TRACEABILITY WITHIN THE DESIGN PROCESS

USING DESIGN CONTROL METHODOLOGIES TO DRAW THE LINE BETWEEN USER NEEDS AND THE FINAL PRODUCT

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ABSTRACT

Industrial designers are an increasingly integral part of medical and healthcare spaces, entering the work stream early in the assessment of user needs. In addition to understanding the needs and requirements of users, understanding the regulatory landscape is imperative for the approval and acceptance of medical devices. Design controls is a process required by the Food and Drug Administration (FDA) and is instrumental in verification and validation of medical devices. This process can be implemented to create a traceable map that links user needs to the tangible design.

Traceability integration provides industrial design students a formal set of checks and balances. This facilitates well-considered and deliberate design decisions throughout the project, culminating in a deliverable that meets project requirements. Incorporating principles of design controls in an industrial design studio setting will reinforce student design process understanding, promote communication through traceable linkages and provide insight into the nuances of medical device design.

1. INTRODUCTION

Medical device and healthcare design is becoming a concentration and specialty in its own right. In 2014, the IDSA held the inaugural stand-alone medical conference to highlight the need of usability and human factors in the development of medical devices. The medical conference scope continues to broaden each year and remains focused on improving quality of care.

Industrial designers are an increasingly integral part of the medical device and healthcare spaces, entering the work stream early in the assessment of user needs. By bringing an empathic understanding of needs and implementing design thinking methodologies, designers consistently add value to the transformation of healthcare (Privitera & Murray, 2009).

There is clear evidence to emphasize the benefits of human centered design and the deep understanding of user needs as they relate to successful products, especially in healthcare (Lang et al., 2013; Martin et al., 2012; Vincent et al., 2014). In addition to understanding the needs and requirements of users, a comprehensive assessment of the regulatory landscape is imperative for the approval and acceptance of a medical device. One form of regulation that helps organize the development process is referred to as ‘design controls’. The design controls process is implemented to create a traceable map that specifically links user needs to the tangible design. This process is required for submission to the Food and Drug Administration (FDA) and is instrumental in the prevention of medical device failures (Sprovieri, 2014). Although industrial designers are not primarily responsible for the management of design controls, the procedure is quite complimentary to the process of industrial designers.

For an industrial design student, a basic understanding of the medical device regulatory space can foster a degree of rigor that exceeds the standard industrial design process. It can also provide an additional level of clarity and understanding to the overall design effort (May-Newman & Cornwall, 2012).

Within the studio environment, students sometimes struggle to see the larger picture while absorbed in presentation deadlines. As students feverously focus on visual communication and design details, it is

important for them to periodically step back to ensure that they remain on the path to success, which includes addressing user needs in both a creative and logical manner.

This paper takes inspiration from the highly structured and regulated process of design controls, distills the underlying values and suggests opportunities to clearly and deliberately trace connections from user needs to associated product functions and features. This application is not intended to add intemperate structure or restrictive constraints to the creative process, but to aid in the understanding of methodical and well-considered design. Incorporating this practice in the industrial design studio setting will benefit students by introducing them to the nuances of medical device development as well as a facilitating a thorough understanding of the industrial design process.

2. DESIGN CONTROLS

The term ‘design controls’ was developed by the FDA to describe the organizational processes used to manage information around the design and development of a medical device. The embodiment of design controls is documentation housed in a central location, the design history file, that serves as evidence that the medical device safely meets the needs and requirements of the intended user. Beginning with the documentation of user needs, these processes are structured to answer the questions, “did we design the proper device?” and “did we design the device properly?”.

Design controls are typically shown as a waterfall diagram as displayed in Figure 1. The diagram represents a simplified view of the checks and balances implemented to ensure safety and efficacy.

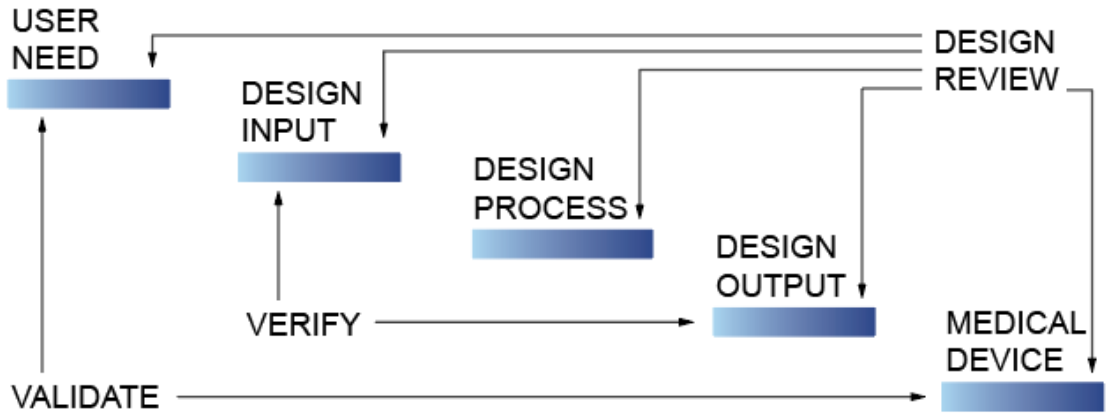

Figure 1. Representation of Design Controls Waterfall Diagram (FDA, 1997).

