Designing Industrial Design in the Highly Regulated Medical Device Development Process. Defining our valuable contribution towards usability

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Abstract: The role of industrial design in medical device development is scantily described in literature. Yet, based on design practice in industry and as evident by design competitions, clearly industrial design is active in the practice of developing medical devices. Only one article provides a description of industrial design activities and contribution to the practice of medical device design and 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, such as the study by Martin, Clark et al whereby team members included: engineering, nursing, medical physics, and clinical physiology, design or industrial design is missing (Martin, Clark et al. 2012, Grocott, Weir et al. 2007). This paper aims at describing the role of industrial designers within the agency mandated processes using a multiple case study methodology to identify contemporary approaches in device development. Case study methodology is commonly used to assess user engagement as well as design and development practices (Elf, Putilova, Koch, Öhrn, et al., 2007; Patricia Grocott, Weir, & Ram, 2007; Medina, Kremer, & Wysk, 2012; Taylor, Furniss, & Blandford, 2007; Yin, 2013). A total of 18 cases were developed with participants from both the EU and US. For this study industry participants were selected by type: medical device manufacturer (large/medium/small) and design firms that have primary focus in designing for medical device development. Participants include the major manufacturers of laparoscopic surgical devices, orthopaedic implants, assistive surgical technologies, endovascular devices, neurovascular devices, critical care devices, cardiac assistive technologies, neurologic diagnostic devices, and general hospital equipment. Results indicate ID leadership was found within large and small organization but are challenged on implant focused device companies; the influence of ID included the application of human factors principles, aesthetic form and branding; ID influence was limited by the lack of clinical training in regards to science and medicine; and the value of industrial design was not well incorporated within agency promoted design
control processes. This paper defines ID practice in medical device development and concludes with a proposed graphic of the regulatory mandated design process highlighting ID involvement.

**Keywords:** medical device design, human factors, usability, industrial design

1. Introduction

The medical device industry requires multi-disciplinary collaboration between researchers and physicians (Freudenthal et al. 2011). In responding to the challenges associated with medical device development, Ogrodnick (2013) proposed a collaborative model in which design teams have a/synchronous access to a repository of information regarding the progress of the development of a medical device. This research investigates the nature of interactions between manufacturers and physicians throughout the process of medical device development to facilitate more effective practice with industrial design involvement.

Leuthardt (2013) ascertained that it was impossible for a single person to be an expert in the clinical, technical, and scientific domains relevant to a particular area of research for the purposes of developing a medical device (Leuthardt 2013). Of note, is the breadth of the medical device industry which includes the following types of products: in-vitro diagnostics, electro-medical and electrotherapeutic apparatus, irradiation apparatus, surgical and medical instruments, surgical appliances and supplies, dental equipment and supplies, as well as ophthalmic goods manufacturing (USA International Trade Association 2016). Within each of these categories, further complexities exist and may include low risk items such as wound dressings or higher risk items such as an artificial joint or pacemaker (ibid). A medical device may be used once for a moment or continuously for many years. Regardless of device type, development requires a synergistic disciplinary effort for the creation of novel scientific and technical insights, being for the translation to clinical application (Leuthardt 2013).

The device industry, along with the practice of medicine, has a history of being highly collaborative and heavily regulated. Since the 1970’s, with the advent of regulatory agencies, a significant emphasis has been placed on clinical efficacy and patient safety for all device development. Designers need to know as much about the individual (patient) end use as they do about all end-users (Ogrodnick 2013). Since the turn of the millennium, usability has become a priority and regulatory requirement for successful medical device development and commercialization (North and Patterson, 2010).

The focus of this research was to investigate the role of industrial design in the process of medical device development. The objective of this research was to determine industrial designs disciplinary influence or lack thereof amongst the broad regulated medical device industry.

