Concept”/Prototyping
    - When you design the *final* product
    - *Prior* to start of Clinical Investigation (21 CFR 812)
    - Mechanism of *change*/revision during any Clinical Investigation (21 CFR 812), and applies throughout (21 CFR 812.1)

# Risk Management/ Assessment/Analysis

- **Definition:**

- Systematic application of:

- policies, procedures, practices, insight/judgment, and experience to the:
    - identification, analysis/evaluation, monitoring, and subsequent control/mitigation of risk.

- Integrated into the Design Control process
- Key component and central requirement

*Consensus Standards, AAMI/ANSI/ISO 14971 and IEC TR 80002*

# Human Factors

- The study of the interactions between ***humans and product*** (i.e., *interface* and *machine*) and the subsequent design of the machine-human interface.
- It plays an important ***symbiotic*** role with Risk Management in Design Control.

# General Requirement

21 CFR 820.30(a)

- **Establish** procedures to control device design:
  - Define
  - Document
  - Implement
- **Maintain** procedures to control device design:
  - Review
  - Approve
  - Update



# Design and Development Planning

21 CFR 820.30(**b**)

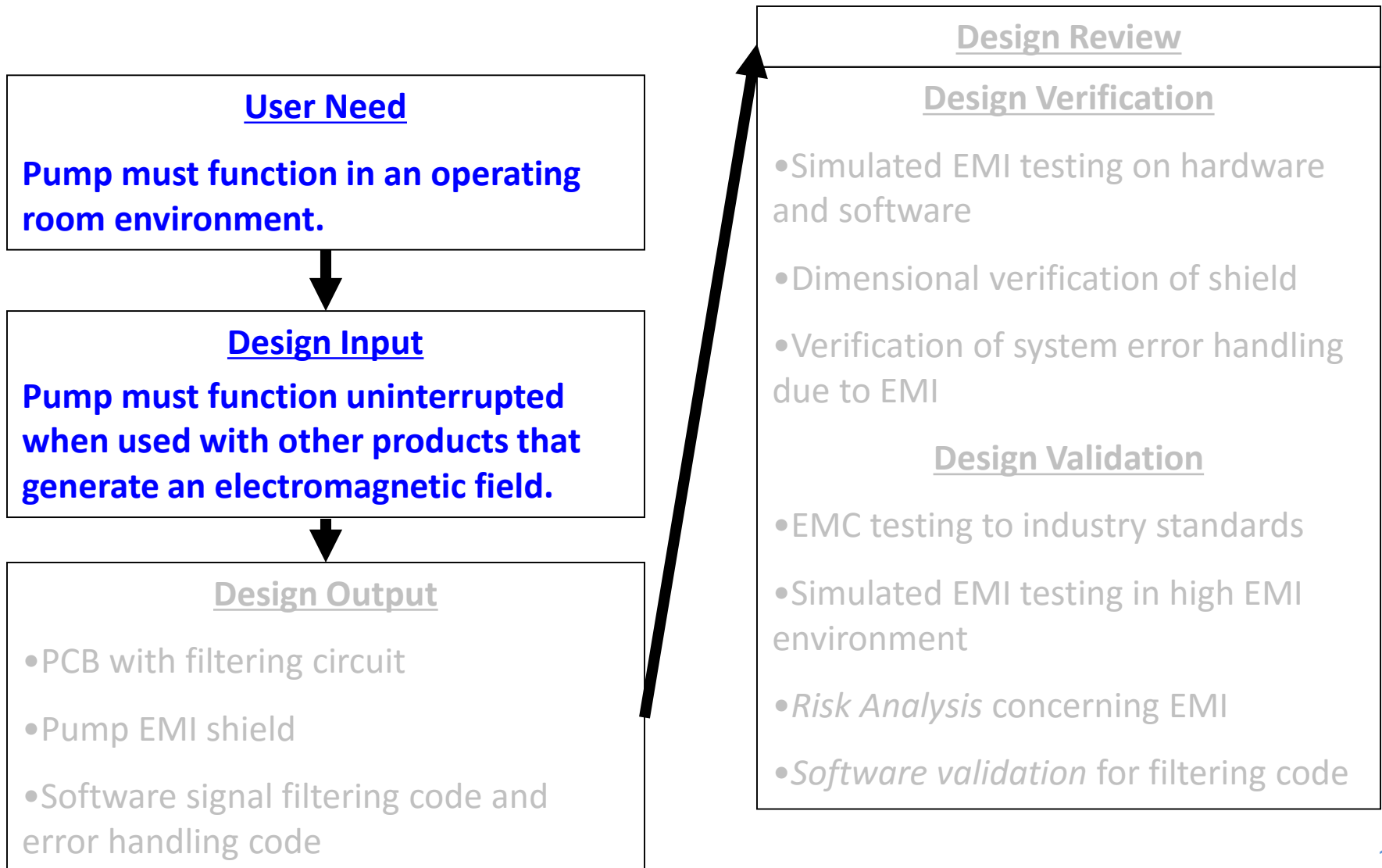
- Procedures are established, maintained, and documented to:
  - Describe or reference design and development ***activities***.
  - Identify, describe, and define ***interfaces, responsibilities, and functions/activities*** impacting device design.
  - Review, document, approve, and update as developments and changes ***evolve***.

