Please sit with your team!

Design Control

Wally, we don't have time to gather the product requirements ahead of time.

I want you to start designing the product anyway. Otherwise it will look like we aren't accomplishing anything.

Of all my projects, I like the doomed ones best.
The Design Process
Design Controls
Design inputs are defined by FDA 820.30(c) and ISO 13485:2003

820.30(c) states: Each manufacturer shall establish and maintain procedures to ensure that design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

ISO 13485:2003 7.3.2 states: Inputs relating to product requirements shall be determined and records maintained. These inputs shall include:
   a) functional, performance, and safety requirements, according to the intended use,
   b) applicable statutory and regulatory requirements,
   c) where applicable, information derived from previous similar designs,
   d) other requirements essential for design and development, and
   e) output(s) of risk management

These inputs shall be reviewed and approved. Requirements shall be complete, unambiguous, and not in conflict with each other.
Writing good design inputs takes time and is somewhat of an art form

Your goals when defining Design Inputs include:

– Capturing all functional, performance, safety, and regulatory requirements.
– Build upon User Needs and intended use.
– Make sure Design Inputs are clear and objective.
– State Design Inputs in a way that allow you to prove / disprove them.
Design Input

“input is really a list of requirements from customers (either direct from customer or indirect through market studies), tempered by realities of budget, competition, capability, capacity, government regulation”

– Wes Bucey, Medical Device Consultant
Functional requirements specify what the device does.

Don’t put what you want to do before how you need to do it.
Performance requirements specify how much or how well the device must perform, addressing issues such as speed, strength, response times, accuracy, limits of operation, etc.

Specific values and target ranges
Interface requirements specify characteristics of the device which are critical to compatibility with external systems.
Design Input
ASSESSING DESIGN INPUT REQUIREMENTS FOR ADEQUACY

Design input requirements should be unambiguous.

– *Each requirement should be able to be verified by an objective method of analysis, inspection, or testing.*

– Quantitative limits should be expressed with a measurement tolerance.
Recall that verification and validation are different tests

**Design output = Design input**

**Validation**: Did we make the right product?  
(Does the product meet customer needs?)

**Verification**: Did we make the product right?  
(Do our processes ensure that the product will do what it is design to do?)
Design outputs are defined by FDA 820.30(d) and ISO 13485:2003 7.3.3

820.30(d) states:
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.

ISO 13485:2003 7.3.3 states:
The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall
a) meet the input requirements for design and development,
   b) provide appropriate information for purchasing, production, and for service provision
   c) contain or reference product acceptance criteria, and
   d) specify the characteristics of the product that are essential for its safe and proper use.

Records of the design and development outputs shall be maintained (see 4.2.4).
The FDA has stated expectations for Traceability in Device & Diagnostic Design

21 CFR 820.30

(a) “General. (1) Each manufacturer...shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.”

Translation for FDA inspectors

“The purpose of the design control subsystem is to control the design process to assure that devices meet user needs, intended uses, and specified requirements:

- Inputs must be documented
- Outputs must be documented
- Confirm that device outputs are traceable to design inputs”
1-10-100 Rule

Verification and validation are required by the FDA and ISO standards

1. Ethical obligation to customer to ensure that product works and is safe to use
2. Reduces liability
Basic testing is required by all projects

Analytical modeling

Bench Testing

Package Testing

Field Testing

Shelf-life Studies

Product Introduction
Medical devices require much more intensive testing

- Biocompatibility Tests
- Bench Tests
- Animal Studies
- Human Clinical Studies
- Package Tests
- Shelf-life Studies
- Product Introduction
Parametric Design is an emphasis on design variables (which the designer sets) and setting values for these variables combined with modeling.
Bench testing gives you an analytical result.

Use/simulate production processes to produce test units:
- same tooling, assembly methods, processes, sterilization, etc.
- Simulate use/function of product in laboratory

Simulate service environment (environmental testing):
- mechanical and electrical loading
- lubrication, wear conditions
- fluid composition, concentration, $T^\circ$, pH
- magnetic fields, other energy sources
- flow rates

Monitor performance characteristics during testing:
- flow rates
- wear debris
- voltage output, leakage current
- mechanical deformation, change in material properties
Field testing is required as well because analytical models are not definitive.