2. Background

2.1 Medical device development

Virtually all medical devices start with a need, a description of the concept or problem (Ogrodnick 2013). Throughout history, basic drivers of device development have included patient conditions,
belief of a particular cure, scientific or engineering advancement and war (Lyons 1987). The advent
of regulatory agencies was noted in the mid-1970s and continues to influence in practice today
(Hedley-Whyte and Milamed 1999). In fact, in order for a new device to be used within the clinical
environment, certain procedures must be undertaken, such as a regulatory plan and design
optimization followed with successfully reviewed submission to a regulating agency (Whitmore 2004;
Zenios et al. 2010; Ogrodnik 2013). As such, with any new technology the requirement of solving a
valuable problem (Zenios et al. 2010), the freedom of trial and error in the safety of a lab, coupled
with a follow-up exploration as to why something worked or did not work, is essential in this process.

The medical device industry is broad and complex within itself. As such, for the purposes of this
research, a medical device was defined as any product that acts on (patient) tissue for the purposes
of therapy and meets regulatory agency requirements for a Class II device. For example, an assistive
surgical tool in which a physician selects to use unbeknownst to the patient. The focus on Class II
devices assures that the research was focused on devices of moderate risk with some degree of
complexity, whilst enabling a wide range of device types including a high probability for significant
industrial design input within the design process. This could include a range of devices, for example,
monitoring devices used in critical care, hand held surgical tools, balloon catheters and drug delivery
devices. Devices that would be considered out of scope include Class I devices, such as a cotton
swab or tongue depressor (too simple, little industrial design required) and Class III devices such as
joint replacement implants or Left Ventricle Assistive Devices, which serve as an artificial heart (too
high risk with very long development times and less opportunity for industrial design input), as well
as any devices used on animals.

2.2 Industrial design

“Industrial design 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” (IDSA, 2010 [web page]). Ulrich and Eppinger
(2008) identify that products on the market can be improved in some way or another by good
industrial design as the primary aim of the profession is to design aspects of a product that relate to
the user i.e. aesthetics and ergonomics (Ulrich and Eppinger 2008). Margolis and Pauwels (2011)
note that the practice of design is inherently interdisciplinary in that it straddles craft and science,
creativity and commerce, the humanities and the social sciences, art and engineering. It is
generative, analytical and demands creative thinking and critical problem solving (Margolis and
Pauwels 2011). Inherently, the skills of an industrial designer are of significant value for medical
device development.

The development of a successful medical product requires not only engineering design effort but also
clinical, regulatory, marketing and business expertise (Panescu 2009). In many articles describing a
medical device development team, there is little or no mention of industrial design. However, it is
acknowledged in commercial 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 and Eppinger 2008). The effective use of
industrial design ensures that devices are targeted to market needs, are appropriate for brand
aspiration and fit/safe for human use. According to Petrie (2011), the approach to industrial design
will increase the speed to market by ensuring that critical factors are considered early in the process
(Petrie & Copeland, 2011). Industrial design creates opportunities, develops the product form and
function (ibid).
The industrial 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 in terms of creativity and design knowledge (Taylor et al. 2011). Industrial designers can support on-going initiatives, can be triggers and make 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 (Kowalewski et al. 2013). In this situation, the role of the designer can be that of the user advocate; providing insight and opinion based on their knowledge as a result of ethnographic studies (Taylor et al. 2011). To some extent, design teams can regard themselves as prospective users, often describing themselves as spokespeople for the users. In an environment where indirect users’ spokespeople often find it difficult to be involved themselves, there may not be consideration of involving the actual user (Schuler and Namioka 1993).

3. Methods

Case studies are effective in the assessment of user engagement and in capturing design and development practices (Elf et al. 2007; Grocott et al. 2007; Taylor et al. 2007; Medina et al. 2012; Yin 2013). Unlike the analysis of an individual case, this study compares practices from multiple cases that were selected based on the size of the company, device specialty, user group and use of industrial design. Multiple case designs were considered as being more compelling, making the overall study more robust when replication logic was followed. Data analysis of case studies consists of using a standard set of variables with openness to new variables in order to form a foundation. Once each case is understood, case level displays can be ‘stacked’ in a meta-matrix, thereby further condensing and permitting systematic comparison (Miles et al. 2013). For this study, a graphic data display was used to develop a meta-matrix enabling the cross-referencing of variables.