# Design Input

21 CFR 820.30(c)

- ***Design inputs*** are the physical and performance ***characteristics*** of a device that are used as the *basis* for device design.
- Procedures are established and maintained to:
  - Ensure ***requirements*** are ***appropriate*** by addressing ***user needs*** and ***intended use(s)*** in *measurable* terms.
  - Address incomplete, ambiguous, or conflicting requirements.
  - Document, review, and approve input requirements.

# Example – Infusion Pump



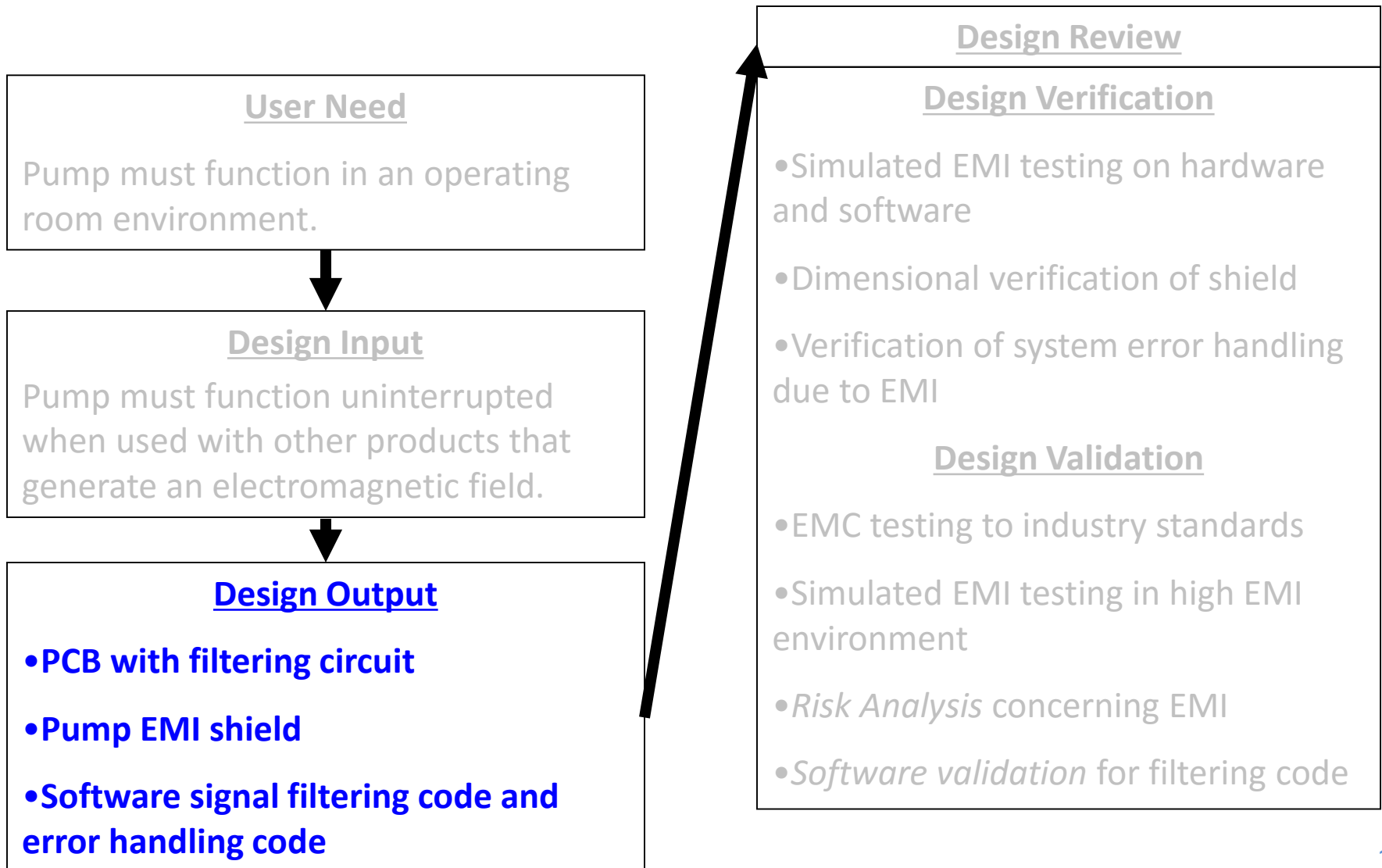


# Design Output

21 CFR 820.30(**d**)

- **Design outputs** are the *results* of a design effort – final or otherwise.
- Procedures are established and maintained to:
  - Define and document essential output to allow *adequate evaluation* of conformance to *design input* (i.e., *input = output*).
  - Reference *definable/measurable acceptance criteria*.
  - Review, approve, and document design output.
- Design Outputs are included in premarket submissions as **Device Specifications**.

