Design Controls, Verification, Validation and Risk Analysis

FDA Small Business
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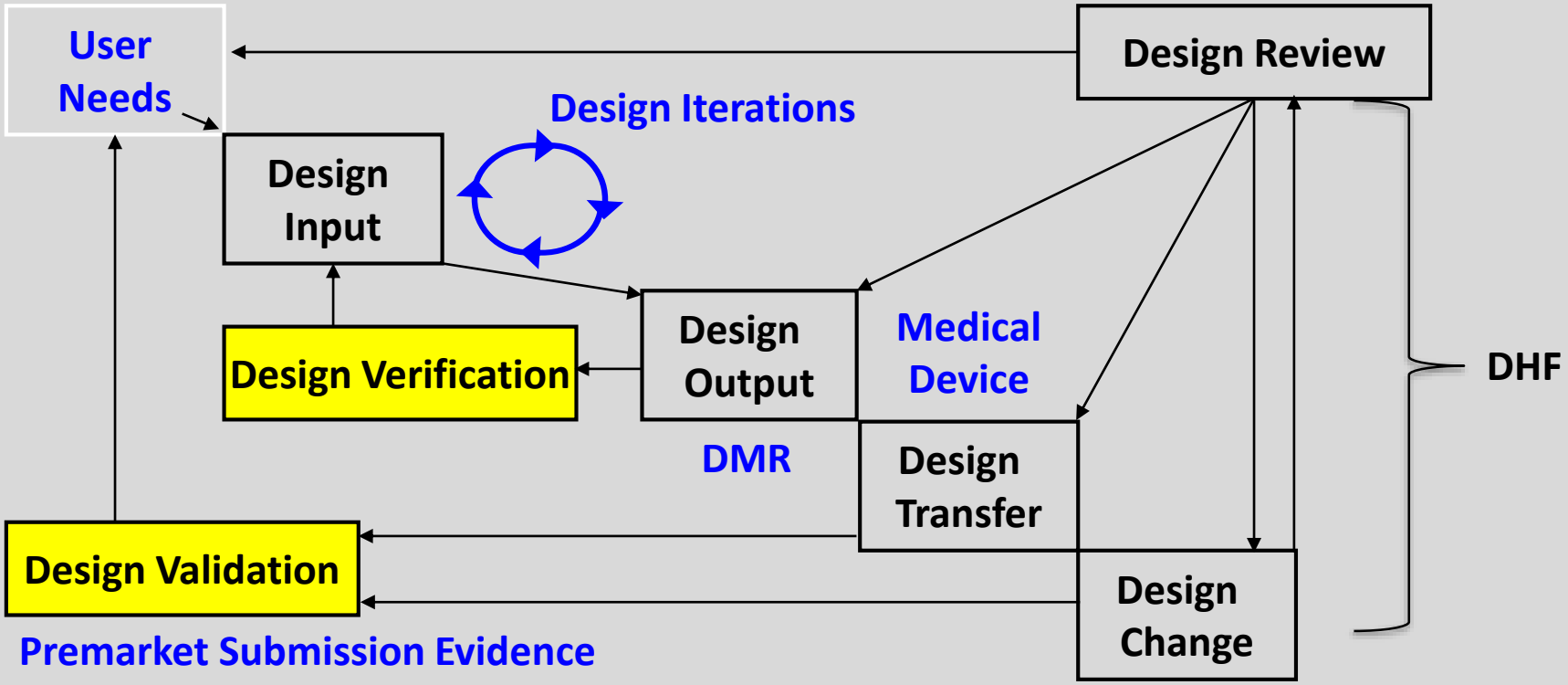
Joseph Tartal
Deputy Director
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Learning Objectives

- Define design verification and design validation
- Identify the requirement for risk analysis in the Quality System Regulation
- Review examples and resources for design verification, validation and risk analysis.

Why Should I Care?

Design Controls Overview



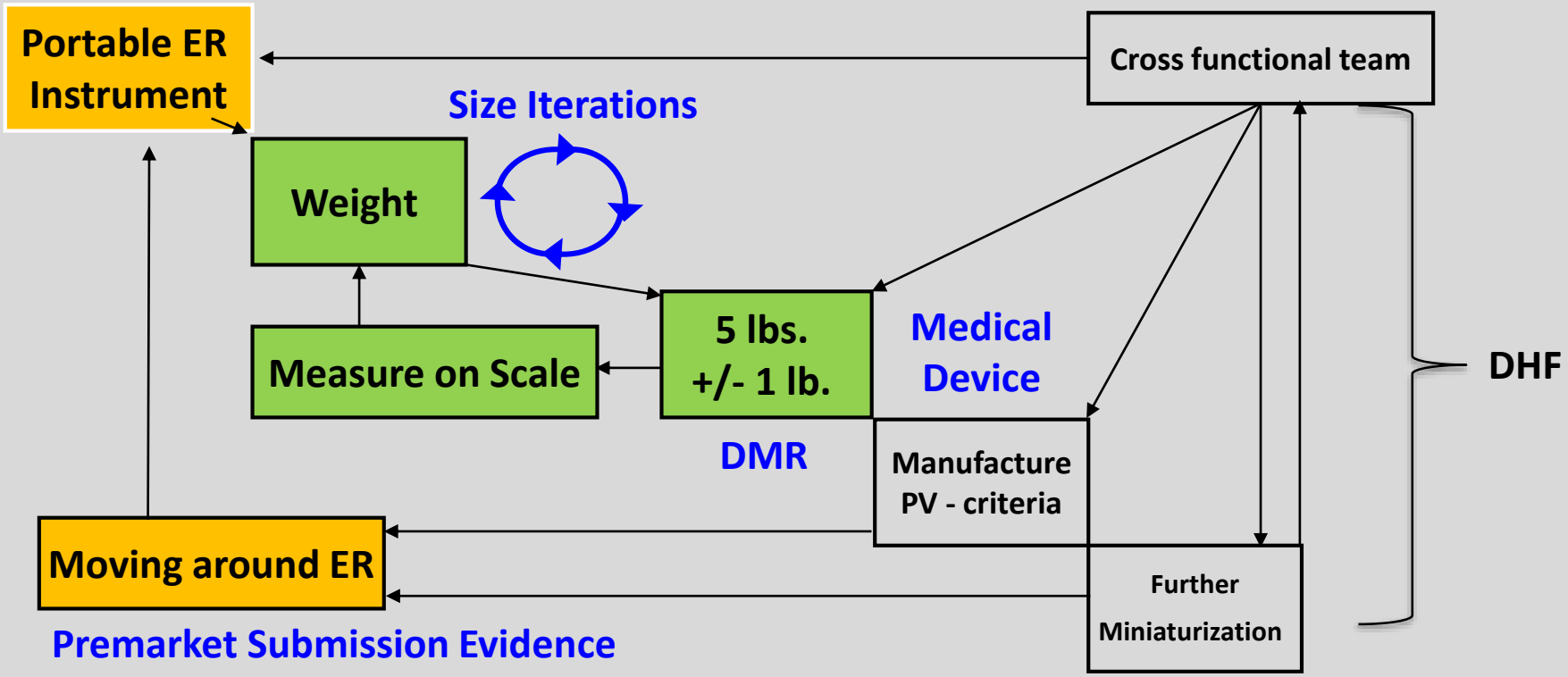
Design Verification 21 CFR 820.30(f)