Medical Device Industry (MDI) manufacturers included interviewees from 13 USA, three EU and two contract manufacturers. Examples of the types of the manufactured devices included laparoscopic surgical devices, orthopedic implants, assistive surgical technologies, endovascular devices, neurovascular devices, critical care devices, cardiac assistive technologies, neurologic diagnostic devices and general hospital equipment such as patient administered drug delivery devices. Selected manufacturers included major medical device developers from each target area. Table 1 provides a summary of the size and location of the participating companies.

| Company          | Small < 50 | Medium 51-150 | Large >150 | Total |
|------------------|------------|---------------|------------|-------|
| US Device Manufacturer | 3          | 2             | 8          | 13    |
| EU Device Manufacturer | 1          | 1             | 1          | 3     |
| US Contract Manufacturer | 1          | 2             |            | 2     |

All interviewees held leadership positions within their organization, therefore responsible for the design process and had an average of 12 years of experience. Table 2 describes the participating disciplines and leadership levels. Interviewees were selected based on their leadership within the organization.
Table 2. Interviewees by discipline

| Discipline     | Manager | Director | Vice President | Chief Technical Officer |
|----------------|---------|----------|----------------|-------------------------|
| Engineering    | 2       | 4        | 2              | 3                       |
| Industrial Design | 3   | 2        | 1              |                         |
| Human Factors  |         | 1        |                |                         |

Qualitative samples tend to be purposive rather than random (Miles et al. 2013). As such, the selected manufacturers had to meet the following requirements (Table 3):

- Type of device - Must manufacture at least one Class II device, which is a regulatory device classification based on risk and the device’s intended use was in/or for the catheter lab (CATH), critical care (CRIT), drug deliver (DELIV), surgery (SURG) or general hospital (GEN)
- User - Any user group was welcome, however, at least one use location must be in a hospital in order to bound the collected data. User groups included physicians (DR), nurses (NRS), patients (PT), caregiver (CARE) and technologists (TECH).
- Size of company - A mix of large (LG) medium (MED) or small (SM) was targeted
- Location - Must be located in either the USA or EU
- Industrial Design (ID) - Must be familiar with the use and value of industrial design

Table 3 Participant summary indicating the device type, user group, size, location and presence of ID

| Company # | Device Type (CATH, CRIT, DELIV, SURG, GEN) | User (DR, NRS, PT, TECH, CARE) | Size (LG, MED, SM) | Location (USA, EU) | Presence of ID (Y, N) |
|-----------|-----------------------------------------|---------------------------------|--------------------|-------------------|----------------------|
|           | CATH                                    | DR, PT, TECH, NRS, CARE        | LG                 | USA, EU           | Y                    |
|           | CRIT                                    | DR, PT, TECH, NRS, CARE        | MED                | USA, EU           | Y                    |
|           | DELIV                                   | DR, PT, TECH, NRS, CARE        | LG                 | USA, EU           | Y                    |
|           | SURG                                    | DR, PT, TECH, NRS, CARE        | SM                 | USA, EU           | Y                    |
|           | GEN                                     | DR, PT, TECH, NRS, CARE        | MED                | USA, EU           | Y                    |
|           | CATH                                    | DR, PT, TECH, NRS, CARE        | LG                 | USA, EU           | Y                    |

Figure 1 represents the template used to visualise each participating manufacturer. The graphic represents the specific requirements for each organisation in one graphic element and was used to enable analysis based on each specific requirement. All manufacturers selected to participate in this study produced one or more of the following: Class II devices used in general hospital (GEN), critical care (CRIT), drug delivery (DELIV), surgery (SURG) or catheter based interventions (CATH). The devices manufactured by participants included users who were physicians (DR), patients (PT), technicians (TECH), nurses (NRS), and care providers (CARE) such as home healthcare providers. Additionally, they ranged in size from small < 50 (SM), medium 51-149 (MED) and large >150 (LG) and additional consideration was given to in-house industrial design (ID) or the lack thereof (NO ID). A large number, represented by the X in Figure 1, provided a unique identifier for each company.
Figure 2 illustrates the collective background on each manufacturer. This figure describes the range in the types of users, with 3 companies developing two different types of devices; 9 companies with multiple types of users; and including the size, location and presence of industrial design illustrated for all companies.
Cross-case synthesis can be conducted by treating each individual case as a separate study and then aggregating findings across a series of studies (Yin 2013). As such, “analysis is likely to be easier and the findings likely to be more robust than having only a single case” (Yin, 2013 p. 164). Cross-case data requires comparison via common codes, common displays of data segments and reporting formats for each case (Miles et al. 2013). All codes, displays and reporting formats are data-condensing for the purposes of distilling data sets into “workable, intellectual coherent units” (Miles et al. 2013 p. 136).