# Example – Infusion Pump

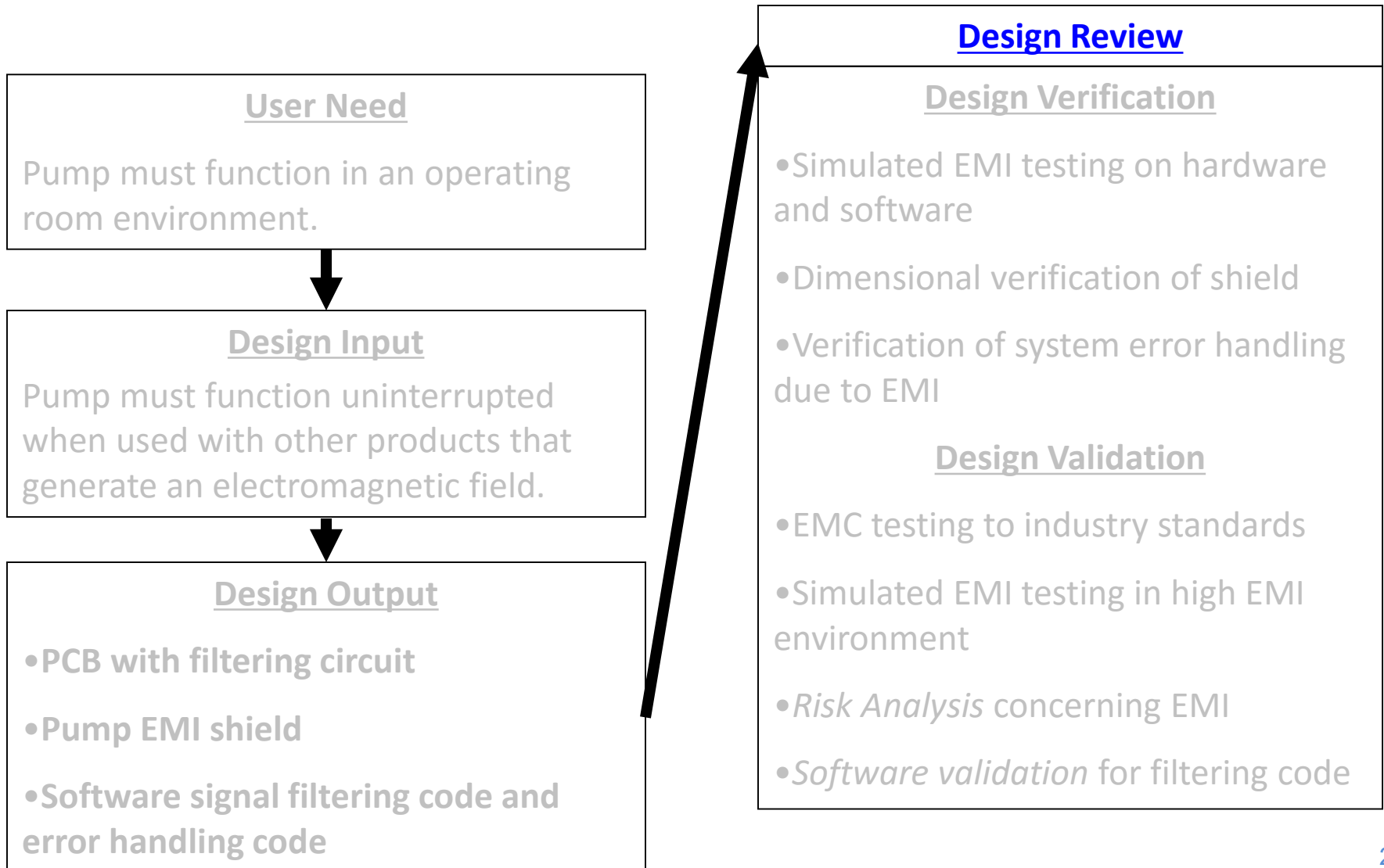


# Design Review

21 CFR 820.30(e)

- **Design Review** is a documented, comprehensive, systematic examination to:
  - Evaluate *adequacy* of the design requirements.
  - Evaluate *capability* of the design to meet requirements.
  - Identify any *problems*.
- Establish and maintain procedures, plan and conduct formal documented **Design Reviews** of design results at appropriate stages, including at each design review:
  - Representatives of all functions concerned and specialists as needed.
  - Individual(s) without **direct responsibility** for the stage being reviewed.
- Document results of design review in **Design History File (DHF)**, including identification of design, date, and individuals performing review.

# Example – Infusion Pump



# Quiz Question

WHO conducts Design Review for a particular design stage? ≡

WHO conducts Design Review for a particular design stage?

<input type="radio"/> Research and Development (R&D)	<div></div>	0%	(0)
<input type="radio"/> Quality Assurance (QA)	<div></div>	0%	(0)
<input type="radio"/> Someone without direct responsibility	<div></div>	0%	(0)
<input type="radio"/> Not sure	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

