

# THE VALUE OF DESIGN RESEARCH

## COLLABORATIVE DESIGN PROCESSES IN MEDICAL DEVICE DEVELOPMENT

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### ABSTRACT

*The medical device industry creates life changing innovation and advances the practice of medicine, the health of consumers and provides employment. (AdvaMed 2014) The device industry, along with the medical practice is highly collaborative and heavily regulated. As such, designers need to know as much about the individual (patient) end use as they do about all end-users(Ogrodnik 2013) In the context of a complex and challenging product development environment, this paper reports on a study to address the following research questions: what are the theoretical approaches to design in the medical device industry; what are the defining aspects of the relationship between device development teams and their respective users; and what is the role of industrial design in this process?*

*The methodology employed a literature review of current device development processes, including the significance and definition of a medical device; the history of medical device development; governmental and regulatory influences; and collaborative design processes. Findings indicate that by suggesting contextual inquiry and formal usability assessments, regulating agencies have only encouraged user involvement but not provided a framework within their mandated process beyond testing after the device design is finalized. In essence, users are passive participants, typically tapped as a resource to meet agency requirements. Additionally, there is a lack of commensurate work on the practicalities of user engagement, such as gaining access. Practices exist promoting user involvement in consumer product design that may be applicable to medical devices. Lastly, the role of industrial design is not recorded, yet it is evident the methods are utilised. Further, in instances where team disciplines or members are defined, such as the study by Martin, Clark et al (2012) whereby team members included: engineering, nursing, medical physics, and clinical physiology, design and/or industrial design is missing. (Martin et al. 2012)*

*Keywords: Medical Device Design, Co-design, Participatory Design, Industrial Design, Regulatory Influences*

### 1 INTRODUCTION

The purpose of this paper is to provide an overview of collaborative medical device design processes with an emphasis on the role of users and industrial design. Through literature the following areas are explored: the significance and definition of medical device, the medical device development (MDD) process, governmental and regulatory influences, collaborative design processes, the role of industrial design, and the role of users.

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## 2 SIGNIFICANCE AND DEFINITION OF A MEDICAL DEVICE

Medical products are part of an increasingly large and complex system of systems (Anon 2013). Medical device design and development impacts patients, healthcare in general, and on the global economy. The international market for the medical device and diagnostics industry in 2000 was \$72 billion in the US, \$35 billion for the EU, \$25 billion for Japan and \$13 billion for the rest of the world (Panescu 2009). All costs associated with the design, development and use of medical devices are increasing. As a result, the ability to innovate new devices, improve the value of current clinical therapies reliant on devices become increasingly vital to the health and welfare of the global society.

The definition of a medical device varies between countries. The common denominator is that in order to be considered a medical device it must be used to diagnose or treat a disease, condition, or assistive need on or by humans. In both the United States (US) and European Union (EU) the definition of a device is broad and ultimately the responsibility lies with the manufacturer to work with the regulating entities to determine appropriate registration and approval. One stark difference between the two countries is inclusion of veterinary use in the US definition (Ogrodnick 2013). For the purposes of this paper, a medical device is defined as any product that acts on tissue for the purposes of therapy and meets regulatory agency requirements.

## 3 MEDICAL DEVICE DEVELOPMENT

New product development is critical to the success of medical device and related healthcare industries. Virtually all medical devices start with a need, a description of the concept or problem (Ogrodnick 2013). This indicates a reliance on knowledge of the clinical practice of users. Companies need to constantly update their portfolio to remain competitive in the global market that characterizes this sector (Dixon, 2006). Annis argues that the discovery of a novel medical device begins with the recognition of a medical need for an improved means of diagnosis or for the treatment of disease (Annis 1984). Intellectual property (IP) analysis, market analysis, identifying and understanding the regulatory pathway for approval to commercialize, along with the consideration of the manufacturability of the product, and a thorough understanding how the product use will be reimbursed are all necessary considerations in device development (Zenios et al. 2010). All of these elements are important issues to be considered in making the decision to move a concept forward and each can serve as a filter to vet a device concept.

