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Multidisciplinary Collaborative Model For Complex

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MULTIDISCIPLINARY COLLABORATIVE MODEL FOR BIOMEDICAL

ENGINEERING DESIGN PROJECTS

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DEDICATION

This thesis is dedicated to my parents, Ernesto Delgado and Guadalupe Franco, who have raised me to be the person I am today and giving me their love.

To my grandparents Blas Franco and Emma de Franco that supported me throughout my career.

MULTIDISCIPLINARY COLLABORATIVE MODEL FOR COMPLEX BIOMEDICAL ENGINEERING DESIGN PROJECTS

By

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THESIS

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Abstract

Nowadays, most devices with advanced technology require the development of embedded systems with mechanical and electrical components as well as software including more than one discipline. These are devices that are usually complex in terms of composition and functionality and that design must follow a methodology in order to successfully design and launch a device of this nature. Hence, the assembly of a multidisciplinary engineering group is required to carry out such complex devices and develop a fully functional product. The group may also need an expert on the field that can provide guidance and knowledge where needed. This is generally required by any field or system using these types of devices; however, in biomedical engineering there is a specific approach to address needs since the end user is a human being requiring a rehabilitation device.

To design an effective biomedical engineering device in today's competitive world, a multidisciplinary collaborative approach needs to be applied. Biomedical engineering projects become more complex when other engineering areas of expertise are engaged in order to optimize the rehabilitation device. Using a multidisciplinary approach to design biomedical engineering devices becomes a necessity. This thesis describes a multidisciplinary collaborative model where different disciplines merge to develop engineering projects of the same kind. In addition, the proposed model mainly focuses on the person affected with a health condition or disability requiring a rehabilitation device. The model consists of core communication components that connect multidisciplinary approaches and strategies.

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Chapter 1: INTRODUCTION

1.1 OVERVIEW

Multidisciplinary Engineering Design is a field of study that utilizes optimized methods to solve design problems by incorporating a number of disciplines [8]. Biomedical engineering is a discipline that relates to two broad fields; engineering and health sciences. By nature, the Biomedical engineering projects are multidisciplinary to the combination of these two areas. Complex Biomedical projects that involve several disciplines cause the design decisions to be more difficult to integrate during conceptual design stages. The proposed multidisciplinary collaborative model will facilitate the working environment among disciplines, consequently, the development of biomedical designs will be enhanced and rapidly achieved [2, 3]. However, combining all disciplines simultaneously significantly elevates the complexity of the problem and increases the challenge as well. The approach of combining disciplines provides a model that explains how biomedical engineering projects interact in harmony. Moreover, this collaborative model will be based on experience from currently developed biomedical projects and further research on how these projects are developed [13]. Furthermore, a biomedical project will be utilized to validate this methodology where various engineering disciplines as well as medical disciplines participate, Mechanical Engineering, Electrical Engineering, Computer Science, Physical Therapy, and Chiropractic Health Care.

1.2 BACKGROUND

In design, there are certain theories and methodologies with the purpose of helping engineers understand and apply proper techniques required to enhance quality and efficiency when a device is being developed. There are generic methodologies on engineering design that can be used in the biomedical engineering field for the same purpose. Nevertheless, there are no

existent methodologies for that specific field dictating what a designer needs to do in order to successfully develop a biomedical device. As a result of the previous concern, a collaborative multidisciplinary model can be proposed to allow constant communication among disciplines and stress the importance of the patients' needs [42]. The collaborative multidisciplinary model provides a model framework that is intended to develop devices based on a "patient philosophy" basis meaning that the design is inspired on the necessity and feelings of a patient. This philosophy is being implemented in Dr. Sarkodie-Gyan's Lab for Human Motion Analysis and Neurorehabilitation at UTEP which focuses on revolutionizing rehabilitation devices for neurologically impaired patients [43]. In accordance with the research in Dr. Sarkodie-Gyan's lab, the LEADER lab also collaborated in the development of this model. The LEADER lab (Lab for Exploration of Advanced Design Engineering Research) develops design theories and methodologies related to engineering design research. The discipline incorporation of the model increases the efficiency during the design stages by providing integrating guidelines [28, 44, 45]. In addition, the model teaches any team member to engage interaction among disciplines. Such model is implemented in a project named "Manipulandum" which is based on developing a device capable of obtaining motion measurements produced by the arms of the human body. Moreover, this device is also capable of recording data that could be helpful in the rehabilitation of people with arm disabilities. Multidisciplinary collaborative approaches and practices will help engineers to address biomedical needs in a more integral fashion with significant learning opportunities and project outcomes [43].

This research project will also function as an instruction manual for EPIC for any collaborative projects involving multidisciplinary approaches. EPIC design studio is a place that will provide hands-on projects involving multiple engineering disciplines, facilitating creative tools to fully develop the multidisciplinary projects and collaborating with engineering departments to acquire the necessary knowledge to carry out a design. The El Paso Innovation

Center (EPIC) is currently being developed by the College of Engineering in partnership with Dr. Noe Vargas Hernandez. In order for a system to successfully address all the needs, requirements must be specified in the development stages of the design. One of the main requirements is that the design studio must interact with all the engineering departments and faculty in order to establish a professional relationship that would lead to multidisciplinary collaboration. Another requirement is that it must provide the students with knowledge and mentoring regarding design methodologies to successfully lead them to a project launch. Last but not least, the design studio must guide the student on obtaining the necessary skills to better perform on a daily basis. All these requirements, among others, must be achieved by the design studio. The following diagram (figure 1.1) and tables (table 1.1 and 1.2) demonstrates the interaction and task clarification among engineering disciplines.

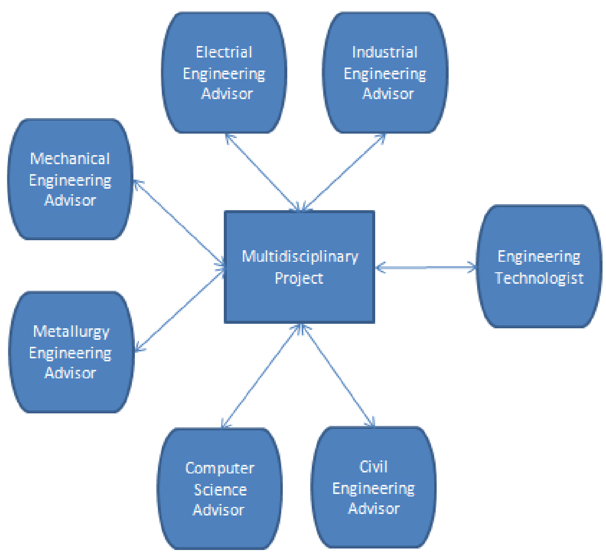


Figure 1.1 DISCIPLINE INTERACTION DIAGRAM

Table 1.1 CLARIFICATION TASK MATRIX

	Conceptual Design Stages						
Discipline	1	2	3	4	5	6	7
Biomedical	X	X	X	X	X	X	X
Mechanical	X	X	X		X		X
Electrical	X	X	X	X	X		X
Computer Science	X	X		X	X		X
Health Physician	X				X	X	X
Discipline Require						X	X
Discipline Require					X	X	X
Discipline Require					X		X

Table 1.2 DESIGN STAGE DESCRIPTIONS

Conceptual Design Stages	
1	**Specs stage**
2	**brain storming**
3	**Mechanical Structure**
4	**Sensors**
5	**Integration**
6	**Functionality and feedback**
7	**Redesign or Adjustments**

EPIC design studio is intended to engage into a multidisciplinary interaction between the various engineering departments with the purpose of enhancing the educational experience of the students. For a better understanding of the approach, the topics in the literature review section provide a framework of the model and the advantages of using it.

1.3 RESEARCH OBJECTIVES AND MOTIVATION

There are many objectives to accomplish during this research; but the main research objective of this thesis is developing a multidisciplinary collaborative model to design complex biomedical engineering devices and take the advantage of using this model as guide to design any function-related device. Other objectives include the creation and development of an educational training model that prepares and train designers to work with other disciplines and the construction of a rehabilitation device called “Manipulandum” that would integrate, apply and address the previous objectives with the purpose of enhancing practical experience. This model also has the objective of developing a design guideline for the EPIC lab that will have multidisciplinary projects where this model can be applied as a reference.

The design of biomedical devices pertains as ultimate goal to improve the life quality of people with disabilities. Biomedical engineers typically obtain their requirements from physicians and other health care providers to design biomedical devices addressing people’s disabilities or medical rehabilitation needs. This situation often introduces a degree of separation between the biomedical engineer and the patient. The biomedical engineer must produce designs that intimately take into account the physical and emotional state of the patient and the technical knowledge that is required from a physician to diagnose a disease or a disability. Physical comfort and motivation play a key role during rehabilitation therapy; hence, rehabilitation devices must guarantee adaptability and be able to include sensing and feedback from the patient.

The major design goal of biomedical devices is to improve the quality of life of those patients with both physical and mental disabilities. Biomedical engineers typically acquire their design requirements from physicians and other health care providers in order to design biomedical devices addressing people’s disabilities or medical conditions in the need of rehabilitation. Moreover, this situation often introduces a degree of deviation between the

biomedical engineer and the patient's relationship. The biomedical engineer must produce designs that intimately take into account the physical and emotional state of the patient and the technical knowledge that is required to diagnose a disease or a disability. Physical comfort and motivation play a key role during rehabilitation therapy; hence, rehabilitation devices must guarantee adaptability and be able to include sensing and feedback from the patient.

1.4 SCOPE

This thesis will provide the reader with information and data regarding collaborative engineering and multidisciplinary project development. The purpose of this thesis is to inform the reader of the various techniques and methods used to integrate several engineering disciplines into interactive design groups that share common information. The main functions of this multidisciplinary model are demonstrating the advantages of using the collaborative multidisciplinary model on a biomedical engineering project and clarifying and defining the areas already mentioned. In other words, the objective is to demonstrate the utility of using a collaborative multidisciplinary model to produce an enhanced engineering device addressing patient's needs. Also the model consists of core communication components that connect multidisciplinary approaches and strategies as a design guide line.

In order to verify the functionality and effectiveness of this model, it was applied to a biomedical model called "Manipulandum" in which the main objective is to rehabilitate peoples' disabilities located on the upper body, essentially on the arms. One of the main approaches of this project is that it is a multidisciplinary model were several engineers from different backgrounds have to interact in order to perform a complex function. EPIC, being a design center located at UTEP, will be requiring guidelines in order to design in the multidisciplinary fashion, the general multidisciplinary model developed for this project can be used as a general baseline to design any product of this nature. This model was applied on an experimental manner and validated through a biomedical framework. The limitations that this model has are that is for

an specific area but also is so abstract that can be applied in a similar multidisciplinary project that have similar characteristics as the ones that this model requires. This means that projects must have collaboration between different disciplines, be multidisciplinary and also that requires a training for the people involved in this kind of project. The use of a biomedical project as an experience will give a better understanding of how this model can be applied.

