User Needs, Design Input, Design Output and Design Review

FDA Small Business
Regulatory Education for Industry (REdI)
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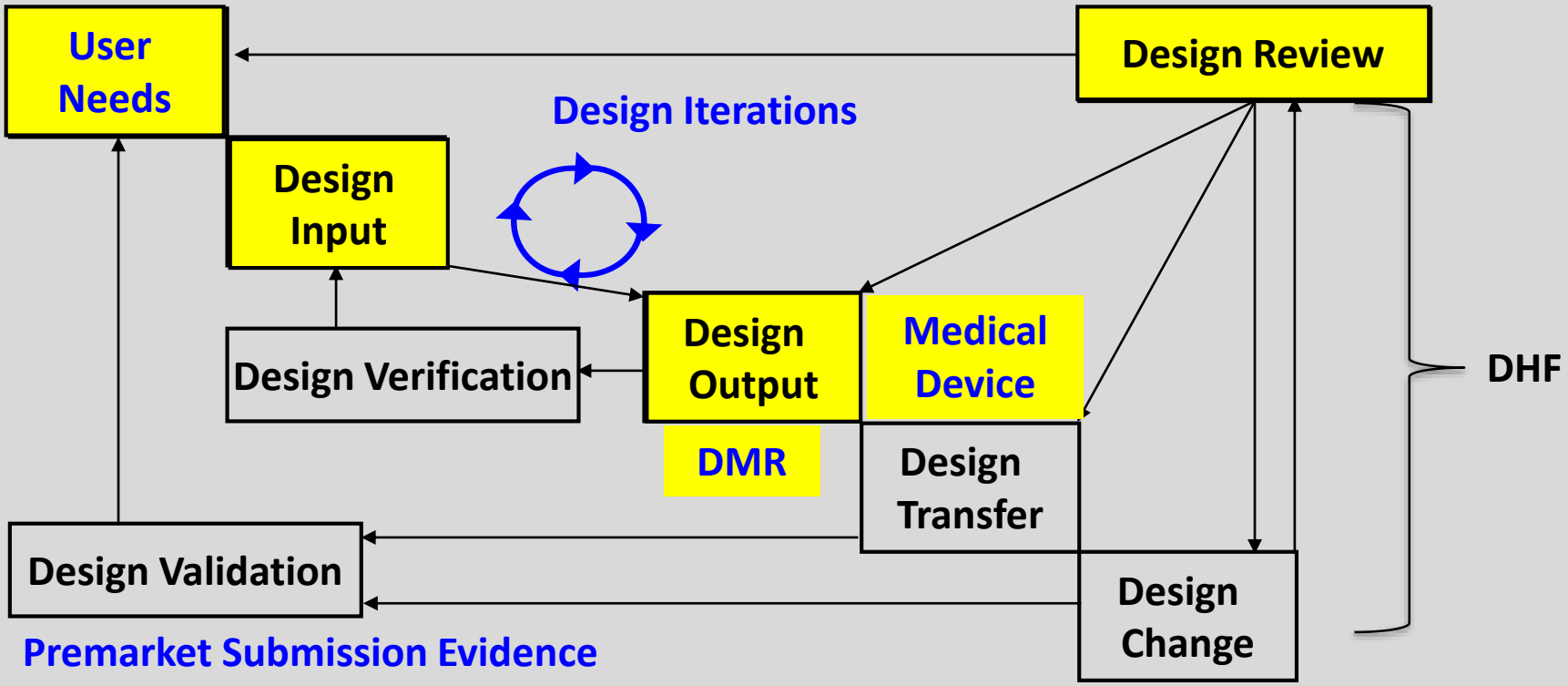
Design Controls Overview