The device development process is an iterative process from concept generation through production of a device and subsequent use (Bridgelal Ram et al. 2008). All factors, stakeholders, and implications must be considered throughout the process. According to a study by Dixon and Brown, having safety and efficacy assumed, the factors of success include the overall quality of the device in rank against competitors as defined by the customer (D.Dixon, A.Brown, B.J. Meenan 2006). De Ana et al outlines the value of a medical device in determination of various "voices" such as voice of customer, business and voice of technology as a means of assuring a comprehensive analysis of all elements required for successful medical device development (de Ana et al. 2013). From this, it can

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be appreciated that a multi-disciplinary team is required to provide the expertise needed to address all of the needs discovered and appropriately design a medical device (Linehan & Chaney 2010).

#### 4 GOVERNMENTAL AND REGULATORY INFLUENCES

Government mandates are one of the most powerful influences on medical device development. They impose and recognise the rules or standards necessary to market a device and have additionally mandated post-market surveillance that is intended to keep the public safe. For the United States (US), the controlling agency is the US Federal Drug Administration (USFDA). For the EU, the controlling unit is the Department of Health Manufacturer Registration Scheme (MRS). The MRS requires device defect investigation, evaluation programs and participation in the writing of international standards (Medicines and Healthcare products Regulatory Agency (MHRA), www.mhra.gov.uk n.d.). The MRS is a voluntary activity by device manufacturers. However, the National Health Services (NHS) uses the platform of standards in order to identify suppliers whose products have a measure of quality assurance and meet the requirements of the quality system standard ISO 9001 (Crisp 1996). Another example, of collective governmental influence is the direct encouragement and motivation of developers to conduct user research during medical device development process through ISO/IEC 62366 Usability Testing and the USFDA Draft Human Factors Guidance June 22, 2011. It is noted that some developers consider standards an unwelcome complication or hindrance. However, guidance on best practice should be net asset to the overall design of the device, particularly those who are unfamiliar with human factors engineering. (A Roundtable Discussion: Understanding Medical Devices and Users in Context. 2013) As a result, it is clear both the US and the EU require the demonstration of a human factors engineering process throughout design and upon submission of a device dossier submitted for agency review (Martin, Barnett 2012). In all instances, the regulations and procedures required by the agencies describe what the documentation should contain but do not prescribe how the design process should actually be completed. (Ogrodnik 2013)

All regulating bodies mandate a robust design and development process wherein it is possible to trace design research to device criteria and subsequent device design. In essence, all steps within the development process must be documented following a Quality System Regulation (QSR).

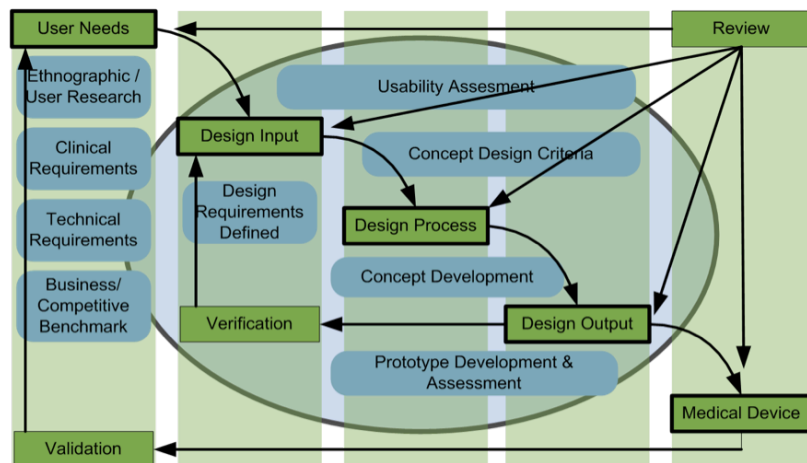


Figure 1 –USFDA Design control process as defined by University of Cincinnati.

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Figure 1 above describes the QSR process required by the US FDA in boxes (green) with an overlay of a typical design process (blue) developed at the University of Cincinnati (Privitera & Grood 2004; Lewis 2010). The framework of this model meets US Federal Regulation 820.30 titled "Design Control" (Justiniano & Gopalaswamy 2003; Panescu 2009; Gilman et al. 2009). This process is termed "Design Control" and is a fundamental requirement for regulatory approval. In essence, Design Control documents the history of development and ensures that the origins of any decision made during the development process are traceable. In order to improve the ability of designers and auditors to ascertain the safety and efficacy of a product, the use of design controls has been adopted which specify the method appropriate for device review at several key stages (Gilman et al. 2009).

