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Engineering design cycle of curriculum and apparatus for encapsulating medicine design project

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Engineering design cycle of curriculum and apparatus for encapsulating medicine design project

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Report

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Dedication

Thank you to my family for providing me with extraordinary support without this would not have been possible. To my husband Jeremy Garcia and daughter Alexis Lang, your patience and unwavering support were much needed and appreciated. Thank you for providing the confidence boosting whenever I was unsure and know that your sacrifices were not unnoticed. To my mother Lenora Cook my inspiration for pursuing graduate level education, words cannot truly express my gratitude for being with me throughout every step, especially the report, as my lab assistant, proofreader, formatter, and academic sounding board.

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Abstract

Engineering design cycle of curriculum & apparatus for encapsulating medicine design project

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The goal of this work is to modify an existing course module on engineering better medicines to produce a more engaging physiologically realistic and pedagogically sound curriculum. The original module explored drug delivery using a one-compartment model, which examined only the dissolution of medicine; the module relied on a traditional teacher lead pedagogy. The curriculum modifications include engineering a two-compartment model students use to test the medicines they design, incorporating both dissolution and transfer to the blood and project based learning strategies have been added to produce a student centered project. The purpose of these modifications is to produce a curriculum successful in providing a diverse group of students, both male and female, of all socioeconomic backgrounds as well as ethnic and cultural groups with a positive engineering experience.

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Chapter 1: Introduction

There is an urgent need to train more engineers in the United States, as evidenced by an initiative underway, supported by the President of the United States, to train 10,000 new American engineers a year. Increasing the number of engineering graduates will require attracting more college graduates into engineering curricula, particularly women, other minorities and those from a low socioeconomic background, who are not traditionally drawn to or successful in the engineering field. One mechanism for attracting more students to enter engineering is to expose more students to engineering in the K-12 educational experience. These experiences should be positive and empowering for a culturally diverse range of students. Developing appropriate engineering material for high school students is paramount to promoting engineering as a career option for students and ultimately increasing the number and diversity of engineers the United States.

The project described in this report is focused on the development of a course module suitable for use as a capstone design challenge in an emerging year-long high school engineering course. The challenge is to design an encapsulated drug that effectively delivers an appropriate dose of simulated medicine for a defined period of time in a cost effective manner. In addition to learning about engineering models, transport phenomena and the role of engineering in healthcare, students will have the opportunity to learn about ethics, innovation and product evolution that have occurred over time in the pharmaceutical industry.

The yearlong high school engineering course, in which this module will be used, employs an engineering design process (EDP) shown conceptually in Figure 1.1. The cycle begins by first identifying a problem and describing a need which includes analyzing specific customer needs, along with any constraints or specific requirements. It is important to then research any existing approaches to the problem. Further description of the problem involves characterizing and analyzing the system. This includes understanding the relevant science and math, identifying critical subsystem designs, developing performance targets and functional models. Generation and selection of concepts is the next phase of the EDP. This phase involves generation of ideas then analyzing and considering tradeoffs followed with evaluation of concept alternatives and choosing the design concept for the constraints identified previously. The final phase of the EDP is to embody the concept by developing engineering models, creating a prototype, testing the prototype and evaluation of the test results. To conclude the EDP, the design is produced and even reproduced as needed, and then the final design solution is communicated.

The design of the course module described in this report was addressed using the design process shown in Figure 1.1. Initially, the needs were defined through a literature review, which is described in Chapter 2. The generation of the module (Chapter 3 and 4) involved embodying the module concepts. The concepts were then evaluated and a final product was arrived at (Chapter 5). Finally, this curriculum module could continue to be improved as needs are further defined, and recommendations for revisions are provided (Chapter 6).