1.5 THESIS ORGANIZATION

Chapter 1 summarizes the importance of the multidisciplinary collaborative model, where can it be applied and what is the motivation driving this research. Research objectives and project information are also discussed in this section. Chapter 2 presents the literate review, specific topics covered include: Biomedical Engineering design, Multidisciplinary Engineering Design, Collaborative Engineering Design, Rehabilitation Devices, Biomedical Engineering Design Education and finally Rules and Regulations for Biomedical Products. Chapter 3 discusses State of the Art presenting an educational process of Biomedical Engineering and different design methodologies that are already applied on the biomedical engineering field. In addition, the chapter demonstrates the importance of having a Collaborative Multidisciplinary model for Biomedical Projects. Chapter 4 explains the model construction in terms of the needed requirements to achieve design functionality effectiveness and provides a description of the key elements helping on the development of rehabilitation devices being management, communication and work dynamics. Chapter 5 describes the training model presenting information regarding the collaborative and multidisciplinary skill generation. Chapter 6 presents how the collaborative model is validated using the Manipulandum project as a justification.

Finally Chapter 7 provides a discussion and conclusion about the model approaches as well as recommendations for future research. The following figure explains the sequence of how the thesis was developed:

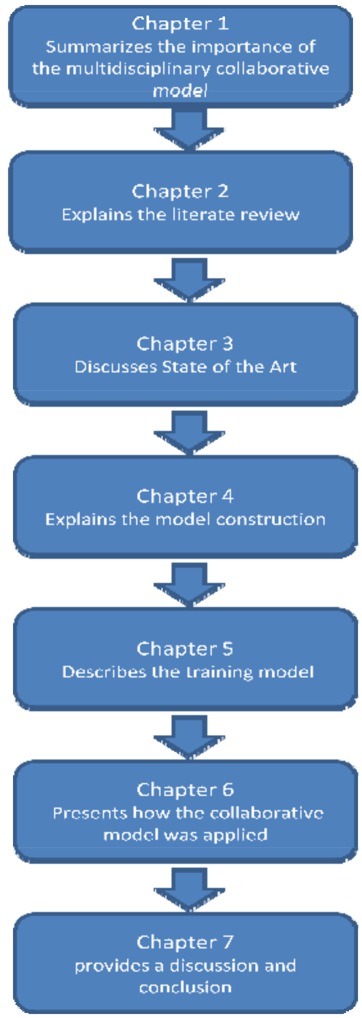


Figure 1.2 THESIS TRACK BY CHAPTERS

Chapter 2: LITERATURE REVIEW

Detailed information about the topics related to biomedical engineering design will be covered in this chapter. This will help us better understand the background and development of this research. In addition, collaborative and multidisciplinary engineering, FDA regulations, rehabilitation devices and biomedical engineering education will be presented as well with the purpose of having a better understanding of the research and content covered in this document.

2.1 BIOMEDICAL ENGINEERING DESIGN

The first step on creating engineering devices is to have an understanding of what is the approach taken by biomedical engineers to design. Usually, biomedical engineers are involved in projects in industry, academic institutions, hospitals and government agencies. They may spend the majority of the time designing embedded electrical circuits and computer software for medical instrumentation purposes. The variety of these instruments include large imaging systems such as conventional x-ray, computerized tomography magnetic resonance imaging and small implantable devices, such as pacemakers, cochlear implants and drug infusion pumps. Other activities include biomedical engineers using chemistry to help translate human organs such as the heart into thousands of mathematical equations and millions of data points which then run as computer simulations. [2, 3, 4] Even though the use of chemistry in biomedical engineering is not directly related to this topic, it is only an example of the diversity covered by this discipline [10, 15, 20].

Design is fundamental to most biomedical engineering activities were knowledge application is required. In order to develop a design, biomedical engineers must have a solid foundation and a considerable amount of knowledge in biology, chemistry, physics,

mathematics, engineering, and humanities. Some topics included within the biomedical engineering field include bioelectronics, biomechanics, biomaterials, physiologic systems, biological signal processing, rehabilitation engineering, telemedicine, virtual reality, robotic aided surgery, and clinical engineering [11, 20]. This thesis will be emphasizing exclusively on rehabilitation engineering and its applications. What is rehabilitating engineering? It is the application of science and technology to improve the quality of life for people with disabilities. Among many advantages, it can include designing medical devices that aid people with paraplegic disabilities to walk, improving the ease of use of computers by designing them more accessible to people with these impediments, and developing new materials and designs for wheelchairs. Biomedical engineering design is an area of engineering were creative minds begin to develop rehabilitation devices for people with different needs [15, 27].

Biomedical engineering is also considered a specific area of engineering design were a combination of the design process and medical field occur. We typically find two stages on the design process; conceptual design and embodiment design. However, in the biomedical design process, a series of health regulations and constraints for designing can be found. But, how does it work? In order to produce a device in the biomedical engineering area, the designer must know the FDA (Food and Drug Administration) regulations and constraints [15, 35]. In other words, to even start the design development of a rehabilitation device, the designer must consider FDA regulations in order to achieve full compliance and functionality of the device. This understanding lies within the requirements list and also in the design specification stage which is the first part of the conceptual design. This first example illustrates that there is a relationship between the design process and the biomedical field [35]. In the early stages of biomedical design, the clarification of the task and the selection of biomaterials are ultimately the most important aspects on the conceptual design phase. During this phase, it is not possible to test or validate any design placed on the human body, nevertheless it can only be tested using software

or another method until there is certainty that the device does not affect the patient's integrity. Finally, the embodiment design stage is almost the same as the one found in the Pahl and Beitz [39] design process textbook. The only difference is related to the manufacturing stages which follow a series of rules on handling health products and their processing taking in account that the validation must be approved by the FDA [10, 15, 20, 35]. Conceivably, biomedical engineering design is a multidisciplinary area were projects combine and increase the complexity level of developing a design [14, 28, 37]. The following diagram is the general biomedical design process where only specifies the basic stages of design on develop of a biomedical project.

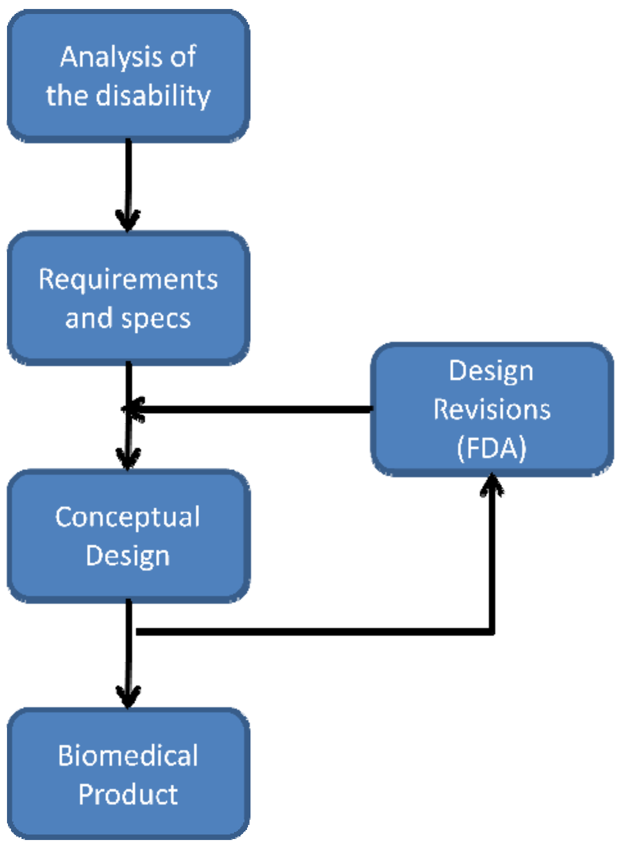


Figure 2.1 BIOMEDICAL DESIGN PROCESS DIAGRAM

2.2 MULTIDISCIPLINARY ENGINEERING DESIGN

Multidisciplinary engineering design is a field of engineering that utilizes optimization methods to solve design problems incorporating several disciplines. Moreover, these methods allow designers to incorporate all relevant disciplines simultaneously. Problem solving being one of the methods, can be optimized if each member from the different disciplines works on a problem simultaneously, hence, the interaction occurring can exploit the information allocated among them. However, combining all disciplines simultaneously significantly increases the complexity of the problem. [1, 17, 24] The following figure explains the discipline interaction between different areas.

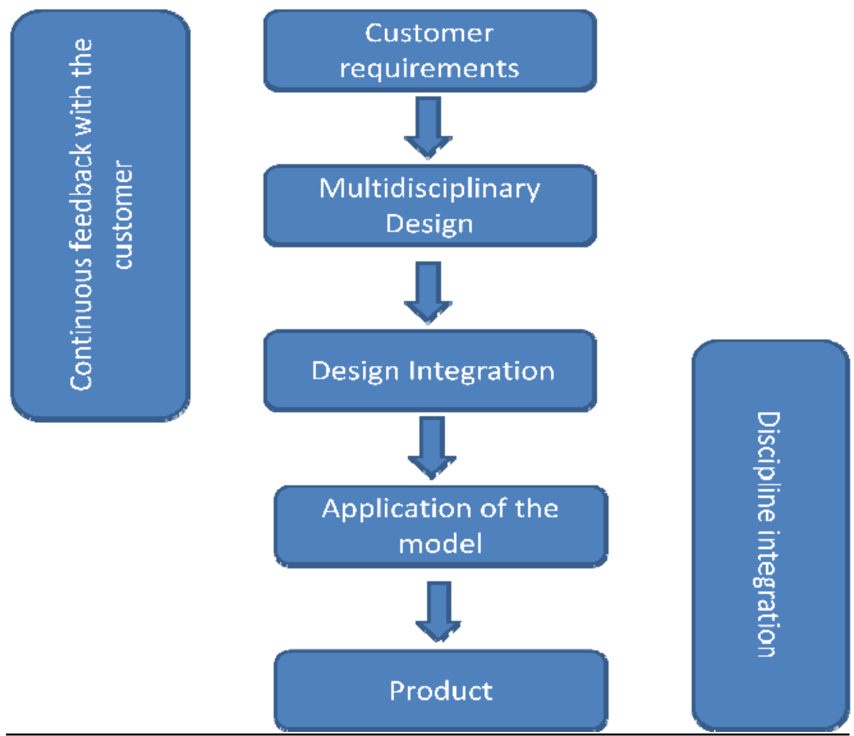


Figure 2.2 DISCIPLINE INTERACTION DIAGRAM

These optimization methods have been exploited in a number of fields including automobile design, naval architecture, electronics, computers, and electricity distribution. However, the largest number of applications has been used in the field of aerospace engineering, such as aircraft and spacecraft design for example on industry Lockheed Martin have a very detail framework of how projects with multidiscipline's can work together. A Multidisciplinary engineering design is formed based on specific characteristics that the designer will explore during the experience of working on a project of this kind [24, 37, 42].

2.2.1 CHARACTERISTICS OF A MULTIDISCIPLINARY DESIGN AND MULTIDISCIPLINARY DESIGN SKILLS

To be a competitive engineer in today's world, institutions must develop and promote multidisciplinary projects were more than one engineering discipline is involved creating new communication skills and technical model approaches to structure and define the work of those that are engaged. These new skills that engineers will acquire can be derived from experience of working with this type of projects. For instance, the selection of the backgrounds of each team member will determine how fluent the development of the project will occur. As mentioned before, a communication model is mainly structured by identifying the disciplines that a particular project needs [33, 41].