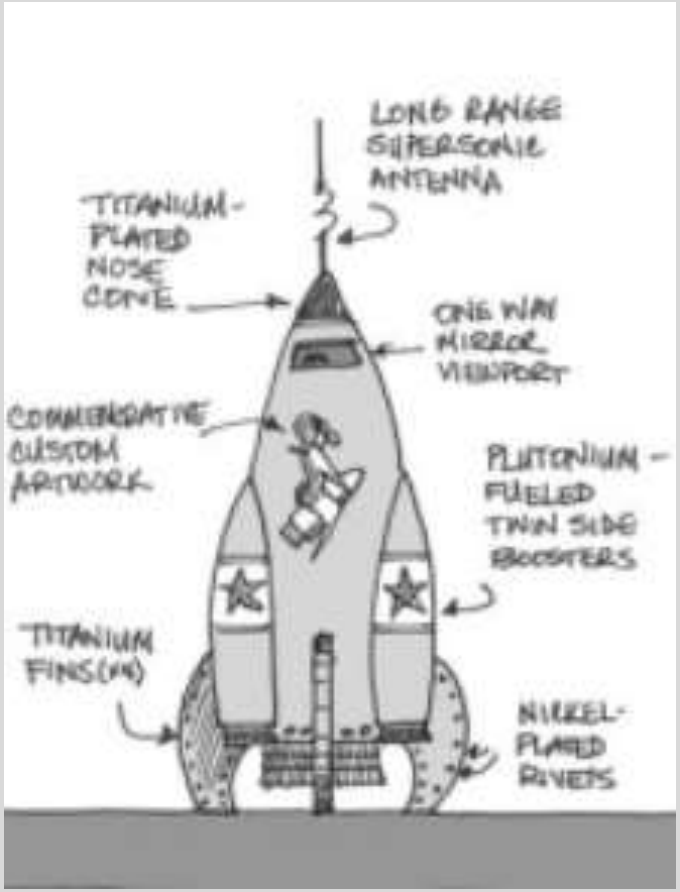


Learning Objectives

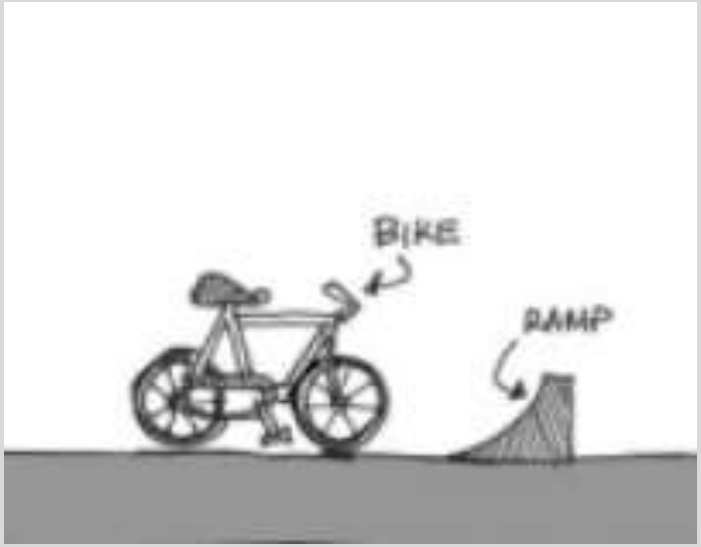
- Importance of User Needs
- Relationship between User Needs, Design Input and Design Output
- Elements of Design Review

User Needs???

What we designed



What the user wanted



User Needs

Users

- People who interact with the device
  - Patients
  - Medical professionals
  - Caregivers
  - Installers, maintenance & cleaning personnel

User needs

- Users' expectations relative to the device's purpose

Design Controls -When to Start?

- Where research ends and design begins
- Premarket
- Mechanism of change/revision

Design Controls – Where to Start?

Design Planning: **Establish**, maintain and document

- 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 development 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 a basis for device design.

FDA's response to the comment # 19 in Preamble states "to use the term **requirements** in the broadest terms possible"

Design Input 21 CFR 820.30(c)

Establish and maintain procedures for Design Input:

- Ensure requirements are appropriate by addressing user needs and intended use(s) in terms that are measurable.
- Address incomplete, ambiguous, or conflicting requirements.
- Document, review, and approve input requirements.

Examples of Design Input

- Device functions
- Physical characteristics
- Performance
- Safety
- Reliability
- Standards
- Regulatory requirements
- Human factors
- Labeling & packaging
- Maintenance
- Sterilization
- Compatibility with other devices
- Environmental limits

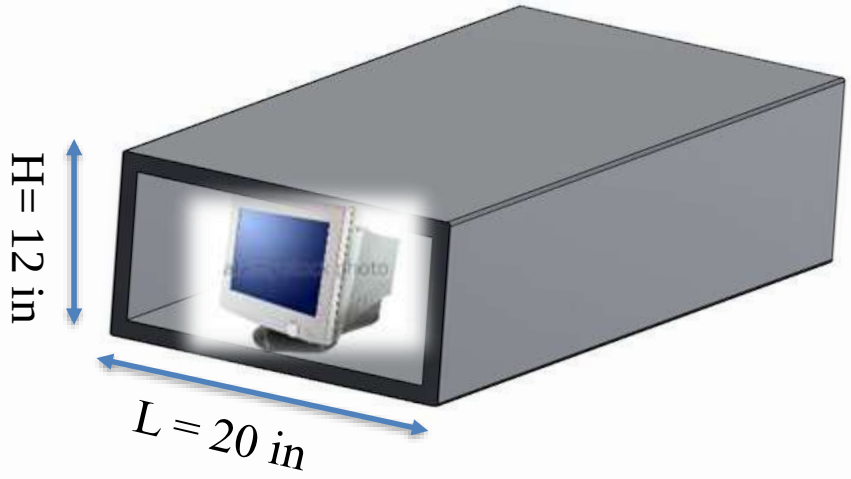
Human Factors

- Study of the **interactions between humans and device** (i.e., interface) and subsequent design of the device-human interface
- Plays an important role in Design Control