## 5 COLLABORATIVE DESIGN PROCESSES

Product development is a collaborative process. Teaming and the reliance of teams for any development venture has been a source of research for many years (Privitera & Zirger 2006; Creveling et al. 2003) and is impossible without some team interaction (Clausing 1994). Regardless of team size or functionality, the ability for teams to have innovative initial plans and tight cohesion tend to have an increased ability for investigation and fostering of collective creativity (Svihla 2010). Johnson 2005 reports that there is a complexity science in collaborative design wherein the design process is computationally irreducible yet the design itself is typically path dependent. There is an evolution of design and an obvious relationship between problem and solution and that the act of constraining the problem itself, the make up of collaborative designers, the means through which they communicate, and their overall process of analysis, abstraction and synthesis influence the overall success of a design (Johnson 2005). In essence, the interactions of the team, the team itself, the problem being solved, and the solution pathways influence each other in either positive or negative manners (Privitera & Zirger 2006).

Teams are increasingly multidisciplinary in order to take advantage of the diversity of skills and perspectives available within an organization. In a case study by DeAna, the innovation team consisted of ethnographic researchers, designers, human factors specialists, engineers, reimbursement specialists, engineers, marketers and sales managers (de Ana et al. 2013). The teamwork required is essential and enhancing communication is co-requisite for coordinating teamwork. To this end, participatory design as described by Schuler, could help create an environment where developers and users can learn to develop processes that better suit the way work is actually carried out (Schuler & Namioka 1993). In organisation situated design, emergence of new ideas arises through cross-functional interaction as well as individual creativity and reflection. Its consequences unfold across a wide range of settings and time. The domain knowledge necessary may be esoteric or highly specialized, with highly creative ideas 'hammered-out' between individuals (Shaw 2010). Failure most often happens with lack of management or planning, or over ambitious project aims (Glen & Lord 1996). The medical device industry is reliant on users to assist in the identification of a deficiency/need/problem that has a device solution. Herein lies the challenge; most medical practitioners whose main purpose is to take care of the sick have only a limited knowledge of, and limited access to, developments in science and technology (Annis 1984). A teamwork approach is suggested to bring an idea to fruition (Buchman et al. 2009).

Participatory design is a practice that involves non-designers in various co-design activities throughout the design process (Sanders et al. 2010). The

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process begins by creating an environment in which users and designers can actively consider the future use scenarios (Schuler & Namioka 1993). It is also a practice of design that moves the design process towards a 'democratic design process' wherein the user or consumer has a voice in the design of the product (Greenbaum & Kyng 1991; Ehn 1993; Gregory 2003). User-centred design is a philosophy based on the needs and interests of the user, with an emphasis on making products usable and understandable (Norman 2002). The approach focuses on the consideration of needs, desires and limitations of users throughout the design process and can be applied to software and product design. User-centred design defines an iterative process where concepts and prototypes employ user testing to inform and optimize the design of the system. It does not define how the concepts and initial prototypes are achieved. Rather, it focuses on evaluation methods in the design process as opposed to the process of design ideation and implementation. What is missing is the rigorous framework to inform design, leading to design solutions that adapt technology to people rather than the other way around (Cafazzo & St-Cyr 2012).

User-centered design, while intended to serve as the introduction to participatory design, is not participatory in and of itself. Participatory design necessitates that users of products should take part in the decisions that affect a system and the way it is designed and used (Schuler & Namioka 1993). In user-centred design, participatory methods are employed to establish collaboration between developers and potential users of the manufacturer's products or services (Buur & Larsen 2010). Dr. Matt Weinger comments that a user-centred design process with a heavy emphasis on understanding the context of use and user needs is critical (in medical device design) (Anon 2013).

Table 1 provides a listing tools and techniques used to promote user involvement in device development.

<b>TOOL/TECHNIQUE</b>	<b>DESCRIPTION</b>
Ethnography/Contextual Inquiry (in product design)	Observing users perform relevant tasks involved in a product design opportunity then organizing findings in order to inform product design (Privitera et al. 2012; Bechhofer & Paterson 2012; Holtzblatt et al. 2005; Spinuzzi 2000; Crabtree 1998; Crabtree et al. 2012)
Context Mapping	A specific organization and visualization of data collected during ethnography or contextual inquiry (Steen 2011; Privitera et al. 2012; Taylor et al. 2012)
Workshops	Multidisciplinary design-by-doing sessions exploring both problem and potential solutions (Buur & Larsen 2010)
Simulation	Exploring potential solutions by acting out particular situations (Anon 2013)
Probes	A self documentation tool kit inviting users to explore their world on a directed topic (Jääskö & Mattelmäki 2003; Mattelmäki & Battarbee 2002; Mattelmäki 2005)
Storyboards	Visual descriptions of 'what happens next' as communicated by users (Taylor et al. 2012)
Personas	The aspect of a person's character that is the perception of others (Grudin & Pruitt 2002; Pruitt & Grudin 2003; Freudenthal et al. 2011)
Prototypes	Representations of design either functional or non-functional used for the purposes of evaluation (Taylor et al. 2011; Schuler & Namioka 1993)