A data display is an organized visual containing a compressed assembly of information that allows conclusion drawing and action (Miles et al. 2013). Further mapping and data visualisation were used to determine patterns across case studies. A matrix display refers to a display chart or table including the codes in order to organise a vast array of condensed material into an at-a-glance format for reflection, verification and conclusion drawing (Miles et al. 2014). In order to facilitate further data analysis, data visualisation charts were developed using individual case images based on Figure 2. An example chart can be seen in Figure 3.

The vertical axis communicates the total number of participants reporting a finding. The horizontal axis represents various topics identified from the data. By using individual company graphics that include the specific requirements, further analysis based on company attributes was enabled. From this visualisation, the data was analysed in both the vertical and horizontal axes. These charts were used for noting patterns, explanations, causal flows and propositions in order to draw conclusions.
4. Results

4.1 Industrial design interaction in medical device development

Because it is necessary to provide further background and analysis on the role of industrial design, this data was redundant from the information collected on the individual manufacturers. While the collective company graphics in Figures 2 provide an overview of inclusion criteria, it lacked the ability to discern whether or not each manufacturer had engaged in the hiring of industrial design services. The following information (Table 4) highlights the engagement of industrial design services as identified during the process of data reduction.

Table 4. Industrial design interaction with medical device development

| Total | Category                  | Explanation                     |
|-------|---------------------------|---------------------------------|
| N=    | Industrial Design Interaction | Experience with industrial design profession |
| 12    | None                      | Did not use ID services         |
| 6     | In-house industrial design | Had industrial design staff     |
| 5     | Hire industrial design    | Sought external industrial design assistance |

Figure 4 indicates a breakdown of industrial design interaction based on the device type, user and location of the participating company.
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Figure 4 industrial design presence in companies
Only 2 of the manufacturers (12 and 15) who did not have in-house industrial design capability contracted external industrial design services. Only 1 (Company 9) had in-house industrial design and utilised external industrial design services. It was significant to note that 11 companies without industrial design had physicians as primary users and only 1 small company (Company 12) used external industrial design services.

All of the manufacturers used cross-functional teams in device development. The key disciplines include research and development personnel, marketing, engineering, clinical affairs, and manufacturing. In the instances of in-house industrial design, the designers were included within the research and development personnel; otherwise this activity was solely the responsibility of advanced researchers in core sciences and engineering. The product development efforts were most often lead by project managers and they were responsible for interfacing with users as well as maintaining the development schedule. Industrial designers may have been project leaders but this was for the user interface design only. Two companies whose devices were aimed at the consumer market where in the patient was the end-user also mentioned human factors as a discipline with which they collaborated. There was a described link between industrial design practice and human factors in which the two disciplines were typically responsible for translating user research into conceptual design. In companies with no industrial design or human factors function, this activity was undertaken by engineering and marketing functions as identified by the comment that: “We do not have industrial design or human factors but understand its role with regards to usability... we don’t really address it fully except to cursory check the box. It was not integrated into our process” (Company 3). Industrial design could therefore be regarded as a priority but was not fully appreciated.

4.2 Role of industrial design in MDD

A total of 13 companies reported ‘aesthetic design’ to be the primary function of industrial design. The application of human factors was also described as a responsibility of industrial design responsibility by 9 of the participants. It was interesting to note that all 3 EU participants (Companies 15, 16, 17) reported that the application of human factors was an industrial design priority. A total of 6 companies reported other functions for industrial design that included needs definition, creating personas and being drivers of the conceptual process. Table 5 describes the role of industrial design within the participant companies.

| Total | Category | Explanation |
|-------|----------|-------------|
| N=    | Role of industrial design in MDD | Activities or responsibilities of industrial design |
| 13    | Aesthetic design | Form giving based on beauty |
| 9     | Human factors | Application of human factors to form (2D & 3D) |
| 6     | Other | Unique role |
| 4     | Branding | Application of company branding principles in product design |
| 3     | None | Not involved |

