Translating User Needs

Into Actionable Design Inputs

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Utilizing a traceability matrix to help define and track product requirements reduces risk and helps carry initial insights through to realized products. At MPE Inc., we call our version the Product Requirements Matrix, the first few columns are shown to the right.

Our process in translating a user need into actionable design inputs starts with our Product Requirements Matrix. Translating a qualitative need requires defining the quantifiable equivalents, in context with the use case. This allows us to create a measurable specification which we can hold the final design to.

NEEDS		DESIGN INPUTS			
		REQUIREMENTS		SPECIFICATION	
Source: MRD, URD	Description	Source: PRD, Reg.	Description	Source: Standard & Section	Description

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It is critical to determine the use specification of the device before attempting to translate user needs. The use specification and product requirements can vary drastically based on who specifically is using the device and the particular environment it is being used in.

Here, we've entered the user need and where it originated. In this instance, it came from the Marketing Requirements Document (MRD) and gained context in the use specification.

NEEDS		DESIGN INPUTS			
		REQUIREMENTS		SPECIFICATION	
Source: MRD, URD	Description	Source: PRD, Reg.	Description	Source: Standard & Section	Description
MRD	Portable				

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With the appropriate use context for "portable", we can begin to generate high-level requirements in the Product Requirements Document (PRD). These requirements can look like:

- must be movable under user control
- by a 5-95 percentile US medical clinician (RN/MA/NP/MD, etc.)
- over a distance of 200 yards

or

- must meet FDA regulatory controls

NEEDS		DESIGN INPUTS			
		REQUIREMENTS		SPECIFICATION	
Source: MRD, URD	Description	Source: PRD, Reg.	Description	Source: Standard & Section	Description
MRD	Portable	PRD	size		
		PRD	weight		
		PRD			
		PRD	handling affordances (grip / handle)		
		PRD			

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Here, we're beginning with usability related requirements. We can apply human factors / usability standards to determine design input specifications.

In this case, HE75:2009 – Human Factors Engineering for the Design of Medical Devices is the appropriate standard.

For example, a high-level requirement like:
- **a 5-95 percentile clinician must be able to carry the device for a flat distance of 200 yards**

Can be translated into quantifiable inputs:
- **must be no larger than 20" wide, 30" tall, and 20" deep**
- **must weigh no more than 20 lbs.**
- **must have handles with diameter of 1.5"**

NEEDS		DESIGN INPUTS			
		REQUIREMENTS		SPECIFICATION	
Source: MRD, URD	Description	Source: PRD, Reg.	Description	Source: Standard & Section	Description
MRD	Portable	PRD	size	HE75:2009: 25.2.7	L x W x H
		PRD	weight		Lbs
		PRD	handling affordances (grip / handle)		Handle Diamter
		PRD			Hangle Length
		PRD			Handle Hand Clearance

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As for regulatory related requirements, let's consider our hypothetical "portable" medical device to be sold and used in the United States. This would mean that it will have some form of FDA classification, for our example we'll say it falls under Class II controls.

In our experience, "portability" almost always has requirements relating to handling affordances, mechanical strength, and stability. The medical electrical device standard IEC 60601 happens to be one of the most applicable standards, with many aspects governing devices that will move in or between environments.

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		REQUIREMENTS		SPECIFICATION	
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MRD	Portable	PRD	size	HE75:2009: 25.2.7	L x W x H
		PRD	weight		Lbs
		PRD	handling affordances (grip / handle)		Handle Diamter
		PRD			Hangle Length
		PRD			Handle Hand Clearance
		REG		IEC 60601-1: 2012 9.4.4	
		REG	mechanical strength	IEC 60601-1: 2012 15.3.1	
				IEC 60601-1: 2012 15.3.2	
				IEC 60601-1: 2012 15.3.3	
				IEC 60601-1: 2012 15.3.4	
				IEC 60601-1: 2012 15.3.6	
		REG	stability	IEC 60601-1: 2012 9.4.2.1	

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The IEC 60601 subsections typically find their quantifiable specification by way of testing metrics.

For example, 60601-1: 2012 15.3.3 describes the criteria for an impact test:
- 50mm, .5kg steel ball
- dropped from 1.3 meters
- any damage sustained that results in an unacceptable RISK constitutes a failure (this risk is determined by the developer / manufacturer)

These criteria are the actionable design inputs translated from the original qualitative need.

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		REQUIREMENTS		SPECIFICATION	
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		PRD	weight		Lbs
		PRD	handling affordances (grip / handle)		Handle Diamter
		PRD			Hangle Length
		PRD			Handle Hand Clearance
		REG		IEC 60601-1: 2012 9.4.4	Grips and other handling devices (wall mount)
		REG	mechanical strength	IEC 60601-1: 2012 15.3.1	Portable: - Push - Impact - Drop - Mould Stress Relief
				IEC 60601-1: 2012 15.3.2	Push Test
				IEC 60601-1: 2012 15.3.3	Impact Test
				IEC 60601-1: 2012 15.3.4	Drop Test
				IEC 60601-1: 2012 15.3.6	Mould Relief Test
		REG	stability	IEC 60601-1: 2012 9.4.2.1	Instability in Transport Position

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As you can see, a user need as simple as "portable" can produce quite the large list of quantifiable design inputs.

It takes many tools like our Product Requirements Matrix (Traceability Matrix), a Use Specification, and regulatory / usability standards to help translate user needs into actionable design inputs.

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				IEC 60601-1: 2012 15.3.2	Push Test
				IEC 60601-1: 2012 15.3.3	Impact Test
				IEC 60601-1: 2012 15.3.4	Drop Test
				IEC 60601-1: 2012 15.3.6	Mould Relief Test
		REG	stability	IEC 60601-1: 2012 9.4.2.1	Instability in Transport Position