- Confirmation by objective evidence
- Design output meets design input
- Establish and maintain procedures for Design Verification:
  - Confirm through measurable means (e.g., test reports, etc.)
  - Review, approve and document in Design History File (DHF)

Design Validation 21 CFR 820.30(g)

- Establish by objective evidence
- Specifications (specified requirements) conform with user needs and intended use(s).
- Establish and maintain procedures for Design Validation:
  - Under defined operating conditions
  - On initial production units, lots, or batches (or their equivalents)
  - Under actual or simulated use conditions

Design Controls Overview



Poll

Is it Design Verification or Design Validation?

A surgeon uses a hand-held surgical tool and describes the amount of pressure needed to grip the device.

A. 21 CFR 820.30(f) – Design Verification
B. 21 CFR 820.30(g) - Design Validation

Poll

Is it Design Verification or Design Validation?

An IVD manufacturer tests a point-of-care assay for sensitivity using a microbial panel from the American Type Culture Collection.

A. 21 CFR 820.30(f) – Design Verification
B. 21 CFR 820.30(g) - Design Validation

Poll

Is it Design Verification or Design Validation?

Catheter dimensions are measured against the design specifications.

A. 21 CFR 820.30(f) – Design Verification
B. 21 CFR 820.30(g) - Design Validation

Poll

Is it Design Verification or Design Validation?

A physicians office uses an IVD point-of-care assay to evaluate clinical samples on site.

A. 21 CFR 820.30(f) – Design Verification
B. 21 CFR 820.30(g) - Design Validation

Examples of Design Verification

- Safety Test
- Performance Test
- Sterility Test
- Measurement Inspection
- Visual Inspection
- Tensile Test
- Bioburden Test
- Burst Test

Examples of Design Validation

- Simulated Use Testing
- Evaluations (Clinical and Non-Clinical)
- Clinical Trials
- Scientific Literature Review
- Historical Use Evidence and Performance

Design - Verification vs. Validation

- **Design Verification**
  - Output meets Input
  - "I made the product correctly"
- **Design Validation**
  - Specifications meet user needs and intended use(s)
  - "I made the correct product"

Risk Analysis in the Quality System Regulation

21 CFR 820.30(g) Design Validation:

"Design validation shall include software validation and risk analysis, where appropriate"

Definition of Risk

- No formal FDA definition of the term “risk”
- Starting Point:
  - risk of medical device to patients, end users and environment
  - including risk if device fails, i.e., not operate as intended
- From International Organization for Standardization (ISO) 14971:2007 2.16. Combination of:
  - probability of occurrence of harm and
  - severity of that harm

What is the Intent of Risk Analysis?

- Identify possible hazards, including use error
- Analyze risk, under normal and fault conditions
- Determine risk acceptability
- Reduce unacceptable risks to acceptable levels
- Ensure changes introduce no new hazards

per Preamble Comment #83

Risk Analysis Tools

- Preliminary hazard analysis (PHA)
- Fault Tree Analysis (FTA)
- Failure Mode Effects Analysis (FMEA)
- Hazard and Operability Study (HAZOP)
- Hazard Analysis and Critical Control Point (HACCP)

Risk Mitigations

Mitigation is a broad term which means reduction of probability or control of the risk by:

- Design and redesign
- Protections and Alarms
- Labeling
- Training

Benefit Risk Determination

Once you've applied all reasonable measures to reduce risk, justify remaining residual risk.

- Applies decision to whole device
- May justify abandoning design
- Considers anticipated clinical benefits
- Must approve and communicate final determination

What is Risk Management?

- Is the current approach
- Is both systematic and comprehensive
- Begins with product design and follows it through the Total Product Life Cycle (TPLC)
- From a practical standpoint, integrate into your Quality System

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

Questions

Please evaluate this session:

surveymonkey.com/r/DEV-D2S04

Your Call to Action

- Know your requirements for design verification and design validation and meet or exceed them.
- Medical Devices pose a risk. Understand the risk of your device.
- Use the knowledge provided to ensure your devices are appropriately designed to be safe, effective and meet user needs.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