2.2.2 TYPES OF MULTIDISCIPLINARY DESIGNS

There are two types of multidisciplinary designs, "Total fusion of disciplines" and "Partial fusion of disciplines". "Total fusion of disciplines" [17, 36] is when the combinations of disciplines are completely mixed from the beginning until the end of the project, meaning that the discipline integration precedes the entire project development. A good example is the aircraft

industry where the combination of two or more disciplines must work in parallel to successfully launch a project. Different from the total fusion, “Partial fusion disciplines” allows engineers to work separately during the entire device launch process, however, at a certain point disciplines must integrate their part into the overall design project, a good example “Manipulandum” [2, 5, 21].

The integration of these two types of multidisciplinary design requires a communication model, tools for multidisciplinary projects and the implementation of a training module which is capable of working with engineering domain knowledge and with diverse disciplines not related to engineering [2, 5]. These disciplines have their particular skills and domains’ on developing, improving, and innovating design techniques using a multidisciplinary communication model to help meet the objectives of a biomedical engineering project. Another important aspect the designer must consider in order to obtain a good performance during a project development process is recognizing how to work with different areas. For this reason, the engineer needs to have extensive knowledge of collaborative engineering.

2.5 COLLABORATIVE ENGINEERING

Collaborative engineering is defined by the International Journal of Collaborative Engineering as a discipline that "studies the interactive process of engineering collaboration, whereby multiple interested stakeholders resolve conflicts, bargain for individual or collective advantages, agree upon courses of action, and/or attempt to craft joint outcomes which serve their mutual interests”. If collaborative engineering is implemented, the project creation is performed in a fluent and efficient manner [25]. Collaborative engineering is also capable of working with different areas not related to engineering science and accomplish successful integration with the use of a knowledge framework learned from their educational background.

The “Manipulandum” design project will be used as an experiment to validate the collaborative model by observing the methodologies through or design techniques that could support this idea. [2] The following diagram shows how collaborative engineering interacts between different disciplines:

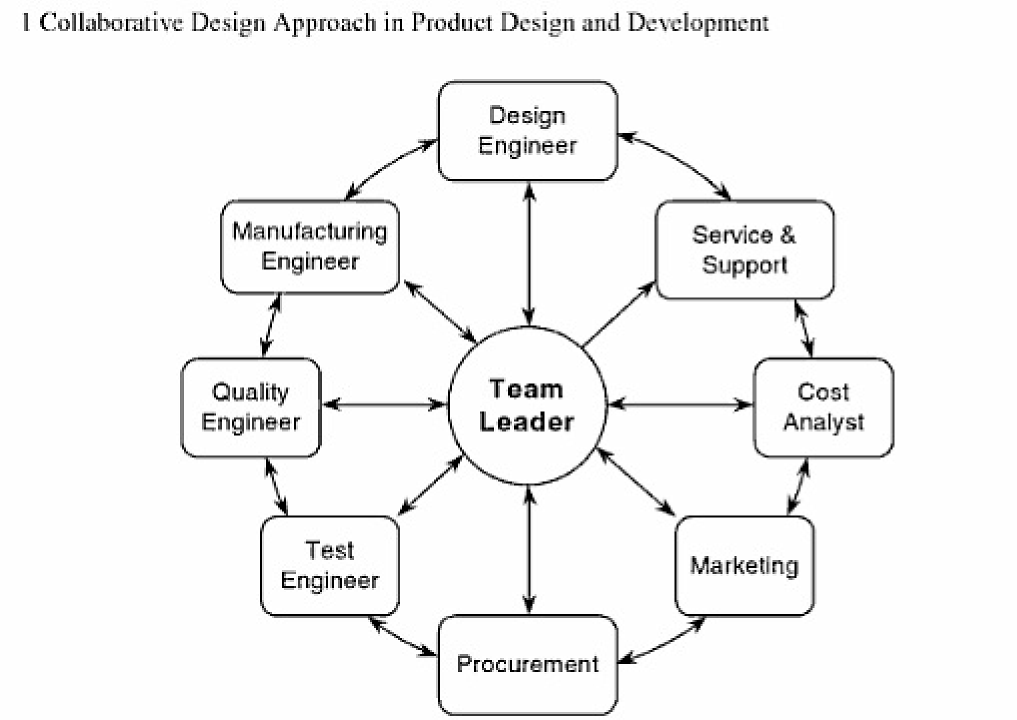


Figure 2.3 COLLABORATIVE MODEL APPROACH [2]

The book of Collaborative Engineering Theory and Practice [2] contains a guideline in which our research can base some hints point useful to understand the Multidisciplinary Collaborative model proposed on this thesis [4]. This diagram show the interaction between disciplines and the how a project que be manage for a Team Leader, also the arrow are indicating the importance of the communication between each member of the team and the team leader

***Collaborative engineering guideline** [2]*

1. ***Understand Customer Needs and Manage Requirements:** Customer involvement increases the probability of the product meeting those needs and being successful in the market. Once customer requirements are defined, track and tightly manage those requirements and minimize creeping elegance that will stretch out development.*

2. ***Plan and Manage Product Development**: Integrate product development with the business strategy and business plans. Determine the impact of time-to-market on product development and consider time and quality as a source of competitive advantage.*

3. ***Use Product Development Teams:** Early involvement of all the related departmental personnel in product development provides a multifunctional perspective and facilitates the integrated design of product and process.*

4. ***Involve Suppliers and Subcontractors Early**: Suppliers know their product technology, product application, and process constraints best. Utilize this expertise during product development and optimize product designs.*

5. ***Integrate CAD/CAM and CAE tools**: Integrated CAD/CAM/CAE tools working with a common digital product model facilitate capture, analysis, and refinement of product and process design data in a more timely manner. Feature-*

based solids modeling, parametric modeling, and electronic design frameworks facilitate the downstream interpretation, analysis, and use of this product data.

6. ***Simulate Product Performance And Manufacturing Processes Electronically:*** *Solids modeling with variation analysis and interference checking allow for electronic mock-ups. Analysis and simulation tools such as finite element analysis (FEA) , thermal analysis, network computer (NC) verification, and software simulation can be used to develop and refine both product and process design inexpensively.*

7. ***Improve the Design Process Continuously****: Reengineer the design process and eliminate non–value-added activities. Continued integration of technical tools, design activities, and formal methodologies will improve the design process.*

This guideline is useful to understand in a generic manner the basic steps and procedures that must be followed by the development of the collaborative engineering projects for our case study (Manipulandum).

2.7 REHABILITACION DEVICES

Neurological diseases are among the most common cause of motor disability [43]. A number of devices for providing therapy to the arm and legs after brain and spinal cord injury occur have been developed.

The design of the interface between the patient's limbs and the rehabilitator is a key consideration if the device is to be used comfortably, safely, and with a minimal level of supervision. In the case of therapy for the arm, many stroke patients do not have hand grasp ability and thus cannot grip a handle [15, 42]. During manual therapy with a human therapist, the

therapist can compensate for the patient's loss of hand grasp by using his or her own hands to grip the patient's arm. Although replicating the gentle grip of a therapist is difficult, simple approaches can provide safe attachment for many patients.

There are many rehabilitation devices that specifically are for this kind of therapy. Two examples of this kind of rehabilitation devices are the MIT-MANUS and MIME that makes use of cone-type splints, whereas the ARM Guide uses a custom-designed grip in which the forearm lies in a padded aluminum trough and the hand wraps around a cylinder that can be slid into the palm and locked [23,40]. Many patients also have decreased range of motion of the arm, constraining the set of postures into which they can self-attach their arms to a machine.

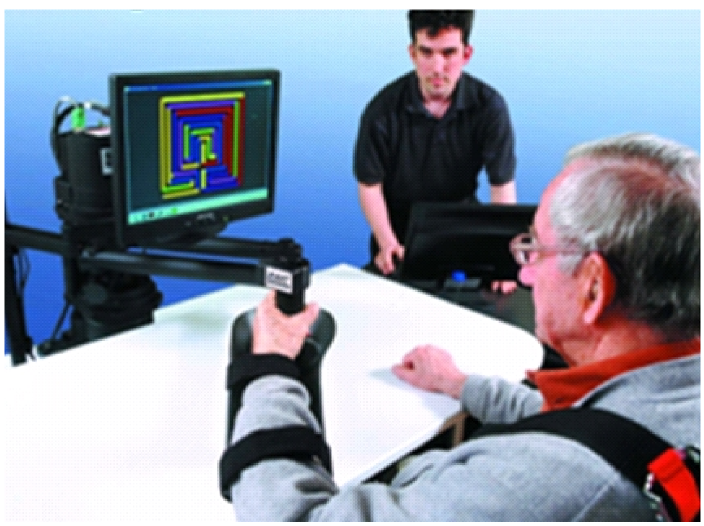


Figure 2.3 MOTOR LEARINING WITH MIT MANUS [23]

The MIT-MANUS, the MIME, and the ARM Guide allow attachment of the hand in a pronated posture directly in front of the torso. With respect to therapy for locomotion, therapists typically grasp the patient's leg with both hands [23, 40]. A common technique is to grasp the

lower shank with one hand below the knee and with the other hand above the ankle. This type of devices also knows as "Manipulandum" that are created specifically to rehabilitate people with these disabilities. These types of devices will be capable to acquire motion measurements produced by the arms of a human body and also capable to record data that could be used to rehabilitate people with arm disabilities [23, 40].

2.8 BIOMEDICAL ENGINEERING

With regard to engineering education, biomedical engineering offers attributes common to the other engineering disciplines while also offering unique opportunities specific to its relationship with the healing professions. Engineering and engineers have long been agents in protecting the safety, health, and welfare of the public [9, 35]. Biomedical engineering holds a unique position within the engineering spectrum in that it deals intimately with human health and wellness. In today's business and global climate, ethics is increasingly principle cannon of engineering practice [3]. It has been a relatively recent phenomenon that increasing and planned opportunities for volunteerism and service learning, whether based on moral values, ethics, or faith convictions, are a component associated with engineering programs [9, 33, 35]. Technology is frequently a central need in designing and solving solutions. Often these valuable opportunities are in association with community service agencies, non-profit organizations, and religious groups [33, 35]. These types of organizations must generally rely on volunteers, especially when the need is to deliver a technical solution. Biomedical engineering education and design projects offer useful opportunities to improve the quality of life for individuals or groups where often the impact can be seen profoundly and immediately [33, 35].