2.1. USER NEEDS

Although the FDA does not explicitly define user needs, they are referenced throughout the design controls process. User needs are what stakeholders want to accomplish and are generally stable over time. The design solutions to these needs are transient and will change over time with advances in technology.

2.2. DESIGN INPUT

Design inputs are defined by the FDA as the physical and performance requirements of a device that are used as a basis for design (FDA, 1997). Design inputs answer the question ‘**what** is this device supposed to do?’. This step allows the designer to clearly define the challenges the device needs to address. The design input should be derived from a specific user need and is intentionally devoid of solutions. This encourages creative liberties in identifying potential solutions. It is important to add qualitative

commentary to the design input to prevent misinterpretation. Design inputs should be objective and measureable.

2.3. DESIGN OUTPUT

Design outputs are the solution phase. The design output is the answer to '**how** does this device accomplish what it is supposed to do?'. The FDA defines design output as "the results of a design effort at each design phase and at the end of the total design effort" (FDA, 1997). Outputs are the selected solutions to solving each design input. The outputs are then verified against the design inputs to ensure the device was designed properly.

2.4. MEDICAL DEVICE

The medical device in its final form embodies all the design output as one complete form. The final device is validated against the initial user needs to ensure that the right device was developed to satisfy all specified user needs. From a user-centered design standpoint, this would include final human factors and usability testing.

3. APPLICATION TO INDUSTRIAL DESIGN EDUCATION

This paper proposes to capitalize on the rigor instituted by the FDA in design controls, without overwhelming or burdening the student with excessive constraints. The proposed implementation adds an additional written deliverable at each stage of the design process. The goal of this additional process is multifaceted. First, it requires the student to practice succinct yet thorough written expression of needs, inputs and outputs. The ability to communicate the design process, and design decisions, in a clear and meaningful way aids in the understanding and implementation of the process. Second, it establishes clear, traceable linkages starting from user needs and ending at the product embodiment. This functions to ensure user needs are addressed, assists in prioritizing features and functions, and facilitates discussions around design decisions. Finally, it provides the industrial design student with a basic overview of design controls, a cornerstone of the regulatory landscape in medical device development, as well as a lexicon that can be beneficial in future career opportunities within healthcare.

Figure 2 maps out the classic design process starting with exploration, or the initial research phase, to refinement, along with some activities that define each part of the process. A specific part of design controls is associated with each design phase, along with a description of the accompanying deliverable.

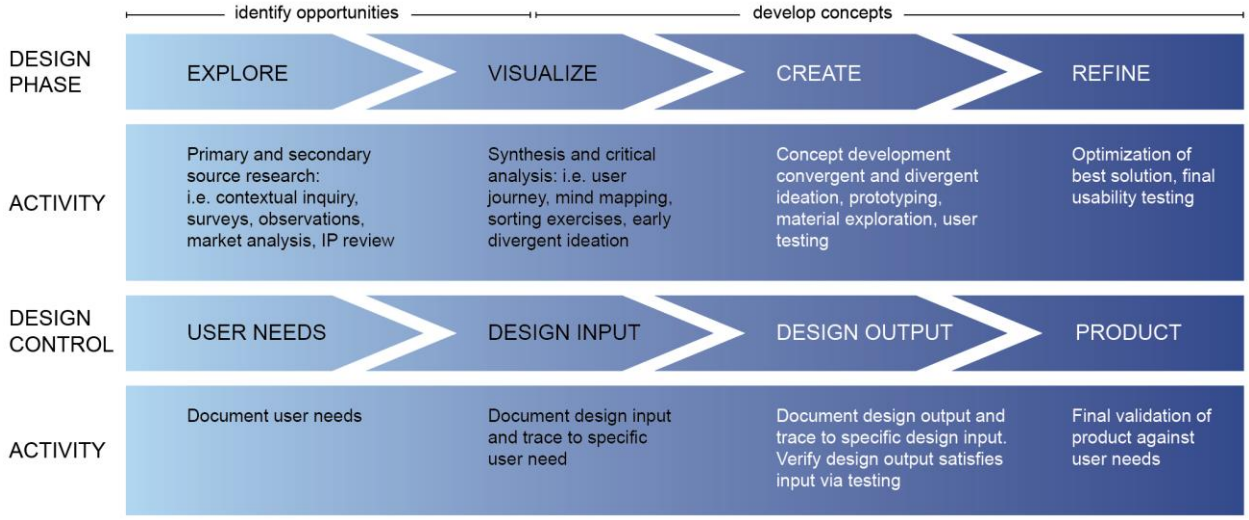

Figure 2. Design controls mapped with phases of the design process.