Figure 5 indicates a breakdown of ID responsibilities based on the device type, user and location of the participating company.
Company 7 reported that “industrial design in med devices was just two thirds putting on lipstick, make it pretty” and that this required every design decision to be justified and explained throughout the process in order to maintain the design intent. This was also confirmed by Company 6 in their statement regarding recent changes within their organization: “In the past we (industrial design) would be responsible for putting the skin on device engineering now we were more involved in Phase Zero and driving the conceptual process.” Counter to this, manufacturers without industrial design had an understanding of industrial design but did not necessarily include it in their practice: “we have individuals who were educated in industrial design but they were involved in more mechanical design” (Company 13). They then went on to comment that, “We typically acquire a new medical device company and it’s evident they have had industrial design involved and we leave the design alone. Sometimes industrial design comes up in select conversations and we wonder if we were missing field feedback or not collecting enough information from users to improve the devices but we routinely seek industrial design involvement” thereby indicating a level of understanding without action.
4.3 Challenges for industrial design involvement

Interviewees readily described their experiences with industrial design and communicated specific challenges in integrating the practice into their organisation. Additionally, those with in-house industrial design also communicated challenges for their involvement. Table 6 includes the categories and descriptions of challenges of involving industrial design in medical device development.

Table 6 Communicated challenges for industrial design involvement in medical device development

| Total | Category | Explanation |
|-------|----------|-------------|
| N=    | Challenges for industrial design involvement | Areas that need improvement |
| 7     | Value    | Cost/benefit not defined |
| 4     | Limited application | Only involved in aesthetic design |
| 4     | Specialisation | Industry so specialised, industrial design can't possibly understand |
| 4     | Quality of industrial design | Lack of criteria to judge good firm from bad |
| 3     | "Box checking HF" | Viewpoint that human factors/industrial design can be completed by cursory effort |
| 3     | Training | Not enough science or medical knowledge |
| 3     | Not described in design control | Not clear of the contribution to medical device development |
| 3     | Expensive | Costs were too high |
| 2     | Over selling skills | Jack of all trades and panacea of user opinion |

Figure 6 indicates a breakdown of ID challenges based on the device type, user and location of the participating company.
Challenges to ID involvement

Box checking HF Specialization

Over-selling skills

Lack of training

Limited application

Design?

Med

USA

Surgery

Pt ID

type of device users size location design?

16

1

2

3

4

5

6

7

S2202

DR

user

size

location

design?

18

1

2

3

4

5

6

7

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user

size

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16

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design?
Seven of the companies reported a lack of understanding in the value of industrial design during their design process. This included manufacturers who developed devices for all user groups, were generally based in the USA (6), and had no in-house industrial design capability. One participant (Company 6) had in-house industrial design however repeatedly had to communicate their value across the organization in order to broaden the impact of industrial design. A total of 4 Companies (18, 16, 8, 3) reported a belief that their devices were so specialised that industrial design had little to contribute. Likewise, 4 companies (16, 13, 12, and 10) reported challenges in discerning good and bad design and, therefore, lacked contributing to value in the device design. Additional challenges included lack of training (3), expense (3), lack of requirement within design control (3) and the over-selling of skills and capabilities (2).

Whist there are industry standards (IEC 62366) and agency mandates (FDA Human Factors Guidance) that promote the integration of human factors into the design process, manufacturers were aware of this but had yet to fully commit to its integrating into their process. This was evident in the comment that, “We don’t really address human factors fully except to cursory check the box. It isn’t integrated fully into our process but probably should be” (Company 3). Other companies believed that the devices they produced were too specialised and more like “an arts and crafts approach” (Company 1).

Complaints about industrial design involvement included: representing the user as if they themselves were the user, being difficult and lacking depth in the knowledge of clinical science. This is reflected in the comments that “industrial designers believe they were the panacea of user opinion” (Company 3), “they were a pain in the butt” (Company 4) and “we have consulted with ID firms and the device comes back very pretty however, they do not understand the (clinical) space. Even if they went out and talked with users, their knowledge of subtle details on the devices these users use daily was limited. They do not always get the simplest solutions” (Company 3). These experiences demonstrated a willingness to try and involve industrial design, however, also demonstrate a disconnection in the communications of the industrial design consultant to the manufacturer.