2.9 RULES AND REGULATIONS

The manufacturing and marketing of a medical product in the United States must be done under the regulations of the Food and Drug Administration (FDA). Medical devices are handled by the agency's branches Center for Devices and Radiological Health (CDRH). Complying to these requirements constitutes to one of the major resource requirements in the development process. As with so many other topics in this section, the extent of effort will greatly vary, depending upon the nature of the product, the potential of it causing harm, and the history of similar products and devices in similar areas. Having an available person knowledgeable about the agency's dealings with similar products is a must [9, 33, 35, 43]. Under the law granting the FDA jurisdiction over devices, products already on the market complying with these regulations were allowed to continue producing. Medical products with common characteristics to other products on the market having evident similarities require only a formal notification from the FDA with the purpose of acquiring full approval to be launched. However, the agency decides whether the product is "equivalent" to other product in terms of functionality and overall characteristics. Devices without absolutely any historical background are subjected to much more stringent controls usually requiring a series of clinical trials and showing statistically that the device is safe and effective. The agency has the responsibility of monitoring organizations producing and distributing biomedical devices in order to verify that business is done in ways of avoiding the endangerment of the public [33, 35]. This includes assuring that quality is adequately monitored, that complaints about device performance are promptly investigated, and that steps are correctly followed to prevent any potential problems, etc. The FDA has a very large and difficult responsibility given the available resources. In order for the FDA to maintain its responsibilities, helpful documents related to previous product development on other projects are facilitated to the customers as a design reference. Most of the useful documents are in the category of "guidance." Available on many topics, including specific categories of products,

these publications aim to assist people to understand what the agency expects. It is important to understand that these documents do not carry the force of law as do the regulations, but they are much more readable and can be very helpful. A suggested example is the Design Control Guidance for Medical Device Manufacturers [9, 33, 35, 43]. These documents are indexed on the Web site ww.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/

Chapter 3: STATE OF THE ART

3.1 INTRODUCTION

The integration and preparation of the collaborative multidisciplinary model was developed from the combination of multidisciplinary and collaborative methodologies. As for similar available concepts, the complexity related to developing the conceptual model lies in the lack of existing biomedical devices performing the rehabilitative functions required. At a glance, there are no current specific biomedical projects that fully comply with the requirements or needs the "Manipulandum" rehabilitation device specify. Pahl and Beitz being a generic guideline to the design process could provide the required tools to integrate the biomedical regulations to the current model [39]. One other issue found in the conceptual development stages is that the model must possess a low level of complexity in terms of understanding basic functionality features. Thus, the model becomes feasible to understand and implement by any designer involved in a biomedical project [35]. Moreover, one requirement the model must have is the ability to educate designers prior to the design process. The designer must be literate on both the rehabilitating medicine and engineering fields with the purpose of fully understanding the human body and its functionality [1, 4, 5].

3.2 MODEL COMPARISON

This chapter presents the state of the art were similar models and methodologies are compared and used as a reference regarding the collaborative models for biomedical projects. Also, engineering educational models will be shown to compare to other concrete educational models already structured. This comparison is intended to demonstrate the research of this thesis approach by specifically underlying the differences on required skills. There are existent

multidisciplinary design theories and methodologies that relate to generic models, however, there is a need for a model yet more inclined to the biomedical field. Pahl and Beitz have created a design process that can be applied to most engineering design since it utilizes a general approach [39]. With the new developing careers such as biomedical engineering involving other medical fields such as health sciences, a general design process is not sufficient to cover the requirements. The medical field entails stricter regulations due to the direct interaction with human beings. There is a need for design process addressing all requirements and regulations specific to these fields. To better understand the design process of Pahl and Beitz [34]. The design process is depicted on the following figure:

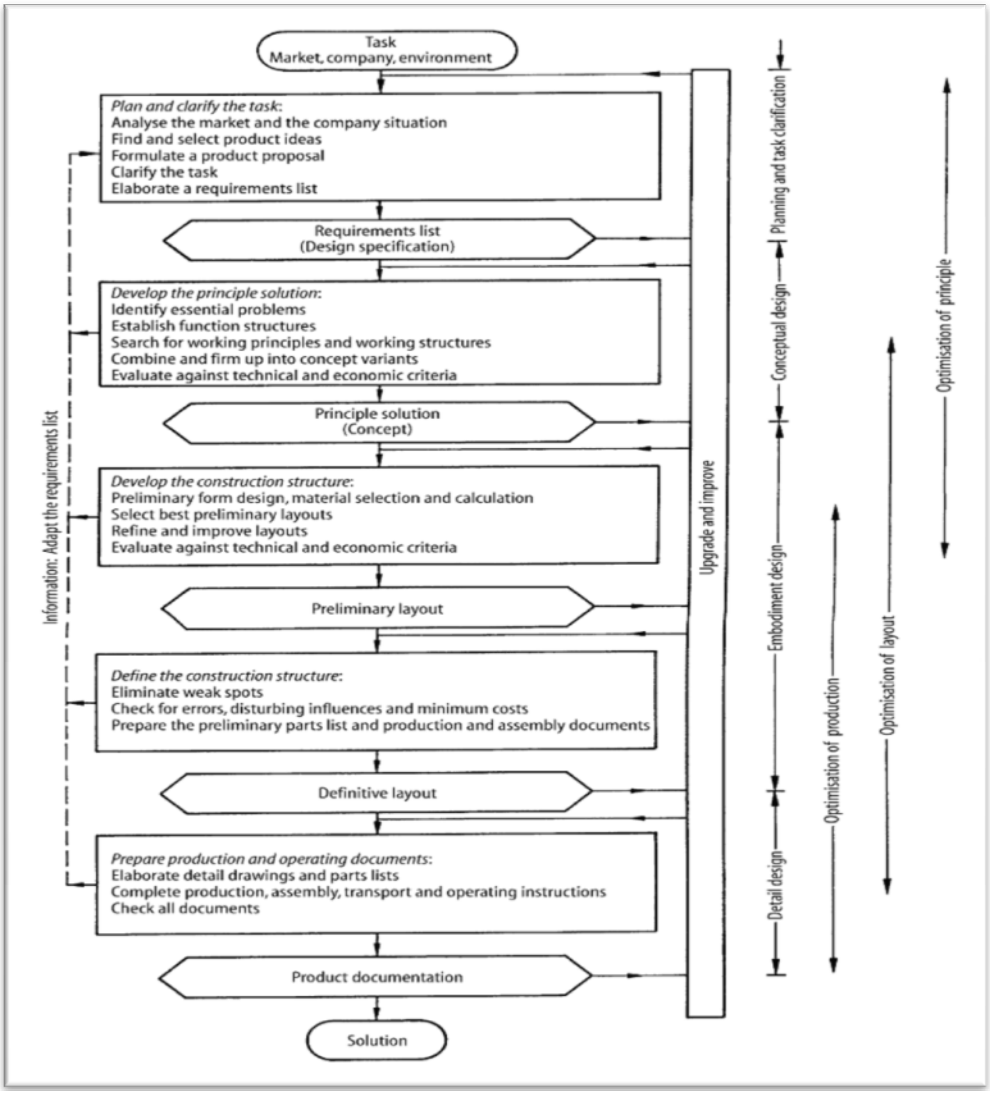


Figure 3.1 DESIGN PROCESS [39]

The design process proposed by Pahl and Beitz is a generalist way for any kind of engineering project, and is divided on different stages that have an specific task for each stage. This task can vary depending of the type of engineering project that is trying it to develop [39]. This design model approach will help us understanding the objectives of the multidisciplinary collaborative model approach. As it is shown on the diagram, the design process is divided into two main stages, conceptual design and embodiment design [1, 2, 39]. Conceptual design is the starting point of the model and it goes further into sub-stages including task stage, requirements

stage, and principle solution. The embodiment design stage is also subdivided into sub-stages being those the preliminary layout, definite layout and product documentation. Particularly, in this research the main emphasis is driven by the conceptual design stage and how can it be improved [6, 8].

To start developing a model, an engineer primarily needs to acquire skills that will ease working environment and interaction with other disciplines. These skills need to be of the collaborative multidisciplinary kind. In Gabriel Davila's research "Engineering Design Educational Model: From Skills to Objectives", provides an explanation of how engineering design skills are transformed into design tasks with a focus on the decomposition and their transformation into educational objectives [18]. Overall, the approaches presented here make well use of known educational theories such as Bloom's and Marzano's, in combination with original contributions such as skill characterization and the overall model integration [12, 31,32]

This approach is used in the education field by various institutions. Queen's university, for instance, makes use of a multidisciplinary educational model that proposes the exposure of a student to real life work environments in order to develop the required skills [17]. The system this university implements to teach and transfer relevant information to the students is also for a generic multidisciplinary engineering design model, hence, the framework can be directly used in this research as a reference point since it is based on a multidisciplinary basis. The following paragraph illustrates an approach being used by Queen's university in accordance with the use of multidisciplinary methods:

The Queen's university is *beginning with a course designed to develop a broad range of fundamental engineering design knowledge, professional skills and attitudes, the stream will continue to enhance the student's capability through a full year experience working on industry based design projects in multidisciplinary teams. The first elective offering of the design engineering fundamentals course attracted students from nine of ten disciplines. The project phase of the stream will be first offered in 2005-2006 to those students completing the*

fundamentals course. This paper will therefore discuss the multidisciplinary design stream as a work in progress [17].

In the biomedical engineering design field, the work-flow found in the Medtech research involving clinical innovation teams is similar to the one proposed in this research [29]. The work-flow emphasizes the strengths of the interdisciplinary teams and provides tools to overcome the obstacles and challenges that a team can face. The main difference from this research (Medtech) and the multidisciplinary collaborative model is that before the teams start designing or confronting the problem, a training module preparing the team with multidisciplinary and collaborative skills is provided [27, 29]. These skills will help the engineer understand the biomedical field which derives a complex area in which the designer is not related to the biomedical design possibly causing a problem.

3.3 RESEARCH APPROACH

The initial approach of the model was accomplished in a parallel basis. How was this achieved? While the collaborative model research was being performed, the "Manipulandum" project design had started as well. Research approach was divided into three main phases describing the principles and main ideas on each stage. The following statements provide a detailed description of each phase:

Stage 1: This stage involves the designer becoming familiar with the project in general including a training module, management of the project, regulations and design specifications. The training module is to facilitate all the information regarding project management, specifications and regulations.

Stage 2: Describes the interaction of the designer with other disciplines to acquire the collaborative multidisciplinary skills needed to carry over a design of this nature.

Stage 3: When designers work separately or simultaneously using an expert as an integrator, ideally a Biomedical Engineer, these types of projects have the support of a framework that helps better understand the background of the medical and engineering areas

The following figure illustrates the topics included to create the collaborative model:

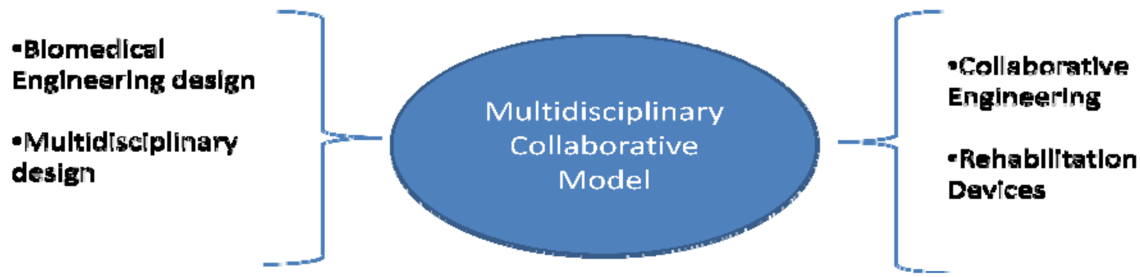


Figure 3.2 TOPICS THAT HELPS TO DEVELOP COLLABORATIVE MODEL

3.4 SITUATION ANALYSIS

There are models and diagrams of a multidisciplinary nature in biomedical engineering; however, there are no references for this specific area. Federal regulations entailed by the FDA do require specific needs for this kind of project. In other words, the design problem primarily indentified in this research is that biomedical engineering does not have any type of collaborative models that can directly perform more efficiently during the built of a project. Already existent collaborative models for multidisciplinary design can help to understand and develop a model for this specific engineering area [5, 7]. The difference in this specific model is that biomedical engineering covers more areas than a common engineering discipline causing an increased complexity on characteristics compared to any other multidisciplinary engineering project. The main objective of this model is finding an integrator that understands engineering and health areas; in this case a biomedical engineer could be that individual. In trying to address the already

discussed problem, the feasible solution is that in biomedical projects the expert, in this case the biomedical engineer, can control, understand and integrate a design [8]. Also, the proposed model has at the core, the person affected with a health condition or disability requiring a rehabilitation device. The model consists of core communication components that connect multidisciplinary approaches and strategies.