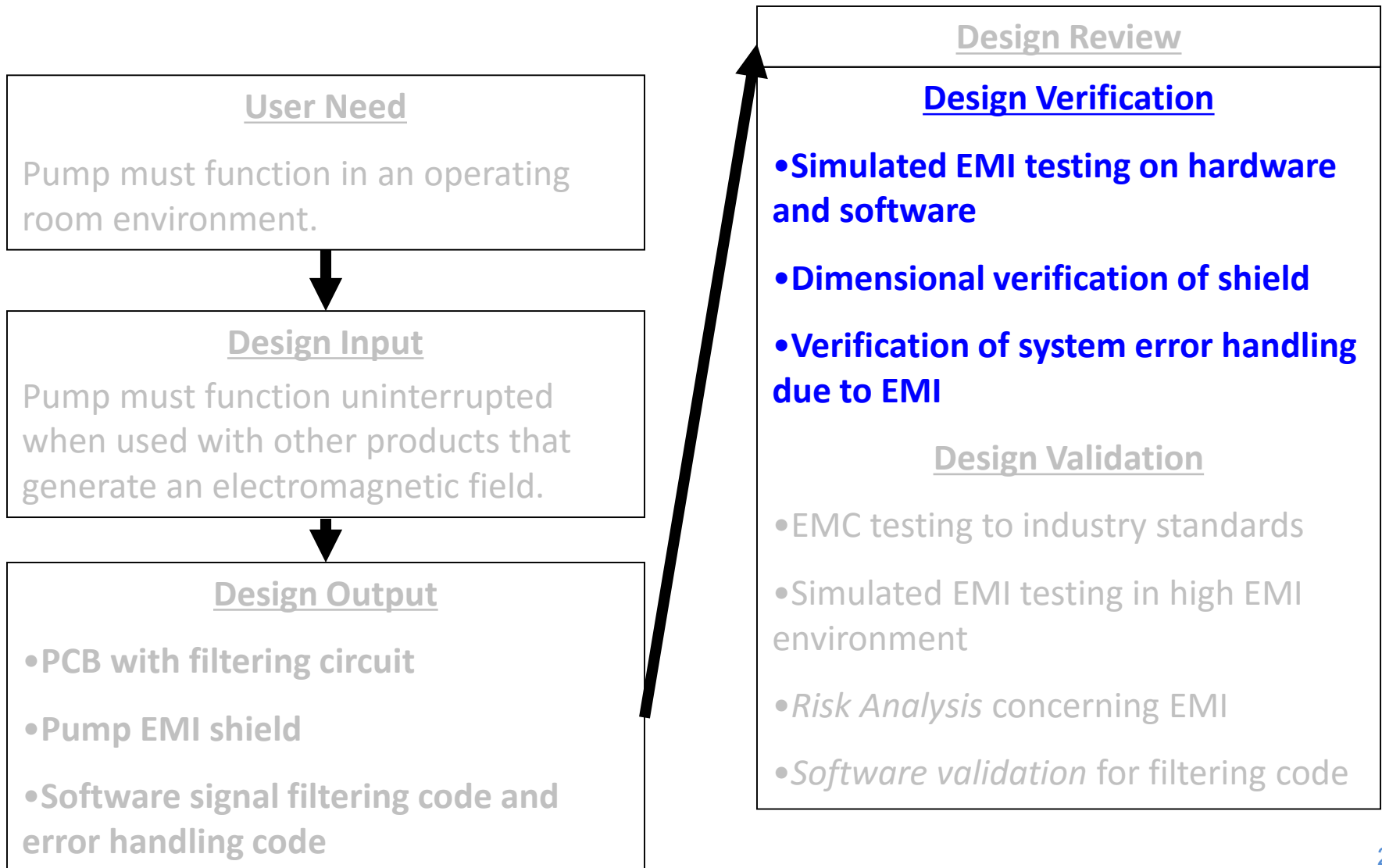
☐ Broadcast Results

# Design Verification

21 CFR 820.30(**f**)

- **Verification** is *confirmation* by examination and provision of *objective evidence* that output meets input requirements (i.e., **Input = Output**).
- Procedures are established and maintained to:
  - Confirm through measurable means (e.g., test reports, etc.).
  - Review, approve and document in Design History File (DHF).