The proposed lexicon retains the terms user needs, design input, design output and adds clarity as follows in Table 1.

TERM	DEFINITION	DESCRIPTOR
User need	User-centered wants, needs, desires	Can be abstract, the more specific the better
Design input	Device-centered performance criteria based on user needs	Maximum value when unambiguous and measurable.
Design output	Selected solution to the design input	Includes features, functions, interfaces, and technology

Table 1. Industrial design student oriented descriptors of design control terminology.

3.1 EXAMPLE IMPLEMENTATION

An example of design control mapping is displayed in Table 2. This example takes the specific user need and examines it from various perspective to generate the design inputs. The user need example of a 'portable system' is both interpreted in terms of the overall size implications of the proposed device, as well as the need for an untethered power source. The design output (derived from the design process) show the chosen solution as it relates directly to the input. This assures traceability from the design output all the way back to the user need. It is possible for outputs to satisfy multiple user needs, and therefore would also imply an appropriate solution.

USER NEED	DESIGN INPUT	DESIGN OUTPUT
Patients need a portable system that can be worn on the body	Device must employ a recharge-able battery	Li-ion battery (5V, 30 x 12 x 5mm)
	Device must use biocompatible material	Medical grade liquid silicone rubber
	Device must fit into a 50 x 50 x 50 mm space	Overall size (45 x 30 x 30 mm)
Patients want immediate real time treatment feedback	Device must visually communicate treatment start and end	Full color LCD screen (30 x 25 x 4 mm)
	Device must audibly communicate treatment start and end	Audio speaker

Table 2. Example traceability mapping.

3.2 APPLICATION EXCLUSIONS

It is acknowledged that this methodology is not a comprehensive representation of design controls. An industrial designer would not be able to fully manage the breadth of information required to constitute complete documentation. Design controls are typically a team endeavor, pulling expertise across various disciplines (i.e. marketing, design, engineering, regulatory, quality, and manufacturing). There is typically a heavy focus on the international standards that govern the safety of medical devices and this is intentionally excluded from this application, as it is well outside the scope of industrial designer responsibilities. The intent of this mapping is to introduce the student to specific medical device development terminology, teach a basic overview of design controls, and provide a development map that shows product embodiments tracing directly back to uncovered user needs.

4. CONCLUSION

The formal process of design controls utilized in medical device development is highly structured in order to aid in the assurance of safety and efficacy of the device user(s). Through the mapping of user needs, design inputs and outputs allow students to trace connections from the user needs to the associated product functions and features. This requires thorough consideration of multiple human centered factors via a careful and logical method. It encourages both micro and macro views of the process and integrates them holistically in each design phase.

Traceability integration provides industrial design students with a design process that utilizes a formal set of checks and balances. This facilitates well-considered and deliberate design decisions throughout the project, culminating in a deliverable that meets all of the project requirements. Integrating this process in an industrial design studio setting will reinforce student design process understanding, promote communication through traceable linkages and provide insight into the nuances of medical device design.

REFERENCES

Lang, A., Martin, J., Sharples, S., & Crowe, J. (2013). The effect of design on the usability and real world effectiveness of medical devices: A case study with adolescent users. Applied Ergonomics, 44(5), 799-810.

Martin, J., Clark, D., Morgan, S., Crowe, J., & Murphy, E. (2012). A user-centred approach to requirements elicitation in medical device development: A case study from an industry perspective. Applied Ergonomics, 43(1), 184-190.

May-Newman K, Cornwall GB. (2012) Teaching medical device design using design control. *Expert Review of Medical Devices*. 9:7-14.

Privitera, M., & Murray, D. (2009). Applied Ergonomics: Determining User Needs in Medical Device Design. In *31st Annual International Conference of the IEEE EMBS*. Minneapolis.

Sprovieri, J. (2014). Design controls help prevent medical device failures. *Assembly, 57*(4), 10.

United States Food and Drug Administration (FDA). (1997) Design Control Guidance for Medical Device Manufacturers. 21 CFR 820.30.

Vincent, C., Li, Y., & Blandford, A. (2014). Integration of human factors and ergonomics during medical device design and development: It's all about communication. Applied Ergonomics, 45(3), 413-419.