*Table 1 – Tools and techniques promoting user involvement*

Medical device ethnographic research entails studying the behaviors of specific users in their work environments. The practice of ethnography for design requires a technique where the user is observed and interviewed in order to

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inform design. It is a form of applied social science that draws from sociology, anthropology and ethnomethodology (Steen 2011). Participatory design and co-design employ ethnography and subsequent context mapping to enable conversations and confirm communication between a design team and user groups (Visser et al. 2005). The process involves presenting critical information concerning user opinion in a visual manner using generative techniques. Context mapping can inspire designers early in the design process and is aimed at uncovering latent knowledge from users about the use context (Kapteina et al. 2009). Additionally, mapping assists to translate observations and specifications into a new product or service (Steen 2011). Privitera et al reports that visually mapping clinical procedures can be used for both physician education as well as product development team education (Privitera et al. 2012).

Workshops, storyboards and probes are also used in order to better understand user needs from the onset of identifying a particular problem of interest through product design. Workshops are sessions involving users with active ideation activities (Buur & Larsen 2010). Storyboards are used to explain a process and/or concept of a new product being designed and are intended to further discover issues inherent to a particular design (Taylor et al. 2012) A persona is the aspect of a person's character that is the perception of others; it is an individual's social façade or role in life that an individual lives (Grudin & Pruitt 2002; Pruitt & Grudin 2003; Freudenthal et al. 2011). The goal is to have a generalized representation of each user type in order to decide which who one is designing to support (Pruitt & Grudin 2003; Freudenthal et al. 2011). Prototypes are physical embodiments of a product concept and are the backbone of user-centred design. These can be functional or non-functional and are aimed at enabling the user to provide feedback specifically focused at individual attributes of a product concept (Taylor et al. 2011; Schuler & Namioka 1993).

## **6 ROLE OF INDUSTRIAL DESIGN**

Industrial design (ID) is a professional service dedicated to creating and developing concepts and specifications that optimize the functional, value and appearance of products and systems that mutually benefit both the user and the manufacturer (Goldberg et al. 2007). As stated in Ulrich and Eppinger (2008) most products on the market can be improved in some way or another by good industrial design as the primary mission is to design the aspects of a product that relate to the user: aesthetics and ergonomics (Ulrich & Eppinger 2008). Margolis and Pauwels discriminates that design is inherently interdisciplinary as well as generative and analytical (Margolis & Pauwels 2011)

The development of a successful medical product requires not only engineering design efforts, but also clinical, regulatory, marketing and business expertise (Panescu 2009) In many articles describing a medical device development team; there is little mention of industrial design. However, it is widely known in industrial practice that industrial design can play a critical role early on and throughout the development process as this ensures that critical aesthetic and user requirements will not be overlooked or ignored by technical staff (Ulrich & Eppinger 2008). Proper use of ID ensures that devices are targeted to market needs, appropriate for brand aspiration and fit or safe for human use. Often the right approach to ID will increase the speed to market by ensuring that critical factors are considered early in the process. ID creates opportunities, develops the best form and function (Petrie & Copeland 2011).

In consumer products, the designer's role in the design process often includes the role of mediator (among different interests) and facilitator (of other participants' ideas and initiatives), but involves more competencies, specifically

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in terms of creativity and design knowledge (Taylor et al. 2011). Designers can support ongoing initiatives, can be triggers, making new initiatives happen. In the practice of user-centred design it is often the case that the user is not invited, may not be available, or may not fully understand the impact of trade-off decisions made by a design team when faced with conflicting design requirements (Jan Gulliksen 1999). In this situation, the role of the designer is often that of user advocate, providing insight and opinion based upon their knowledge as a result of ethnographic studies (Taylor et al. 2011).