# Example – Infusion Pump



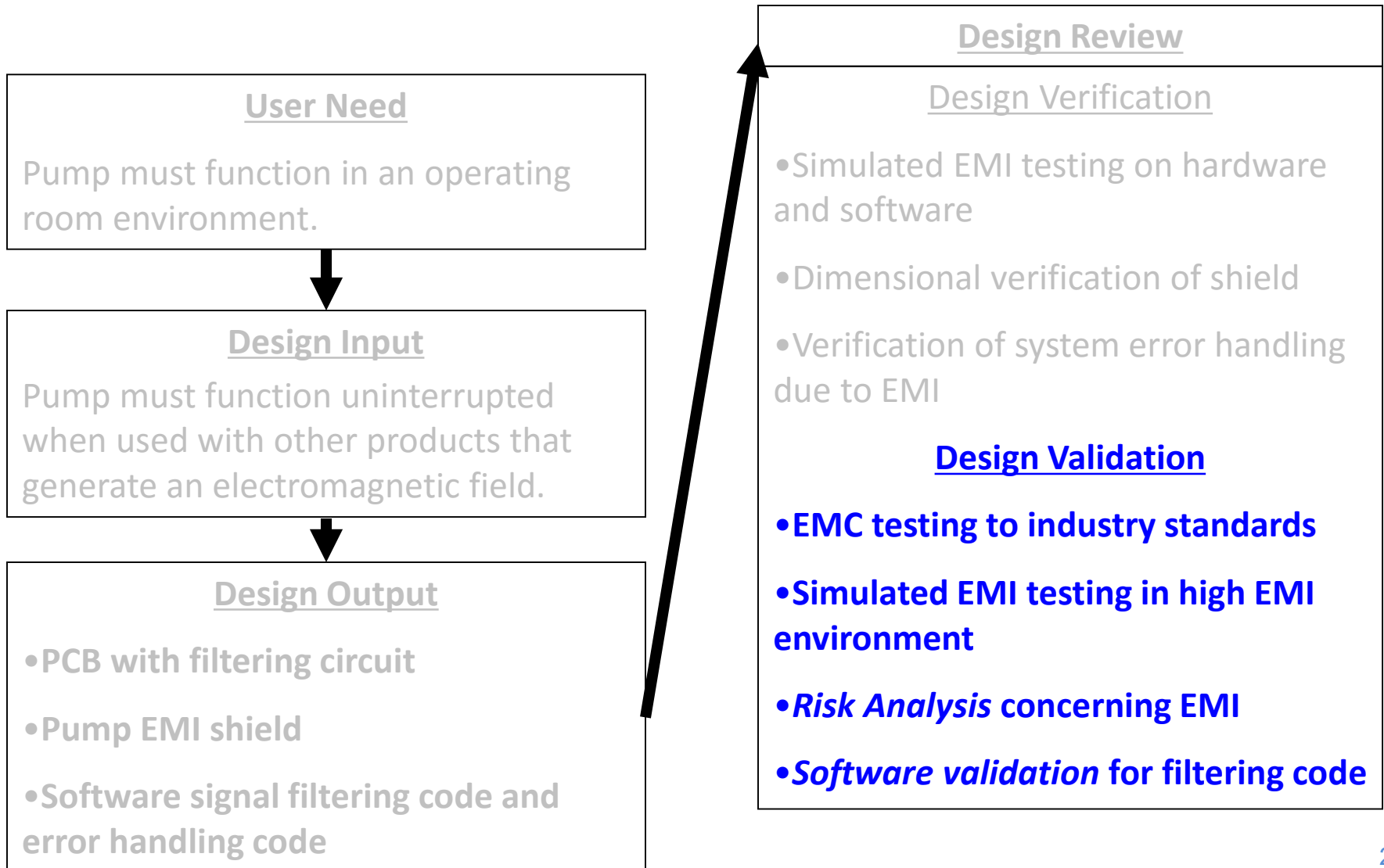
# Design Validation

21 CFR 820.30(**g**)

- **Validation** is the establishment by *objective evidence* that specifications conform with *user needs* and *intended use(s)*.
- Procedures are established and maintained:
  - Under defined operating conditions.
  - On initial production units, lots/batches (or their equivalents).
  - Under actual or simulated use conditions.
- Perform *software validation* and **risk analysis**, where appropriate.
- Review, approve, and document in Design History File.



# Example – Infusion Pump



# Verification vs. Validation

- **Design Verification**

- Output meets Input
- “Did I make the product correctly?”

- **Design Validation**

- Specifications meet user needs and intended use(s)
- “Did I make the correct product?”