Chapter 4: COLLABORATIVE MODEL DEVELOPMENT

This chapter details the development of the collaborative model where three fundamental elements must be accomplished such as the collaborative model requirements, the educational requirements related to the "Manipulandum" design and manufacturing and practice application being the training model. In addition, this chapter explains how the model was developed, the composition, and the components that entailing the structure. In other words, it provides an thorough explanation of the model context.

4.1 MODEL REQUIREMENTS

In order to be fully functional, the model must achieve certain requirements related to identifying potential uses of the model and the time efficiency advantages during the design process of any biomedical device. The diagram below describes and explains how the model started its development including how the discipline integration occurs.

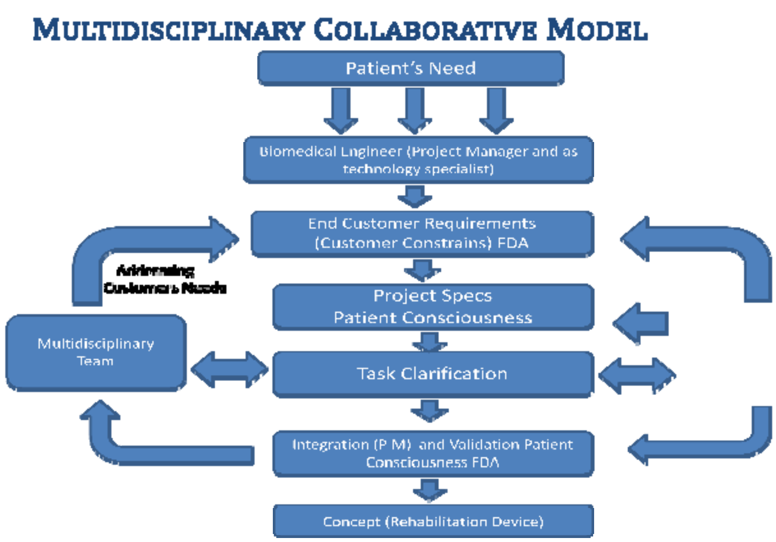


Figure 4.1 COLLABORATIVE MODEL

The collaborative model has at its most important the patients' needs being directly communicated to the biomedical engineer who interprets the information and needs [1, 2]. The specification and customer requirements must also be addressed by defining the project purpose and functionality. These specification and needs from the customer are then assigned to the multiple engineering disciplines and the task clarification stage is developed. From here, the project is carried over the project manager and patient, altogether this process yields a rehabilitation device. Feedback from the engineers to the biomedical engineer to the customer occurs in the developmental stages shown in the diagram. Such feedback must improve and address any questions or concerns from the customer and engineers working on the project. The biomedical engineer is in charge of integrating all these needs to ensure proper communication and quality on the end product [2, 7, 10, 35, 43].

4.1.1 COLLABORATIVE REQUIREMENTS OF THE MODEL

One of the collaborative requirements that the model must have is a communication structure and management between each discipline. In addition, the selection of a biomedical engineer is also a fundamental requirement to control and integrate the biomedical design. It is of high priority to establish an expert that could understand the disciplines the project requires [2, 5, 38]. Due to the characteristics of the project relating to a biomedical rehabilitation device, the best fit for an engineering discipline would be a biomedical engineer. The biomedical engineer facilitates the integration of ideas and concepts related to the project thanks to the available knowledge and understanding the engineer has over the health sciences field [7, 9, 15]. The biomedical engineer is familiar to the objectives and end product requirements thanks to the experience acquired from previously developed devices. The following diagram refers to addressing the customer's needs explaining how the costumer and the designers interact with each other in order to obtain the best of each one, and creating a design that satisfies the

necessities from the patient, in this case the costumer and how the designer can obtain specifications from the costumer[7, 16, 26, 44].

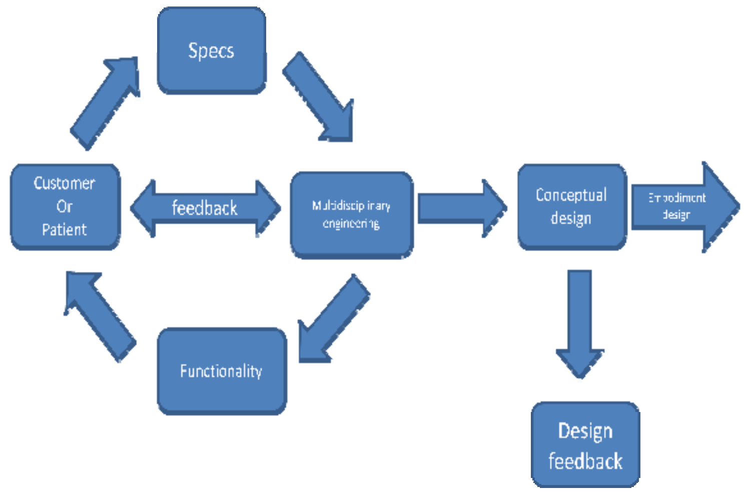


Figure 4.2 ADDRESSING CUSTOMER NEEDS

Other requirement that the model must accomplish is the multidisciplinary approach. Such requirement was very simple to achieve since biomedical engineering is a multidisciplinary topic by nature. Communication skills among team members are also needed to enhance interaction within the multidisciplinary team. Such interaction between disciplines is very important to occur due since disciplines have to work together and they need to at least converse a common language that every team member understands [44, 45]. This requirement can be addressed with a training module were general biomedical information is transferred to the collaborative engineering team in order to better understand the problem and what is needed to solve it. This diagram explains the importance of how the task must be clarified for each member of the multidisciplinary team and how the manager can assign the task. Also this diagram shows in which order the can be develop the design process on its first stage: The Training module as the course crash that will teach and explain the designers about the project, the multidisciplinary approach that the manger can applied to choose the disciplines requires for

the project. The clarification task that assign the job for each discipline using a matrix technique that will be explain in this thesis. And finally, the integration process that the project manager can follow [2, 44, 45].

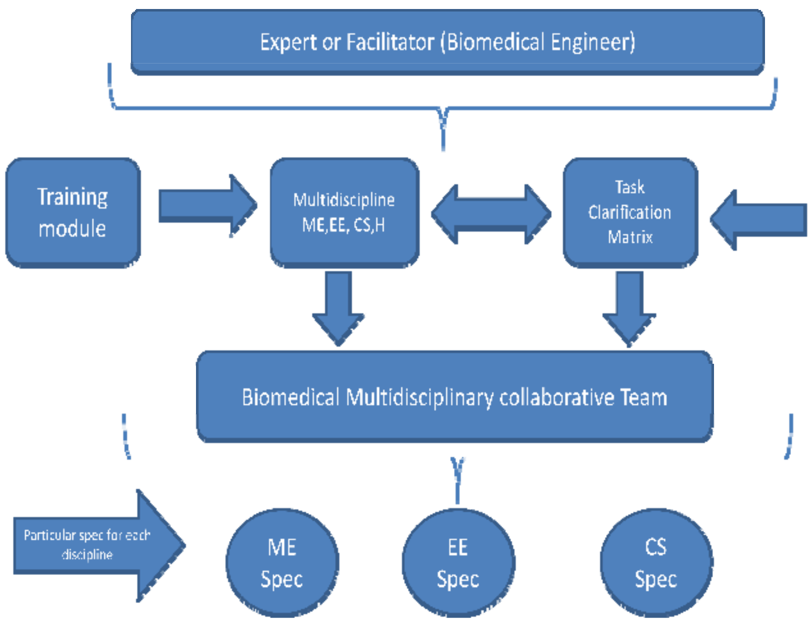
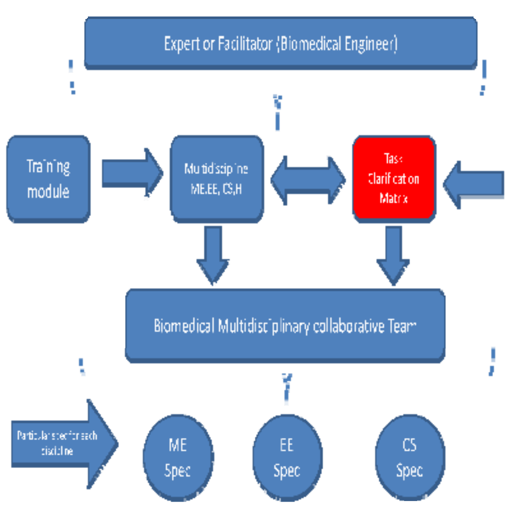


Figure 4.3 TASK CLARIFICATION MODEL

Clarification task:



	Conceptual Design Stages						
Discipline	1	2	3	4	5	6	7
Biomedical	X	X	X	X	X	X	X
Mechanical	X	X	X		X		X
Electrical	X	X	X	X	X		X
Computer Science	X	X		X	X		X
Health Physician	X				X	X	X
Discipline Require						X	X
Discipline Require					X	X	X
Discipline Require					X		X

Figure 4.4 TASK CLARIFICATION MATRIX

This training module consists in a short technical course providing the general aspects of design in a generic manner before starting any stage of the design. On this training the members of the team will learn a series of topics that will help develop collaborative and multidisciplinary skills necessary to acquire for designing biomedical devices [5, 6, 44]. The topics taught on this training module are collaborative multidisciplinary communication, work dynamics, project management, regulations, and client consciousness. The following diagram explains how the training module must be executed and the topics included.