Conduct prior to market release to prevent defective or inadequate designs (those that do not meet customer needs) from entering market.

- Software – Beta test sites
- Consumer products – limited market release
- Medical products – human clinical study
All projects will conduct usability studies at Jump Simulation and Education Center in the spring.
Basic biocompatibility tests can tell you basic information about your product.

Need to ensure that materials

- remain stable
- do not significantly degrade
- do not harm body (not toxic, etc.)
- are not adversely affected by processes (sterilization, lubricants, mold releases, cleaning agents, etc.)
Animal Studies are needed to confirm biocompatibility, bioactivity, bioresorption, etc.

• Requirements:
  – appropriate animal model
  – written protocol
  – approval of animal use committee

• Test for safety and efficacy
  – monitor performance of device
  – perform histological evaluation
  – inspect for damage to tissues, organs, structures
Human Clinical Studies are reserved for situations only where benefit exceeds risk.

- Cannot exactly duplicate physiological environment in lab
- Animal models not identical to human model

- Need to conduct human clinical study to accurately evaluate performance of device in humans, verify claims

- Will often encounter new problems in clinical study that were not observed in animal study or bench testing.
There are two main ways to determine shelf life, depending on expected shelf life.

- **Real time shelf life studies**
  - conduct distribution simulation
  - simulate storage environment
  - evaluate product and packaging for changes in properties and function over time

- **Accelerated aging studies**
  - higher temperature, reduced time
  - must be correlated with real-time study
Shelf life testing is important to make sure that the customer gets the same product at day 1 or day XX.
**Traceability matrix**

- input requirements are enumerated in a table, and references are provided to each section in the output documents (or software modules) which address or satisfy each input requirement.
- "backwards," - list each feature in the design output and tracing which input requirement bears on that feature.
The concept of requirements tracing is quite simple: to follow relationships or links.

Backward traceability is the ability to trace a work product back to its source or requirement.

Forward traceability is the ability to trace a requirement from user needs to components of a design.
Needs and Design Requirements

• Functional Requirements
  – Saliva Storage Efficiency

• Performance Requirements
  – Portability
  – Safety
  – Quiet
  – Re-usable

• Interface Requirements
  – Comfort
  – Aesthetics
  – Ease of Use
## Example Traceability from Dryson

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevents drooling</td>
<td>Device quickly and easily removes mouthful of saliva</td>
</tr>
<tr>
<td>Portable</td>
<td>Attachable to wheelchair; no power outlet required</td>
</tr>
<tr>
<td>Safe</td>
<td>Non-toxic materials, not brittle, especially where interacting with mouth</td>
</tr>
<tr>
<td>Quiet</td>
<td>No loud motors</td>
</tr>
<tr>
<td>Cleaned/emptied for repeated use</td>
<td>Saliva can be dispensed to bags or containers; parts with saliva can be easily cleaned</td>
</tr>
<tr>
<td>Comfortable</td>
<td>Materials do not irritate the skin</td>
</tr>
<tr>
<td>Looks cool/fashionable</td>
<td>Blends in with normal wardrobe</td>
</tr>
<tr>
<td>Operable by user or aid</td>
<td>Simple or mechanized application</td>
</tr>
</tbody>
</table>
Wrap Up

• The biggest advantage of Traceability Matrix is backward and forward traceability.
  – (i.e) At any point of time in the development life cycle the status of the project and the modules that have been tested could be easily determined thereby reducing the possibility of speculations about the status of the project.
Wrap Up

• What happens if the Traceability factor is not considered during the design process?
  – The system that is built may not have the necessary functionality to meet the customers and users needs and expectations
  – If there are modifications in the design specifications, there is no means of tracking the changes
  – If there is no mapping of test cases to the requirements, it may result in missing a major defect in the system
  – The completed system may have “Extra” functionality that may have not been specified in the design specification, resulting in wastage of manpower, time and effort.

Traceability is part of Component F