# Verification vs. Validation (continued)

- **Design Verification**

- At a “lower” level
- Evaluates the results

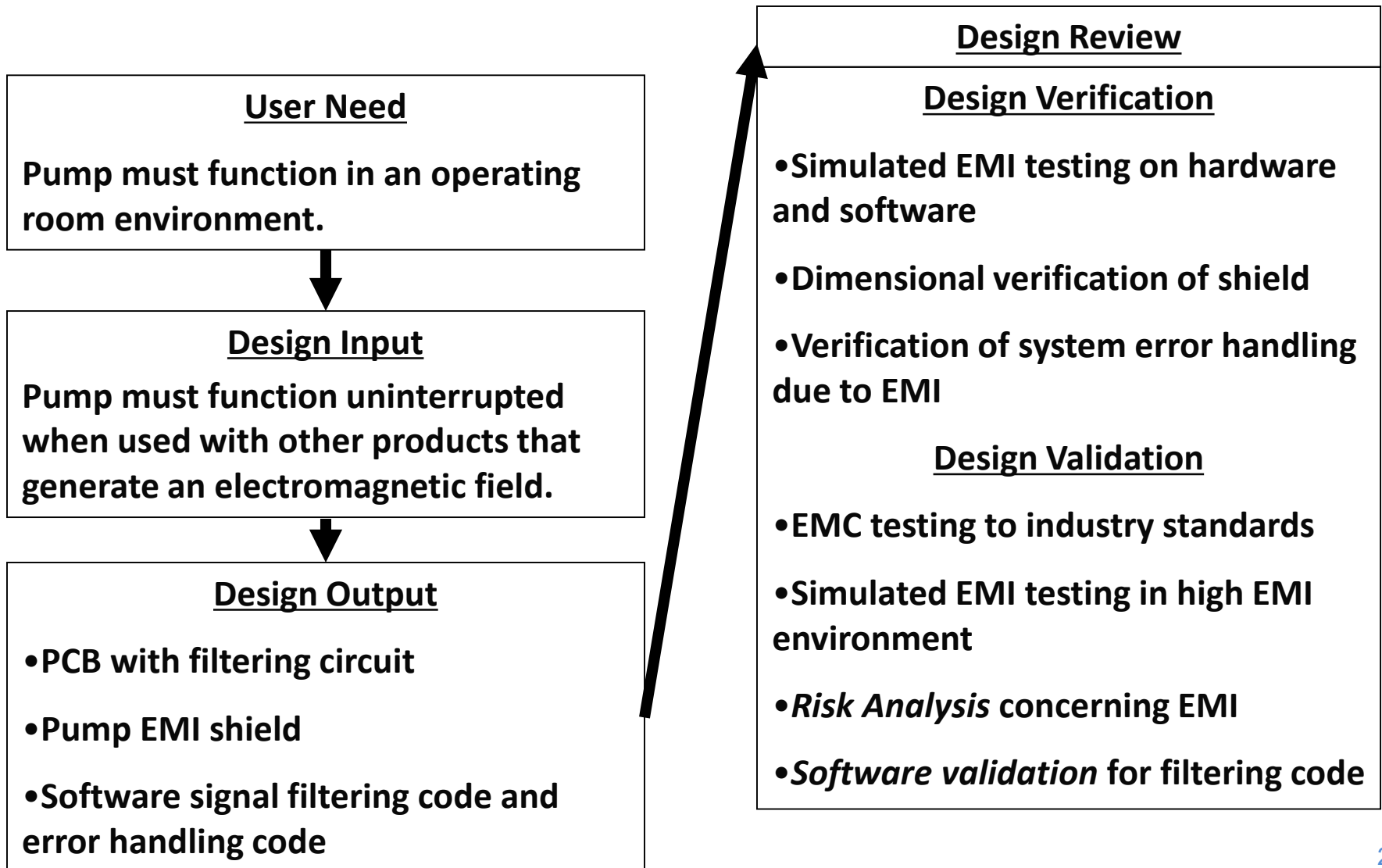
- **Design Validation**

- At a “higher level
- Evaluates the design

# Verification vs. Validation (continued)

- Not to be confused with **Production**  
**Verification and Validation**
  - **DESIGN** refers to design outputs and design specifications (*theoretical*)
  - **PRODUCTION** refers to production inspection and processes (*practical*)

# Example – Infusion Pump



# Design Transfer

21 CFR 812.30(**h**)

- Procedures are established and maintained to ensure correct and accurate ***Design Transfer*** into production specifications.
- Although ***Design Transfer*** happens throughout, there frequently is a *final stage* of development intended to ensure all outputs are adequately transferred.

# Design Changes

21 CFR 820.30(i)

- Procedures are established and maintained for the identification, documentation, validation and verification, review, and approval prior to implementation.
  - Often overlooked, but of critical importance.
  - System in place to enact *future* changes?
  - Improvements with no system for change?
  - Changes may require a new Premarket Submission.
  - Changes must be communicated to FDA if the device is under premarket review.

# Design History File

21 CFR 820.30(j)

- ***Design History File (DHF)*** is a compilation of records which describes the design history of a finished device.
- It is a *summation* record of all Design actions, from *start* to *transfer*, including *changes*.
- A Design History File must be generated for *each type* of device.
- Include in the DHF, or reference records to demonstrate that the design follows the **Design Plan** and Quality System.



# Design Controls - Summary

- Design Control should be viewed and understood as a ***subsystem***
  - A subsystem within the main Quality System.
- **Processes** –A set of quality practices and procedures incorporated into the design and development process.
- **Goal** - Control the design process – Premarket to Postmarket - to assure that device specifications meet user needs and intended use(s).

# QS Regulation and Guidance

- **Quality System Regulation and Preamble**  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm>
- **Guidance: Design Control For Medical Device Manufacturers**  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm>
- **General Principles of Software Validation**  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm>

# Questions?



Please complete the session survey:

[surveymonkey.com/r/DEV-D1S3](https://surveymonkey.com/r/DEV-D1S3)

# Call to Action

- Design controls range from Premarket to Postmarket
- Design controls provide a mechanism for change and improvement in your product

Use Design Controls to Build **Quality, Safety,**  
and **Savings** into your product