The lack of clinical knowledge was further expressed as a lack of education and training required to be involved in the areas of the device that interfaced tissue, thereby limiting the application of industrial design services to those features of the device that directly interacted with the user. For example, “we use clinically driven data to determine the end-effector and only a small amount of our development was dedicated to the operator interface outside the body” (Company 2). This was echoed by the internal design department of Company 14’s description of their responsibilities: “we were not responsible for the design of the implant itself, rather the tools that help place the implant.” Another example from Company 3 reports that timing of engaging industrial design was important as a result of this knowledge gap. Company 3 comments that “if we engage industrial design too early, we get 10-15 concepts that do not go anywhere due to lack of clinical knowledge” (Company 3).

### 5. Conclusion

The primary role of industrial design in medical device development was to resolve issues relating to aesthetic design and human factors. This involved developing the form of the device based on the application of ergonomic principles and ensuring a visually desirable appearance. Other roles for industrial design include the application of branding, needs definition, creation of personas and drivers of the conceptual process. Typically industrial design was not involved in the design of
catheter based tools and/or directly involved in the design of an implantable design rather limited to the design of the assistive placement tools.

There was confusion on the role of industrial design within the industry and not all companies had in-house industrial design. The hiring of outside industrial design consultants was found in both companies with and without an in-house practice. There was a general opinion in the industry that the value of industrial design was not well understood; it had limited application; and lacked specialization in medical device development. As section 7.2 addresses, the lack of specialization was in regards to knowledge of clinical sciences, the regulated process required for medical devices and integration within design control practices. Other challenges for industrial design included, expense of using the profession and the over-selling of capabilities by consultants.

This research found issues regarding the role of industrial design in medical device development included the following:

- The practice of industrial design was not always included in device development however all of the organizations utilized cross-functional design teams.
- The role of industrial design included aesthetic design and the application of human factors however the value of their contribution remained unrecognized by peers.

Industrial design involvement lacked clear value was perceptively of limited application in the development process, lacked specialized skills and knowledge in science for the purposes of medical device development.

The barriers of ID involvement presented in this research have the potential to be resolved but only with greater commitment by both industrial designers and device developers. Alternative practices that may further promote collaborative industrial design involvement can be recommended. These include the following:

- To broaden the impact of industrial design, develop educational tools for designers in regards to anatomy/physiology and clinical practice.
- To clearly identify the role of industrial design, develop a Design Control model which better integrates it into the process of medical device development.
- Conversely, to promote the practice of industrial design in medical device development, develop an educational program for cross-functional disciplines.

Clearly, industrial design practice is important to medical device development, especially in regards to the application of human factors towards safe, effective and usable devices.

References

Elf, M., Putilova, M., Koch, L., & Öhrn, K. (2007). Using system dynamics for collaborative design: a case study. *BMC Health Services Research, 7*(1), 1–12. https://doi.org/10.1186/1472-6963-7-123

Elf, M., Putilova, M., Koch, L., Öhrn, K., von Koch, L., & Ohrn, K. (2007). Using system dynamics for collaborative design: a case study. *BMC Health Services Research, 7*(1), 1–12. https://doi.org/10.1186/1472-6963-7-123

Freudenthal, A., Stüdeli, T., Lamata, P., & Samset, E. (2011). Collaborative co-design of emerging multi-technologies for surgery. *Journal of Biomedical Informatics, 44*(2), 198–215.

Grocott, P., Weir, H., & Ram, M. B. (2007). A model of user engagement in medical device development. *International Journal of Health Care Quality Assurance, 20*(6), 484–493.

