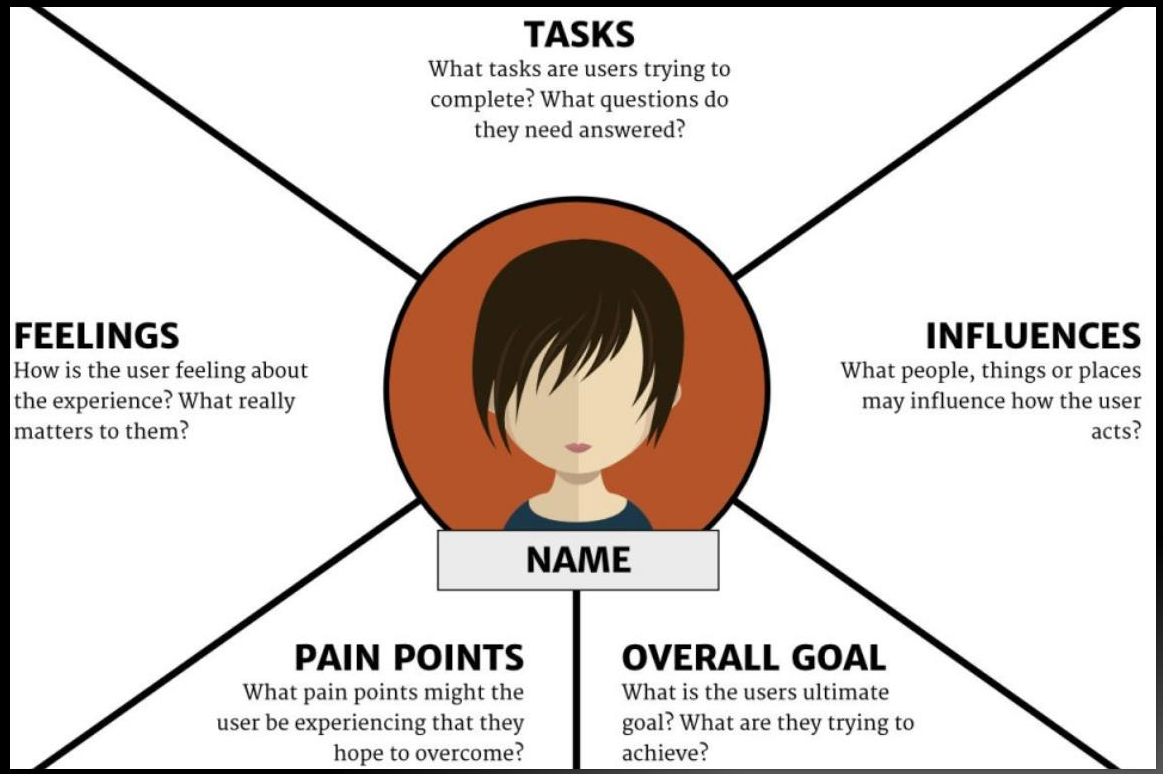
Design Inputs: User Needs

- How to define User Needs
  - Enough time should be taken at this stage of design to completely assess the needs of the customer and/or market
  - Data from marketing, sales, service and quality tasked with dealing with customers is critical
  - Scientific affairs, data from conferences and trade shows, key opinion leaders and industry standards are all sources of intelligence for User Needs

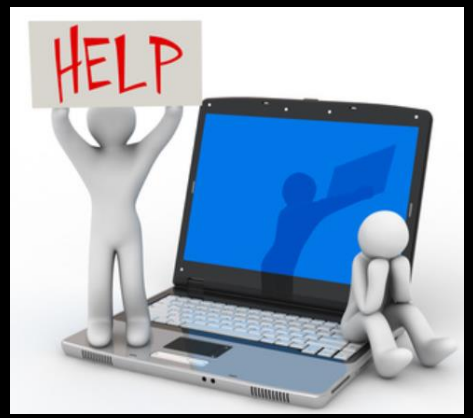


Design Inputs: User Needs

- User needs are normally stated in "general ways"
  - "The alarm must be heard at a distance of at least 5 meters in an ICU"
  - "The assay must be completed in a standard work shift"
  - "The sample volume has to be less than 1.0 ml"
  - "The interface has to be colored coded"
- These inputs need to be able to be directly translated into measurable Product Requirements

Design Inputs: User Needs

- Results of poorly defined (or non-existent) User Need:
  - Lots of time and money spent developing the wrong product
  - Low sales
  - Lots of complaints after market launch
  - Lots of time and money spent after launch to fix what should have been designed the right way the first time