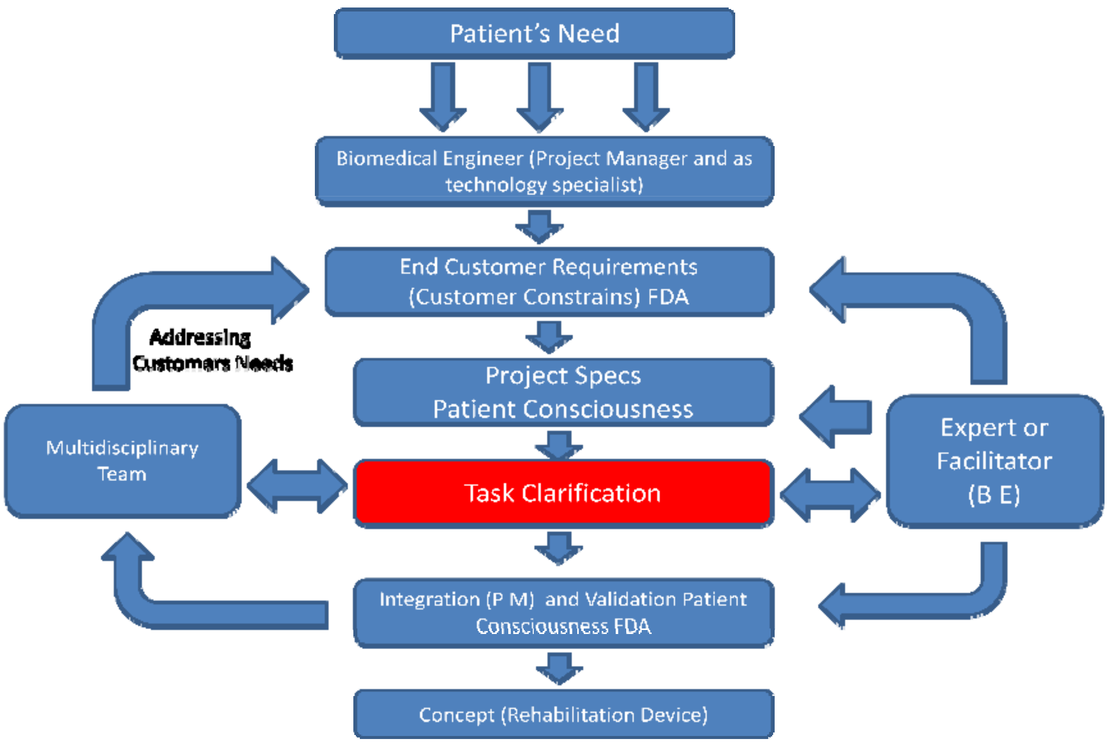


Figure 4.5 COLLABORATIVE MODEL/TASK CLARIFICATION

On the communication topic, the team will learn a common technical language to have a better understanding of the problem needing clarification. In other words, the purpose of the communication topic is to ease technical interaction thanks to the fact that all the members of the team do not have a background on the health sciences field and its complexity and requirements

need clarification [4, 6, 8, 21, 46]. All disciplines, on a basic level, must fill this knowledge gap and start developing a biomedical skill in common manner. Therefore, the communication between the members of the team is fundamental in order for the project development to become more efficient and prevent any misunderstanding at the time the any design phase is carried over. A collaborative skill will be developing on the communication topic because it will be teaching what the communication techniques are in order to interact among disciplines [2, 17, 30]

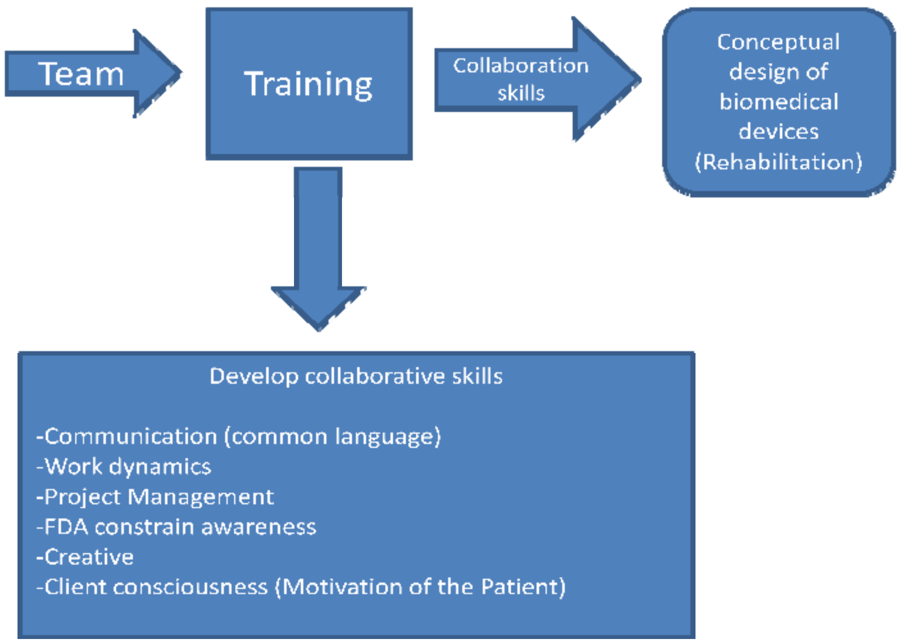


Figure 4.6 TRAINING MODULE

Work dynamics is the second topic to be taught. Moreover, the purpose of this topic is to let the team know how to interact among disciplines in a fashion of separating and clarifying the design tasks and how the expert will be integrating the biomedical design [2, 28, 30, 47].

Project management, on this part of the training module, will be determining the role of each member of the team and how the tasks will be assigned to each one of them. In addition,

project management is also in charge of explaining the responsibilities each member must follow and the role each one is subjected to when developing a device.

Regulations, as the majority of the designs, specify constrains that the products must follow in order to accomplish a certain level of safety on the health sciences field. The FDA is the authority that regulates and proves that a product is safe in terms of full compliance with the regulations. The team members need to be aware of these regulations since all design activities and concepts must be performed to comply with the regulations already mentioned [15, 28, 35].

Patient consciousness, this other stage relates to describing the requirements based on the end user. The sense of feeling comfortable when utilizing the biomedical device is a big motivation for the patient to rehabilitate. It is also important to consider the ergonomic aspect of the design since the end user is not a healthy individual and special functionality may be required in order to transform the device into a usable product. In conclusion, the objective of this part of the training is creating consciousness on engineers because this product may affect a patient's way of life.

Chapter 5: TRANING MODULE

5.1 TRAINING MODULE

After understanding the need and use of a collaborative model, now we need to ask ourselves: how will it be taught? Engineering design educators have developed several pedagogical models that involve curricular structures on how to better teach design within engineering programs. However, these models lack the fundamental didactics required for an effective educational teaching. Here is where the educational Skill-Task Model from the paper "Improving engineering design education: a relational skill-task model", can fill in the blank by applying teaching and learning theories in the engineering design educational system [12,13, 18]

The Skill-Task model begins by selecting the skills and knowledge the student needs to develop. First, defining the desired knowledge and skills during the learning process is required to achieve a solid skill framework. Second, organize the skills in complexity levels to recognize which are of empirical nature and which need to be taught. Third, generate educational objectives for each of the skills to define what is the end result desired. This information is then transformed thru educational theory yielding a more efficient learning process in the student. For instance, teaching styles will help us define the teacher's role in accordance to a desired scenario. In this case, mentoring may be the optimal choice for collaborative design education [12,13, 18]. Therefore, teaching skills will help us choose the optimal teacher profile that fits the engineering design activity, for this specific application the "achiver" profile may fit the needs. [12, 18,31]

Learning styles will help us understanding how engineering students desire knowledge to be transferred to them. Some of the characteristics found in the majority of engineering students are that they are introverted, intuitive, thinkers and judgers. Learning styles must be created based on these characteristics in order to achieve an effective knowledge transfer. Finally, cognitive learning can help us in the improvement and development of optimal thinking models of the learner [18,31,32].

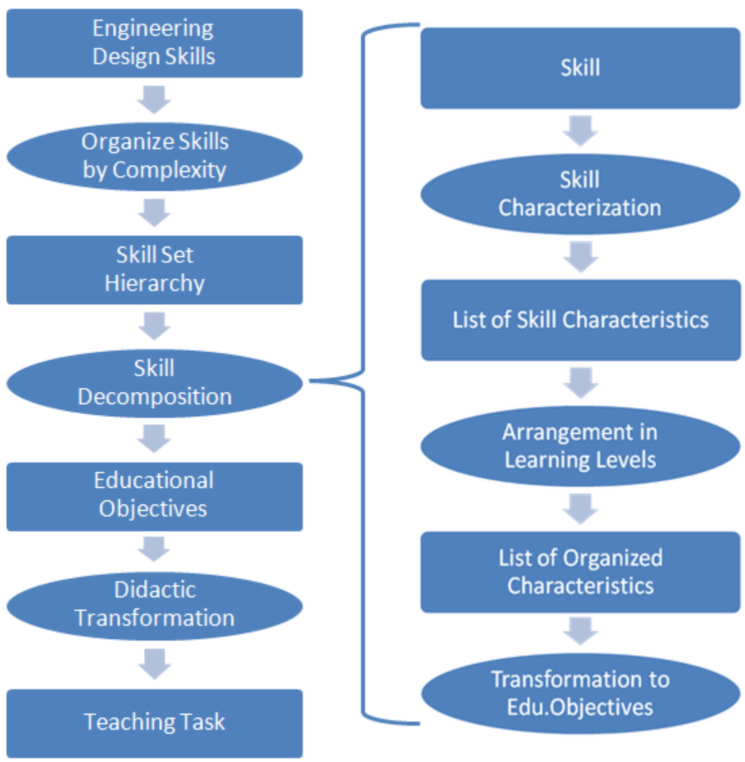


Figure 5.1 EDUCATIONAL SKILL-TASK MODEL DIAGRAM

Chapter 6: COLLABORATIVE MODEL APPLICATION

6.1 APPLICATION OBJECTIVE

In order for a system to function as specified and to provide a desired outcome, validation is required. Validation of a system will not only verify its functionality but it will find any potential failures that can cause any model to not perform correctly. Both the Collaborative model and the Manipulandum project were developed in parallel. As the collaborative model made progress, the framework and information within was being validated by applying the principles to the Manipulandum project. The collaborative model has the objective of performing discipline interaction in a more efficient and fluid manner following a biomedical engineering basis. Taking in consideration this approach, the following text will detail the application and validation used to explore the model functionality. Moreover, this validation is based on the experience acquired throughout the project development and on the knowledge obtained from this research. To have a better understanding of the model application, first a demonstration regarding the utilization of the model followed by a detail explanation of the Manipulandum project has to be provided. Such explanation will be in the detailed on the next section of the chapter. The approach to be used in this validation will be to authenticate the already discussed requirements on the Manipulandum device.

6.1.1 MANIPULANDUN PROJECT

The biomedical project discussed on this research consists on a rehabilitation device called Manipulandum. The robotic rehabilitation device is required to generate imposed forces on the linkage system to effectively quantify limb movement. The Manipulandum device will be capable of acquiring motion measurements produced by the arms of a human body and also

recording data that could be used to rehabilitate people with arm disabilities. The objective of the project is to re-design and fabricate a low-cost alternative to the traditionally expensive Manipulandum systems. The robotic Manipulandum is required to generate imposed forces on the linkage system to effectively quantify limb movement. It is important to clarify, however, that the extent of the project was to create a sturdy base and lightweight manipulator, and that the electrical systems will be developed and implemented by the electrical engineering side [23, 40].

The "Manipulandum" will be created in reference to the main structure used on the base project but it will be enhanced by adding sensors and developing a more rigid structure. The sensors will measure position, distance, and force produced by any patient. A rigid structure is needed to fully constrain the mechanism on the three axes to avoid any unwanted fluctuation due to vibration. The measures will provide data that can aid in the rehabilitation of the patient by providing feedback whenever the mechanism senses force input. For example, a patient with disabilities reaches up to 3 N of force and the average people is capable of reaching 10 N. This mechanism will record data and provide feedback to the motor in order to automatically adjust the settings to accommodate the patients needs, meaning that the device will change the configuration to continue with the rehabilitation process. The next photograph shows a 3D CAD model of the Manipulandum.