Hedley-Whyte, J., & Milamed, D. R. (1999). Equipment standards: history, litigation, and advice. *Annals of Surgery, 230*(1), 120–7. Retrieved from
http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1420853&tool=pmcentrez&rendertype=abstract

IDSA. (2010). What is Industrial Design? Retrieved from http://idsa.org/what-is-industrial-design

Kowalewski, S., Arning, K., Minwegen, A., Zieflie, M., & Ascheid, G. (2013). Extending the engineering trade-off analysis by integrating user preferences in conjoint analysis. *Expert Systems with Applications, 40*(8), 2947–2955. https://doi.org/10.1016/j.eswa.2012.12.010

Leuthardt, E. C. (2013). Developing a New Model for the Invention and Translation of Neurotechnologies in Academic Neurosurgery, *72*(January), 182–192. https://doi.org/10.1227/NEU.0b013e318270c7cfec

Margolis, E., & Pauwels, L. (2011). *The SAGE handbook of visual research methods*. Los Angeles: Sage Publications. Retrieved from http://uc.summon.serialssolutions.com/link/0/eLvHCXMwY2BQMEg2TwLWuqZpFmaWackmwaRskBmo0DQFwPUmGhqnolZlg15auwkxMKxmiTJu7mGOhvOlhQ4cw4pOAKQXYTrE0MxRj4E0ELf30KwFvEUsRZ2BNA82Tjqio7BQHmiPOwBfHaRTkf2E2AQeEKwbh6xeB9THqFJeLohoczbgGeqYAW8Aqw

Medina, L. A., Kremer, G. E. O., & Wysk, R. A. (2012). Supporting medical device development: a standard product design process model. *Journal of Engineering Design*. https://doi.org/10.1080/09544828.2012.676635

Miles, M. B., Huberman, A. M., & Saldaña, J. (2013). *Qualitative Data Analysis: A Methods Sourcebook*. SAGE Publications. Retrieved from https://books.google.com/books?id=3CNrUbTu6Csc&pgis=1

North, R., & Patterson, P. (2010). A Guide to Navigating the Expanded Human Factors Standards. *Biomedical Instrumentation & Technology / Association for the Advancement of Medical Instrumentation, (May/June), 245–247.

Ogrodnick, P. (2013). *Medical Device Design: Innovation from Concept to Market*. London: Elsevier Inc.

Panescu, D. (2009). Medical device development. In *Conference proceedings : Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual Conference* (pp. 5591–4).

Petrie, A., & Copeland, D. (2011). The value of industrial design in medical device development. *Schuler, D., & Namioka, A. (1993). *Participatory design: principles and practices*. Hillsdale, N.J: L. Erlbaum Associates. Retrieved from http://uc.summon.serialssolutions.com/link/0/eLvHCXMwY2BQMDY0E82TQLW5aaZjOEpINHCIskSWFgMscblqXODVt47CTEweaMIk7uYy4e-iWJsddHzDiK0Dn3AEb2maGygy8iaCtHkIC1kikMrGnAeoVB5Wd4kBx8k4iNgwv1AMgXCEYV68Yv9Jr77EHFhUg6Nz11DPFADNW5nr

Taylor, P., Furniss, D., & Blandford, A. (2007). Understanding emergency medical dispatch in terms of distributed cognition: a case study Understanding emergency medical dispatch in terms of distributed cognition: a case study, (July 2014), 37–41. https://doi.org/10.1080/00140130600612663

Taylor, P., Manzini, E., & Rizzo, F. (2011). CoDesign : International Journal of CoCreation in Design and the Arts Small projects / large changes : Participatory design as an open participated process, (May 2012), 37–41.

Ulrich, K., & Eppinger, S. (2008). *Product Design and Development* (Vol. 4th). New York: McGraw-Hill Higher Education.

Whitmore, E. (2004). *Development of FDA-Regulated Medical Devices Prescription Drugs, Biologics and Medical Devices*. Milwaukee, Wisconsin: American Society for Quality, Quality Press.

Yin, R. K. (2013). *Case Study Research: Design and Methods* (5th ed.). SAGE Publications. Retrieved from https://books.google.com/books?id=0gYqBAAAQBAJ&pgis=1

Zenios, S., Makower, J., & Yock, Paul, Briton, T. (2015). *Biodesign: the process of innovating medical technologies* (2nd ed.). Cambridge University Press.
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**Acknowledgements:** This work was supported by Drs. Mark Evans and Darren Southee of Loughborough University. Their excellent and consistent guidance for this research is gratefully appreciated. Additionally, this work would not be possible without the contribution of the professional industrial designers and engineers currently working in the medical device industry. A heartfelt thank you to those who volunteered their time to speak with me.