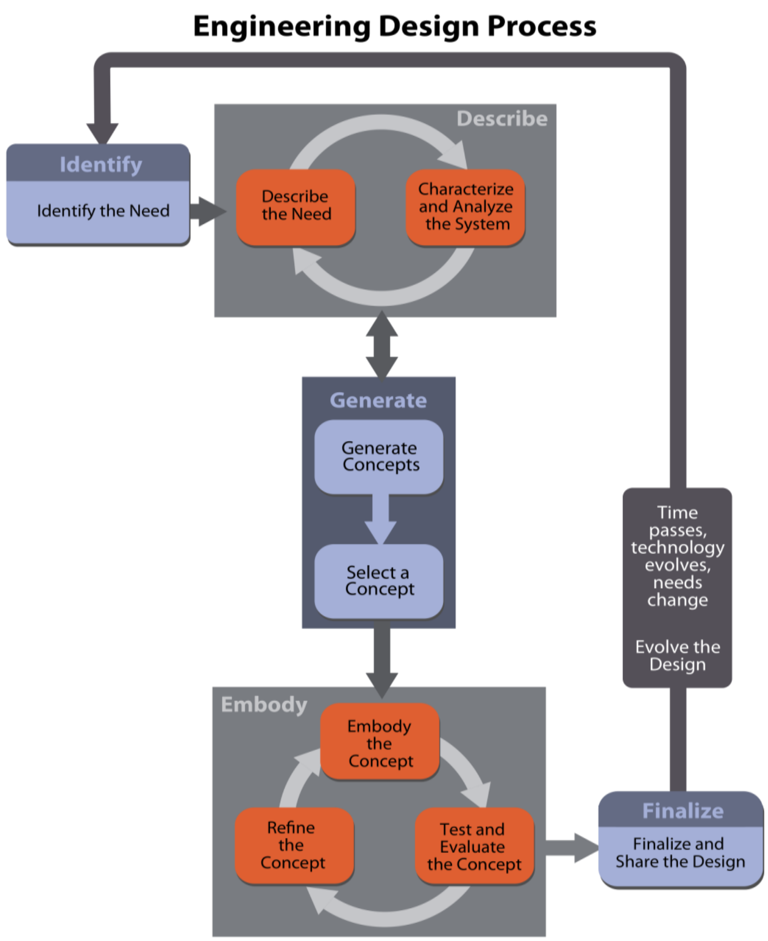

Figure 1.1 Engineering Design Process

Chapter 2: Literature Review

The majority of the literature review presented in this chapter is focused on describing the needs for a design module in a yearlong high school engineering course. A first section will describe the pedagogical approach to be used in the module, which is based on current research in project based learning in engineering education. Second, this module combines elements of both chemical and biological engineering and requires foundation in both chemistry and biology. The literature review describes how current research of the pedagogic practices in engineering and science education can be integrated in this application. Third, literature on providing projects to expose students to a wide range of engineering disciplines has an impact on attracting diverse students to engineering and will be reviewed. Fourth, there will be a review of literature on incorporating career awareness in curriculum since one goal of high school engineering is to expose students to engineering as a career. Finally, the module involves mathematical modeling of the fate of a drug in the human body, so mathematical pharmo-kinetic models are reviewed for appropriateness to represent the encapsulated medicine in the design challenge.

In the end, the goal of this work is to produce an engaging pedagogically sound curriculum that is successful in providing a diverse group of students, both male and female, of all socioeconomic backgrounds as well as ethnic and cultural groups with a positive engineering experience.

PROJECT BASED LEARNING

Project based learning (PBL) is well suited for an engineering education curriculum according to the findings by Mills and Treagust (2003) because it engages students in the real world applications being studied and provides opportunities to develop soft skills such as teamwork and communication which is important to being successful in the engineering field. Also, PBL provides opportunities to integrate math and science into the curriculum as well, which has many advantages for the students. Project based learning is conducive to engineering education because it mimics the professional world (Mills & Treagust, 2003).

There are a number of other benefits of project based learning as a pedagogical approach. "The result of such an approach in the classroom is that learners are motivated to persist at authentic problems, meld prior knowledge and experience with new learning, and develop rich domain-specific knowledge and thinking strategies to apply to real-world problems" (Blumenfeld, Soloway, Marx, Krajcik, Guzdial, & Palincsar, 1991, p. 371). In addition, students construct knowledge by learning in a social context, by working in teams, and gain an understanding of systems, all of which are critical aspects of engineering (Blumenfeld, Soloway, Marx, Krajcik, Guzdial, & Palincsar, 1991, p. 371).

A key step in implementing PBL is defining an appropriate problem. A project begins with the definition of a real world problem for students to solve, which in turn creates a situation for students to need to know the content that includes the desired learning objectives. It is critical that the problem is open ended and not so constrained that the outcome is predetermined (Blumenfeld, Soloway, Marx, Krajcik, Guzdial, & Palincsar, 1991, p. 372). Authentic, open-ended problems have been shown to be effective in science, engineering, and medicine education (Felder, Woods, Stice, & Rugarcia, 2000). In this report, the problem is designing an encapsulation around a simulated medicine in order to deliver a specified dose, over time. Students investigate the mechanism of a dissolving tablet or capsule and how time released medicine works; this is an authentic challenge that is currently being addressed by scientists and engineers. In the past thirty years, pharmaceutical research has had an ever-evolving influx of understanding of the human body as well as bioactive molecules and gene therapies (Vogelson, MDD, 2001). Current methods of medicine delivery are problematic and scientists and engineers are attempting to address these concerns. An example of just one of these many challenges is that the potency and therapeutic effect of a drug is limited due to the partial degradation that occurs before it reaches the intended target in the body. In addition, for some ingested medicines, the dose is delivered all at once; time released medicines allow dose to be released continuously or as needed (Vogelson, MDD). Thus, examining the time release of drugs represents an authentic engineering challenge, suitable for a PBL activity.