Design Input: Example

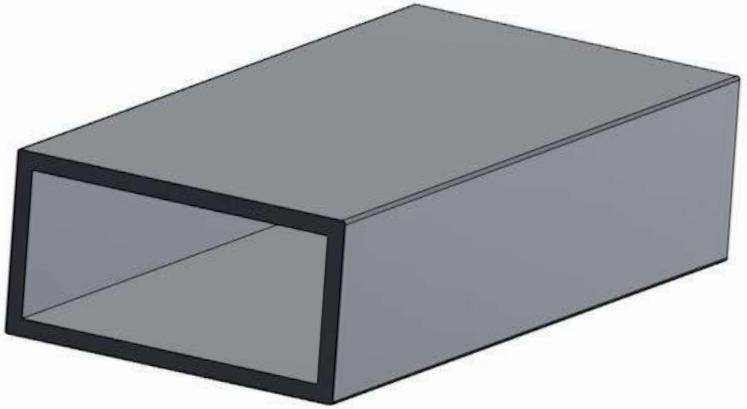
User Need	Design Input
A. Portable Instrument	A.1 L 15.0” x W 13.0” x H 7.5” (± 0.1”)
	A.2 Weight ≤ 5 lbs (± 1 lb)
	A.3 Can be carried with one hand

What we wanted



What we Specified
18 X 15 X 11

What we Got



Resolving Incomplete, Ambiguous, or Conflicting Inputs

Useful hints for resolution:

- Use risk analysis information to prioritize/resolve
- Conduct specific design reviews and revisit input issues for ambiguous or conflicting inputs in each life cycle phase
- Resolve input issues by a certain project milestone (e.g., before design verification)
- Escalate to senior management for decision

Design Input: Conflict

User Need Example: "**Portable**"

5 **lbs** ± 1 **kg**

- Identify conflicting requirements (different units of measure)

5 **lbs** ± 1 **lbs**

- Resolve discrepancies

Design Output 21 CFR 820.30(d)

- Results of a design effort at each design phase and at the **end of the total design effort**.
- Establish and maintain procedures for Design Output:
  - Define and document design output in terms that allow an adequate evaluation of conformance to design input.
  - Reference definable/measurable acceptance criteria.
  - Identify design outputs **essential** for the proper functioning of the device.
  - Review, approve, and document design output before release.

Examples of Design Outputs

- Specifications for
  - Components
  - Raw materials
  - Subassemblies
  - Finished device
  - Product labels
  - Labeling such as User Guides
  - Packaging
- Bill of Materials, parts list
- Drawings, data sheets, diagrams
- Device software (source code, build instructions, libraries, executables)
- Installation instructions, Service manuals
- Manufacturing process
  - Specifications
  - Process flowcharts
- Acceptance activity
  - Procedures, instructions, sampling plans, acceptance criteria

Device Master Record (DMR)

- Current Recipe for making the device
- Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff

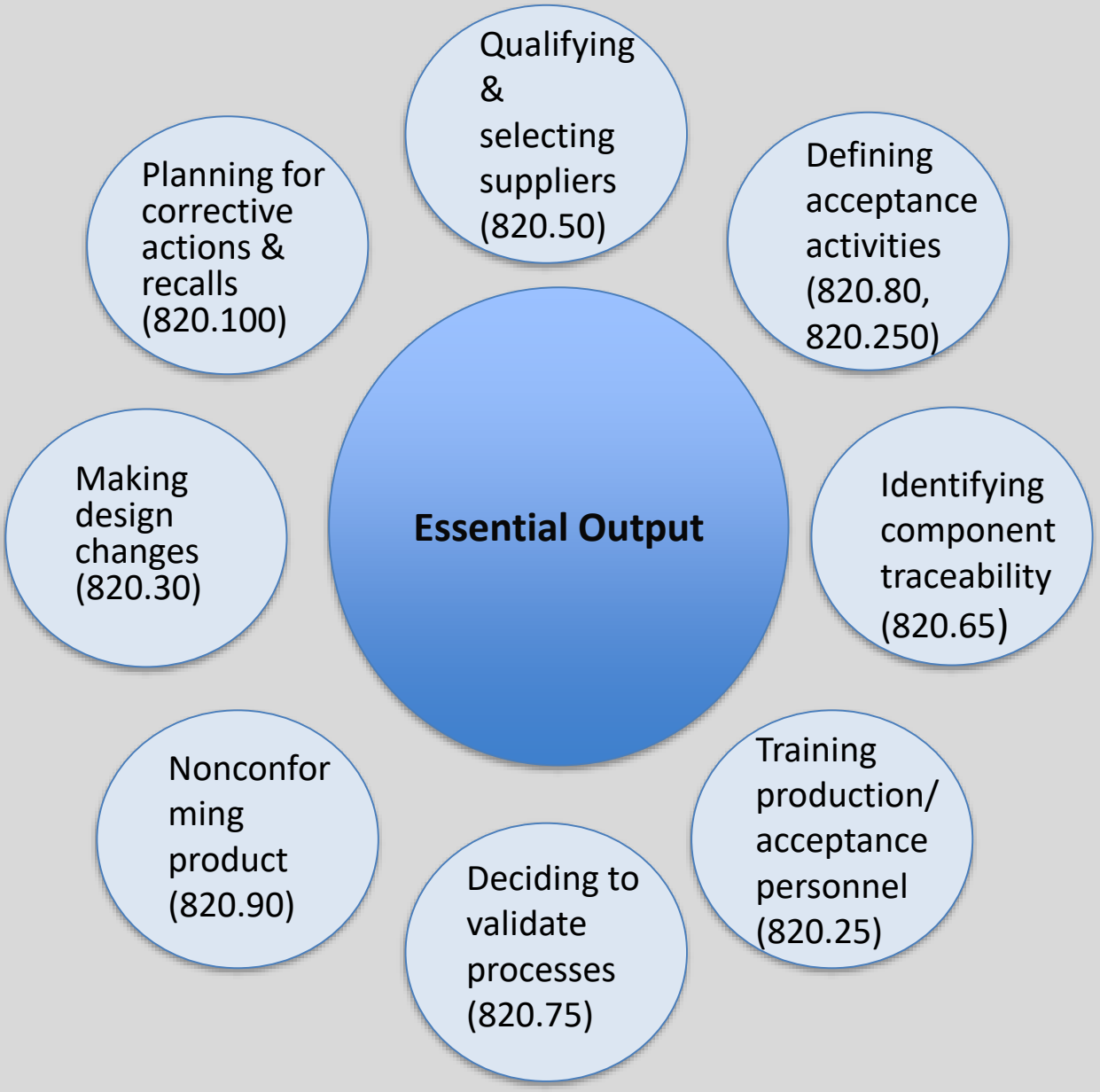
FDA response to comment # 20 and comment # 76 in the Preamble contain the elements of a DMR

Design Input and Output

User Need	Design Input	Design Output
A. Portable Instrument	A.1 L 15.0” x W 13.0” x H 7.5” (± 0.1”)	Drawing # 123 - XY
	A.2 Weight ≤ 5 lbs (± 1 lb)	Port Model 123
	A.3 Can be carried with one hand	Handle Drawing #123- AB

Identifying Essential Outputs

- Outputs that are essential for the proper functioning of the device must be identified
- Various methods can be employed
  - Risk analyses tools(e.g., FMEA, FTA)
  - Comparative analysis with other products (e.g., test failures, complaint investigations)
  - Reliability testing (e.g., Mean Time To Failure)
- Documenting essential outputs is required
  - Specific lists of essential outputs, specifications, drawings, inspection plans, Bills of Material, within Risk Analysis, Material Resource Planning systems, …


Qualifying & selecting suppliers (820.50)
Defining acceptance activities (820.80, 820.250)
Planning for corrective actions & recalls (820.100)
Making design changes (820.30)
Essential Output
Identifying component traceability (820.65)
Nonconforming product (820.90)
Training production/ acceptance personnel (820.25)
Deciding to validate processes (820.75)

Design Inputs to Design Outputs

Methods for confirming that all design inputs have been addressed by outputs:

- Design review
- Traceability analysis
- Design verification planning

Design Review 21 CFR 820.30(e)

A documented, comprehensive, systematic examination to:

- Appropriately review the design at pre-determined stages
- Include appropriate representation as well as an **independent reviewer**
- Evaluate adequacy of the design requirements
- Evaluate capability of the design to meet requirements
- Identify any problems

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-D2S03

Your Call to Action

- Ensure your design inputs address user needs
- Resolve Incomplete, Ambiguous, or Conflicting Inputs
- Identify Essential Outputs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