## **7 ROLE OF THE USER**

The definition of who a 'user' is of a medical device can vary. It might be a clinical provider, however, it could also be the patient, a parent or caregiver. For example, one definition by Martin and Clark identifies any healthcare worker who may regularly or occasionally to locate, examine patients, or to assist with these tasks (Martin et al. 2012) De Ana notes that careful analysis of all stakeholders is required to determine precisely who the user is for any device in development it may be that through the use of the device the user may change from the provider to the patient or vice versa (de Ana et al. 2013).

Currently, medical device users seem naïve about the role that device design can play in enhancing or degrading safe and effective performance (Fairbanks & Wears 2008). A realisation that human error in operating a device can be a major cause of patient death and injury in an age of sophisticated machinery identifies a need for collaboration throughout the design process rather than at formal mandated intervals (Cafazzo & St-Cyr 2012). Device manufacturers have publicly taken the stand that it is up to the end user to use the device correctly, as long as there is an instruction manual that describes 'correct operation' (Fairbanks & Wears 2008).

In a study by Money et al, there was a mismatch between the users that were consulted and those that would actually use the device in practice. In this study, some manufacturers held the belief that the needs of the patient themselves, and that patients' needs are better articulated through a hierarchy of health professionals including surgeons and 'clinical champions' rather than through direct channels of user input (Money et al. 2011). This supports the notion that the user must be defined for each device development opportunity and that the user is often multiple people rather than a sole individual person as a user can change over the course of device use.

Medical device users are not homogeneous but are constituted by different types and stakeholders such as healthcare professionals, careers, and end users all with different experience and different interest (Shah, Farrow, et al. 2009). Users of medical devices can be divided based on their professional and personal traits, into different groups. Precisely who makes up the user group can vary and include non-medical users as well as professional users with different professional careers (Shah, Robinson, et al. 2009).

In large companies, such as Johnson & Johnson, there are users (physicians), who may not be actively providing clinical care on the design and development staff (Parkinson 2010). These users are or were experts in their field and as they no longer practice, they may not necessarily be current in their knowledge of the clinical field. That said, they do provide basic information and act accordingly in providing user information. In addition to this model, user information is also gathered through what is known as key opinion leaders (KOL's) or podium speakers (Parkinson 2010). These are physicians who have published and/or invented a device or approach that has impacted the practice of medicine within their field and are viewed as experts by their peers. They may

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or may not have a casual relationship with the development team; however, they have been shown to influence design decisions, especially when the team is faced with conflicting design requirements.

Fairbanks (2008) predicts that the role of the user in medical device development will increase to foster a greater sense of shared responsibility and an understanding among hospital supply officers and root cause analysis teams that the design of medical devices. Further that direct involvement of users can have enormous influence on patient safety and thus warrant more attention (Fairbanks & Caplan 2004; Fairbanks & Wears 2008).

## 8 CONCLUSION

The description of the role of industrial design in medical device development is sparse. Only one article provides a description of industrial design activities and contribution to the practice of medical device design yet it is evident design methodologies are utilized in MDD. This is evident in the practice of applied ergonomics. This includes the following areas: aesthetic design, form giving, human factors application and testing, along with contextual inquiry/ethnography methods (Petrie & Copeland 2011). Further, in instances where team disciplines or members are defined design or industrial design is missing (Martin et al. 2012; Grocott et al. 2007). Lastly, there is no coupling of team member/discipline and the overall process. The current body of literature clearly describes a process whereby the process for idea implementation morphs from a free process to a highly rigorous and controlled process with a multi-disciplinary team.

In practice and literature, there remains a lack of understanding with regards to user involvement beyond formal mechanisms in MDD processes. The fundamental regulatory process is widely disseminated as a result of agency efforts, yet specific best practices remain unknown. There are practices promoting user involvement in consumer product design that may be applicable to MDD. The extent to which participatory design and co-design are used as an approach to MDD is unclear.

Furthermore, observational research, such as contextual inquiry and the mandated usability testing, formalize user involvement in the design process at specific points. Yet, many decisions that affect the ultimate design of a device happen during the design process when trade-off decisions must be made.

Given that most designers and subsequent medical device development team members will not ever be practicing medicine or be the users of medical devices, participatory design/co-design approach, rather than user-centred approach, may be warranted. This will enable a target user (physician) to be a significant contributor to device development throughout the process.

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