Design Inputs: Product Requirements

- Product requirements trace directly back to User Needs
  - One user need may have several product requirements traced to it
- Product Requirements are how the development team knows what to develop
- Basis for project management
- What is being built and why
- Basis for design verification requirements
- Basis for ensuring proper function of the device

Design Inputs: Product Requirements

- Benefits of good Product Requirements
  - Build it right the first time
  - Everyone on the team will be working off the same design
  - Can help minimize feature creep during development
  - Helps define what is being build and why
  - Define requirements for design verification

Design Inputs: Product Requirements

- Functions to be performed
- Physical characteristics
- Performance requirements
- Safety (manufacturing and user)
- Reliability in the field
- Environmental considerations
- Regulatory standards
- Labeling
- Human factors considerations
- Maintenance
- Compatibility with other devices or equipment (Company's or others)

Design Inputs: Product Requirements

- Common Industry Practice
  - Functional
    - What the device does
    - Performance Capabilities
  - Performance
    - How does the device perform
    - Performance parameters
  - User Interface
    - Safety
    - Usability
  - Environmental Considerations
    - Physical environment
    - Local environmental law
    - Manufacturability

Remember: Product Requirements must Be measurable!

Design Input: Examples

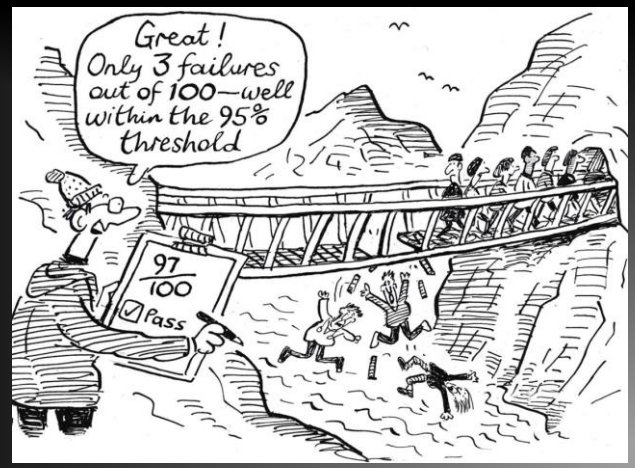
- Functional Design Input Examples
  - Should be expressed as a “verb” not a “noun”
    - The product should:
      - Detect an infection
      - Infuse a drug
      - Monitor respiration rate
      - Inject the proper dose…

Design Input: Examples

- Performance requirement
  - Validity rate for the assay should be ≥ 95%
  - Infusion rates adjustable between 1.0 ml and 5.0 ml/min
  - Accuracy of respiration rate readout to be ≥ ± 1.0%
  - Injection accuracy of within 0.01% of dose

Design Input: Examples

- Human Factors Design Input Examples
  - Invalid assay results should be clearly flagged on printout
  - Digital flow readout should be readable from a minimum of 2 meters from the device
  - Respiration alarm should be a minimum of 100 decibels at 15 meters
  - Dose indicator should change color after injection



Design Input: Summary

- Trace from User Needs to Product Requirements
- Defined during development phase
  - Must be approved
- Maintained in the Design History File (DHF)
- Traceability
  - Product Requirements to Design Risk Documentation
  - Basis for trace to design output
  - Basis for Design Verification studies

Design Outputs

- Results of design program at each design phase
- Results after total design program
- Finished design output is the basis for the Device Master Record (DMR)
- Finished design output consists of:
  - The Device
  - The Device Specifications
  - The Device Testing
  - The Device Manufacturing
  - The Device Packaging
  - The Device Labeling
  - The Device DMR

Design Outputs

- Design Outputs – FDA
  - 21 CFR 820.3 (d)
    - (d) *Design output.* Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

Design Outputs

- Design Outputs – ISO 14971:2016
  - 7.3.4 Design and development outputs
    - Design and development outputs shall:
      - a) meet the input requirements for design and development;
      - b) provide appropriate information for purchasing, production and service provision;
      - c) contain or reference product acceptance criteria;
      - d) specify the characteristics of the product that are essential for its safe and proper use.
      - The outputs of design and development shall be in a form suitable for verification against the design
      - and development inputs and shall be approved prior to release.
      - Records of the design and development outputs shall be maintained

Design Outputs

- Quality System Requirements
  - Design Outputs establish procedures for the final device
  - Document in terms that allow the design output to be verified against the design input
  - Must include acceptance criteria
  - Design output must identify output essential for the correct functioning of the device
  - Must be reviewed and approved before release