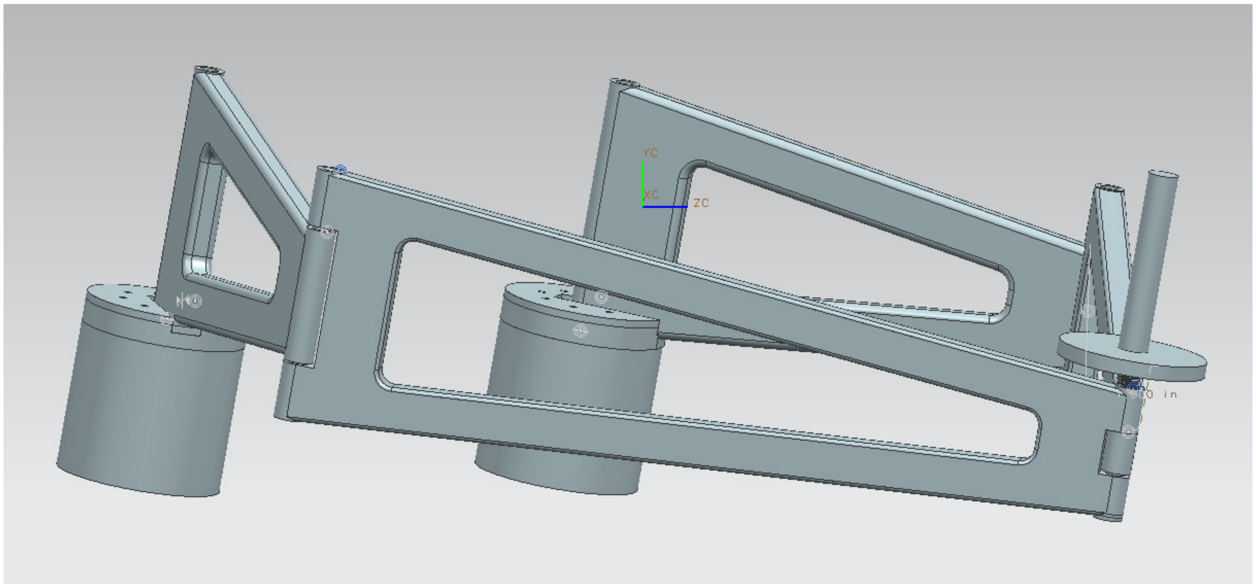


Figure 6.1 3D MODEL MANIPULANDUM

With a better understanding of the relationship between motor functionality and the central nervous system, robotics could assist in the rehabilitation process for those people with motor disabilities, such as spinal cord and stroke patients. In fact, over 5 million people suffer from the after-effects of stroke, “the leading cause of adult disability in the United States”. To limit these disabilities, physical and occupational therapy is offered for several weeks after the initial injury has occurred. However, problems arise because of the increased costs of health care and inconsistent training provided by and for the occupational therapists. Taking in account all the previous statements, one can easily view the advantage of developing this technology.

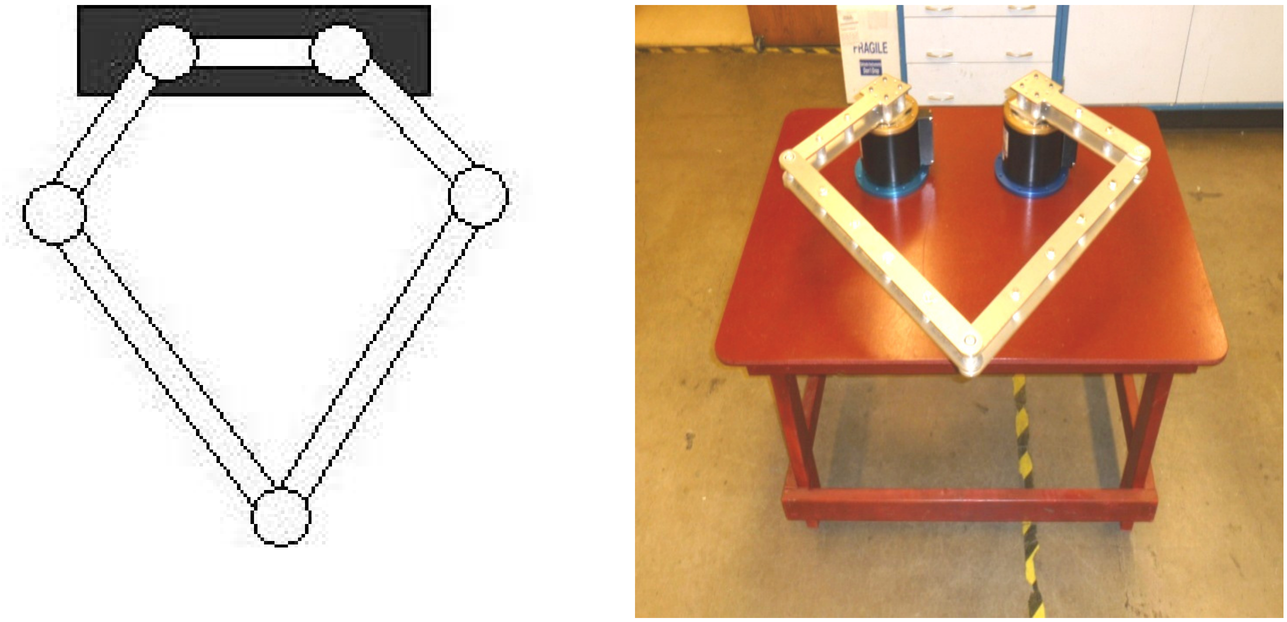


Figure 6.2 MANIPULANDUM

During the development of this research, the Manipulandum project did not have the opportunity of having a biomedical engineer with experience related to the multidisciplinary collaborative context. Instead, the project had the guidance and advising from Dr. Sarkodie-Gyan who provided experience related to neurological design. Dr. Sarkodie-Gyan with a major in electrical engineering has a broad background on biomedical engineering. Dr. Sarkodie-Gyan helped interpreting the physician's requirements needed in order to rehabilitate his patients. According to the feedback provided by him, the team started compiling the engineering requirements that the project could need with the purpose of starting the brainstorming and other conceptual work related to the project. The integration of ideas, requirements of the project and specifications are translated by the biomedical engineer to the other disciplines by using the appropriate technical language. This means that the role of the biomedical engineer is very similar to a systems engineer in terms of managing teams at a technical level. To summarize, the biomedical engineer's job is to provide assessment to the team in order to work fluently and efficiently. The next picture shows the final biomedical product for this project [23, 40,43, 19].

Figure 6.3 TESTING MANIPULANDUM

6.1.2 MODEL APPLICATION AND VERIFICATION

The application of the collaborative model on the Manipulandum project will provide the benefits of using the model as a design methodology. This model was developed in a simultaneous fashion, whenever the biomedical project started; the research of collaborative multidisciplinary models had also begun. The first part of the collaborative model requires selecting the members of the team regarding the background of each member and also accounting for the possible disciplines that the project requires.

In this particular case, the rehabilitation project relies on various disciplines such as mechanical, electrical, computer and health science to accomplish the overall desired outcome. These areas were selected in accordance to the engineering requirements and potential design needs. After selecting each team member from the different disciplines, the next step is to train

them in order to assure a constant technical communication. This is done with the purpose of enhancing interaction in a common approach causing the team to perform fluently in terms of solving complex topics. This model has the main objective of creating collaborative and multidisciplinary skills necessary to engage interaction during a project involving more than one discipline.

All members of the team must have a training module were multidisciplinary and collaborative skills will be developed to fully understand the nature of the system. In our case study, this training was not possible due to the way the project advanced. While the manipulandum project was being developed, the creation of the model had started as well. It was at the end of the project development when it was realized a training module had been needed. The closes to a training module were the meetings held with Dr. Sarkodie-Gyan and Dr Vargas were the development of skills could be compared [23, 40,43].

The next stage of this model is the task clarification for each discipline. During the manipulandum project development, it was decided that the team will split into mechanical and electrical to tackle different tasks [34]. The following collaborative model explains in detail the clarification task:

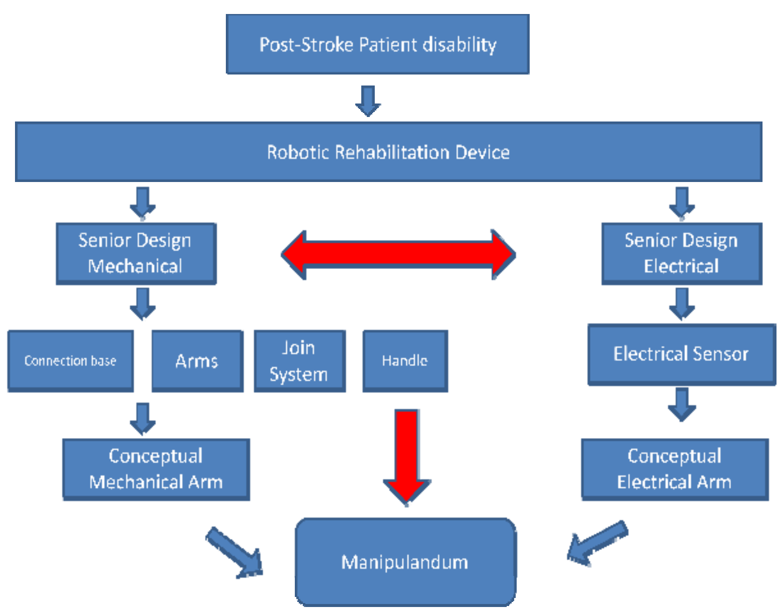


Figure 6.4 INTEGRATION MODEL

As this model shows, there is an existent separation of activities from the two teams; however, at the final stage the teams integrate a design with the help of an expert which in this model is the biomedical engineer. This approach references to the partial fusion design discussed on chapter 2 [2, 7, 10, 35, 43].

The next stage is the integration of the design that can be divided into sub-stages, were depending on the complexity of the design, there is a necessity of integrating the model several times to better formulate the design [2, 7, 10]. The following diagram explains more in detail how many times the expert or integrator needs to perform discipline integration depending on the complexity of the project:

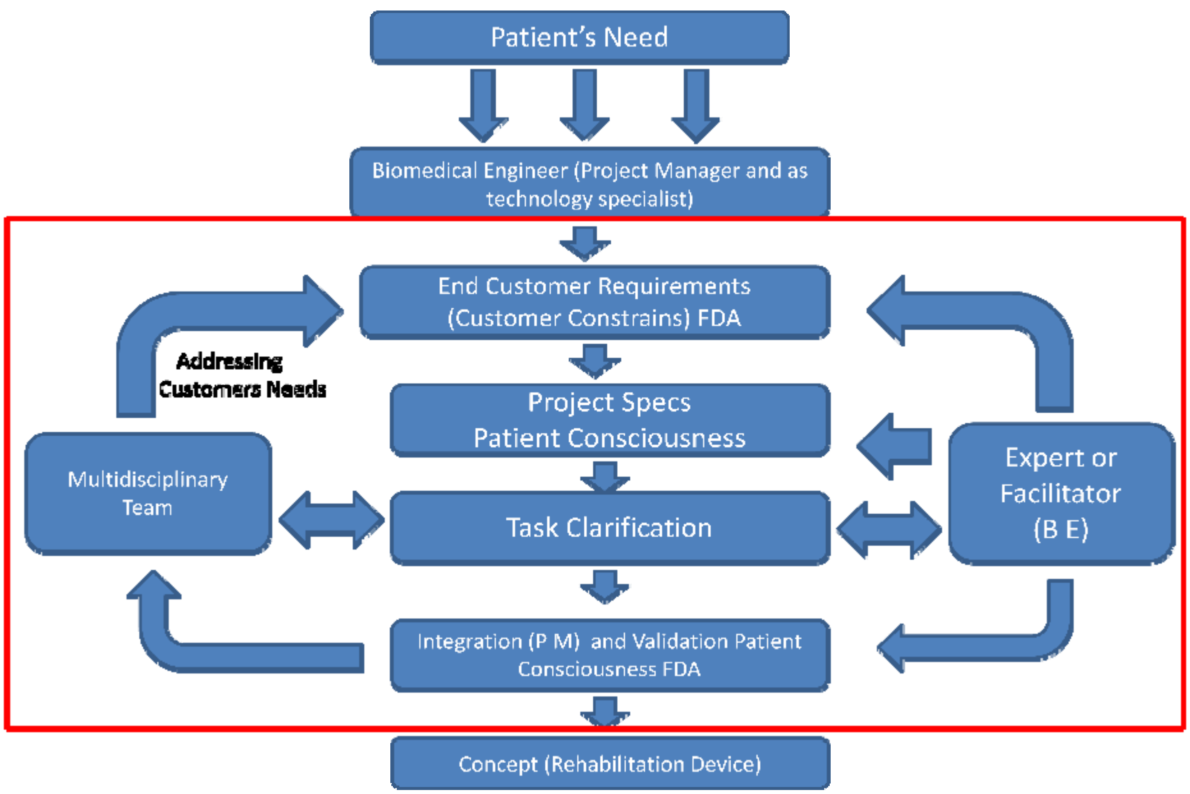


Figure 6.5 MODEL SECTION

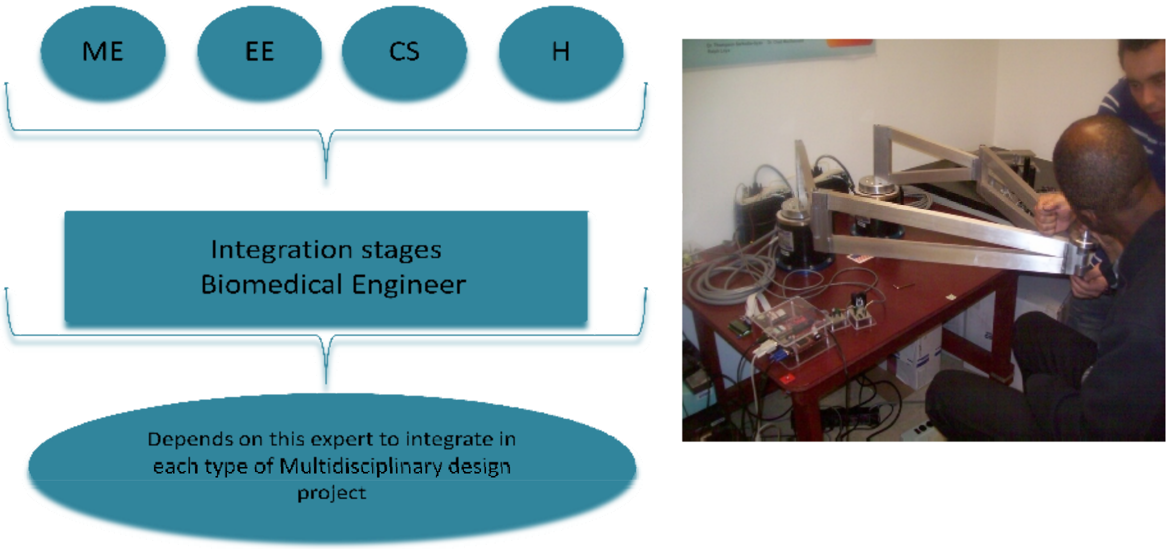


Figure 6.6 EXPERT INTEGRATION MODEL

As this model shows, the biomedical engineer has to perform the integrating task due to the available knowledge on that specific area of understanding projects involving more than one discipline. Each discipline provides knowledge on their specific field and the biomedical engineer integrates all that knowledge to apply it to the design project [2, 7, 10, 35].

Figure 6.7 MECHANICAL TEAM

6.2 DISCUSSION

The model demonstrated an effective method of managing a design development process involving multidisciplinary projects. Along with the collaborative model, the "Manipulandum" rehabilitation device was utilized to verify the functionality and effectiveness of the collaborative model or in other words to validate its effectiveness by following the guidelines and processes contained within. As a result, the model application verifies the benefit of using the collaborative model as a design tool. The many approaches of the multidisciplinary collaborative model are to explain how can a biomedical project be managed, communication interaction between disciplines, clarification task for each participating discipline, project manager role, interaction between customer and designers throughout the development of the device.

The model also allows designers be prepared before the project development commences, this is an important advantage because the designers know more about the problem that they need to solve. This first issue that is presented during the conceptual design stage can be solved with the previously explained training module where the project manager is in charge of this training choosing the topics the designers need to successfully perform during the project development.

The communication interaction among customers and engineers is explained in the addressing customers needs model where it shows the important role that the project manager has and the multidiscipline's interaction with customers. The following model is a potential solution to a multidisciplinary design project where the interaction and flow is presented globally addressing customer needs, discipline integration and top management.

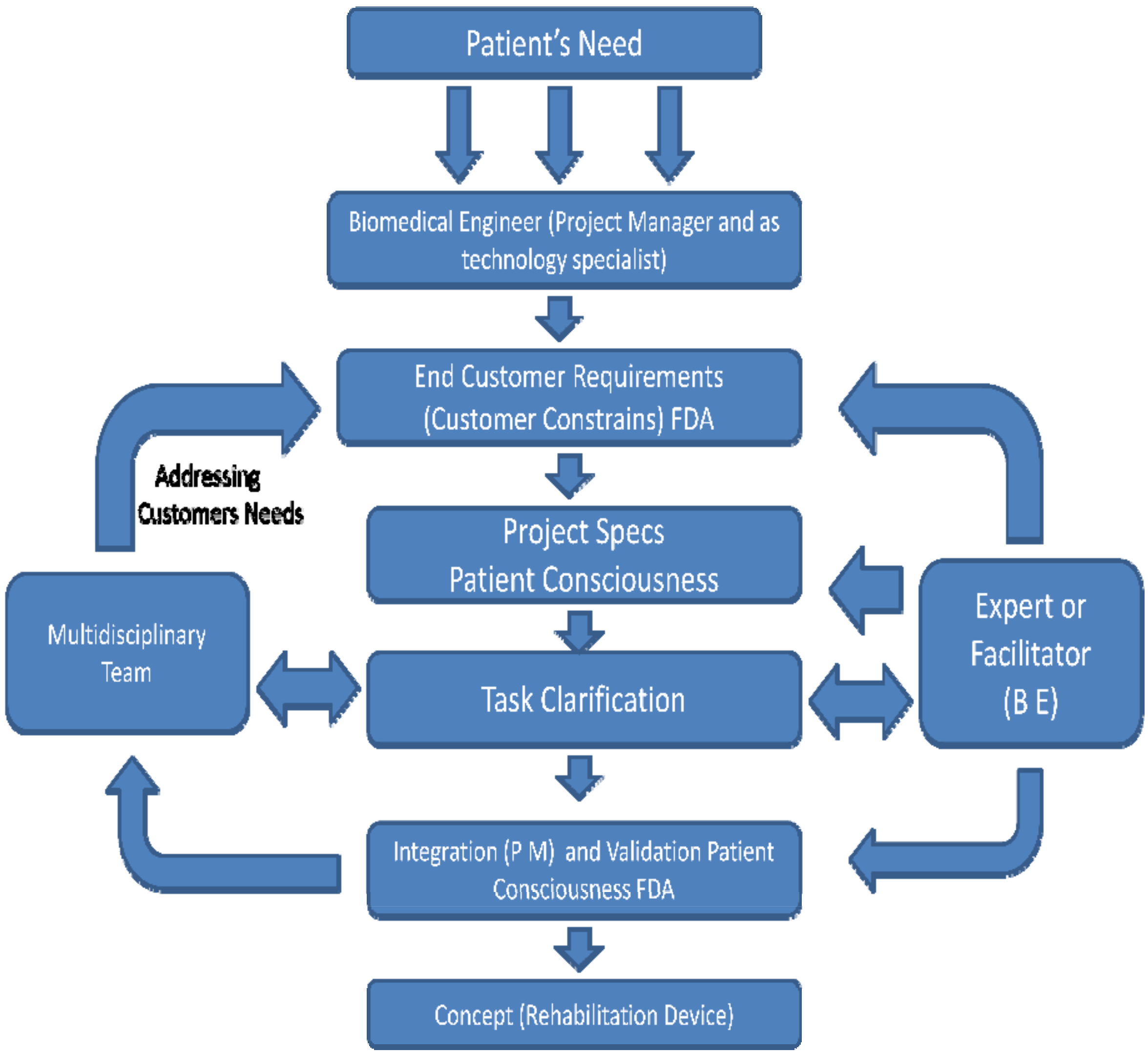


Figure 6.8 MULTIDISCIPLINARY COLLABORATIVE MODEL

As previously stated, the sole purpose of the model is to provide a technical guideline for successful project management at a multidisciplinary level taking the advantage of having continuous feedback with the customer and engineers to enhance product quality.

Chapter 7: CONCLUSION

The development of a complex design is followed by a complex methodology that requires multidisciplinary task clarification. Such task clarification, involves assigning activities and functions to each member of the group with the purpose of diminishing the complexity of the design. As stated before, there is a need for a different approach in order to successfully achieve a functional product. The main contribution of this thesis is to propose a multidisciplinary model providing guidelines on how to successfully manage a biomedical design project by facilitating the use of models that allow the integration and interaction among disciplines. The models presented in this document benefit collaborative design of complex biomedical engineering devices. As a result, the multidisciplinary model organized and provided a general model or approach that can be used to solve any biomedical problem related to rehabilitative kind areas. This model was validated through the use of the "Manipulandum" device as a practical project. Each guideline was followed by the different disciplines including the expert and the result yielded a rehabilitative arm for patients with disabilities.

Multidisciplinary collaborative approaches and practices can help engineers solve biomedical needs in a more integrated manner providing significant learning and improving project outcomes. The research shows that there is an existent problem related to the integration of a biomedical engineering project. As explained in the proposed model, an integrator will cause the project development phase to be more efficient. Biomedical engineering education provides the tools to understand this kind of projects. The future research performed on this topic will focus on detailing this collaborative model by defining the roles of each project participant based on the design process. Also as a future work this model must have an experiments process to validate the theory proposed in this thesis, this is because this thesis only focus on one project application. Being biomedical engineering a relatively new area, new methodologies to enhance the design in terms of efficiency and time are required to better design a product and to ensure the desired outcome.

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Vita

Angel Ernesto Delgado was born on May 13, 1983 in Cd. Juarez, Chihuahua, MEXICO. The eldest son of Ernesto Delgado Burciaga (R.I.P.) and Guadalupe Franco, he graduated from "Colegio Bachilleres N. 6" high school in Cd. Juarez, Chihuahua, MEXICO in 2001 and joined The University of Texas at El Paso (UTEP) in 2004 to pursue a Bachelor of Science in Mechanical Engineering. After completing the BS degree he began attendance in the same university for a Master of Science in Mechanical Engineering. During this time he performed as Research Assistant for LEADER Lab and under Dr. Noe Vargas- Hernandez advising. During his first semester as graduate student he attended a summer internship with Lockheed Martin in El Paso, TX, in which he was part of the Production and Manufacturing Group. His accomplishments include being part Society of Hispanic Professional Engineers (SHPE) and previous Treasurer for the Society of Automotive Engineers (SAE).

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