INTEGRATING SCIENTIFIC AND ENGINEERING PEDAGOGICAL APPROACHES

The second area of need to be described in this literature review is research on pedagogy of engineering and science education relevant to the design of encapsulated medicine. . According to Christian Schunn in *How Kids Learn Engineering: The Cognitive Science Perspective*, there is a debate about the focus of pre-college instruction regarding whether it should try to develop engineering thinking and habits of mind or focus more on math and science prerequisites. There are several principles that have been found helpful to support learning engineering. First, significant design challenges engage students and therefore should be introduced to students from the beginning not saved for the end after teaching the foundational concepts first. Second, constructing visible models supports the design task. Just as models help engineers to solve design problems, they can also help students represent and interpret the problem. Finally, taking the time to allow students to iterate and refine, which is more indicative of actual engineering practice than single design cycles, is important and provides additional time for exposure to engineering material (Schunn, 2009). Each of these principles is addressed in the drug delivery design module, as described later in this report.

ATTRACTING DIVERSE STUDENTS

In 2006, women earned the majority of bachelor's degrees in biology, one-half of bachelor's degrees in chemistry, and nearly one-half in math (Corbett, Hill, & St. Rose, 2010). The report, *Why So Few?,* indicates that both males and females in minority groups are underrepresented in higher education and careers of engineering. Therefore including a chemical engineering project into the curriculum, particularly a project with a biological basis, may be more engaging for female students.

ENGINEERING CAREER AWARENESS

High school engineering curricula expose students to engineering; this may ultimately increase the number and diversity of practicing engineers in the US, particularly if the high school experiences attract groups that are currently under-represented in engineering. By 2050, almost half of the US population will be non-white according to the US Census Bureau in 2002; so the engineering profession will have to rely on underrepresented groups for the country to keep up its technological capacity (Davis & Gibbin, 2002). Attracting and retaining more women and minorities into the field of engineering will capitalize on innovation, creativity and competitiveness that would be absent without them. When women and other underrepresented groups are not involved in designing the products of the future their needs and desires can easily be overlooked (Corbett, Hill, & St. Rose, 2010).

> It is unrealistic to expect that the challenges facing U.S. innovation can be addressed solely by boosting the number and diversity of K–12 students interested in technical and scientific fields. But broadening the appeal of

> engineering and related careers to American pre-college students will almost certainly be part of the solution (Education, 2009).

According to the U.S. Department of Labor and Statistics in 2009 52% of biological scientists, 33% of chemists and materials scientists and 13% of chemical engineers were women. This contrasts with only 6.7% of mechanical engineers being women (Hill, Corbett, & St. Rose, 2010). According to the *Why So Few?* report, these data indicate that women prefer disciplines and applications of engineering outside of the mechanical devices often encountered in high school engineering. Incorporation of biological sciences in a high school engineering design project through an application to human health may promote the interest of young women in the field of engineering.

The inspiration for the design unit reported in this work, along with additional evidence of its relevance, comes from using the National Academy of Engineering (NAE) grand challenge of engineering better medicine[1] (Engineering challenges, 2008). This authentic challenge includes redesigning medicine, exploring how medicine works in the human body, understanding the process for how medicines are engineered, biochemical engineering practices and other concepts. Adverse drug reactions are one of the leading causes of hospitalization and death in the U.S. so the field of study is important to humanity

[1] Dr. Karen High, chemical engineering professor of Oklahoma State University, has designed this engineer better medicine unit for the UTeach engineering high school curriculum inspired by an engineering grand challenge and a lab from her chemical engineering course.

and that is highly engaging to students (Davis A., 2009). The idea of making a difference has a strong appeal as students make career choices and supports the need to provide a curriculum that engages a diverse audience of students. One of the recommendations, from *Changing the Conversation* is to emphasize that engineers can make a difference in the world, rather than describing engineering in terms of required skills and personal benefits (Changing the Conversation, 2008).

CORE ENGINEERING CONCEPTS

In this design module, students employ a simple pharmaco-kinetic model that while simple, has the basic features that are used in modeling the fate of drugs in the human body. These types of models, often referred to as compartment models, are also used in environmental engineering and in a number of other engineering disciplines (Allen & Shonnard, 2002).

Compartment models derive their name from the fact that they describe the concentrations of materials such as drugs in well mixed regions or compartments. In a pharmaco-kinetic model, the compartment might be the digestive system (if the medicine is ingested), the blood system, and/or a target organ. Flows of medicine into and out of the compartments are tracked over time. A one-compartment model examines drug concentration in only one location in the body. A one compartment model is used in pharmacokinetic analysis if the medicine distributes uniformly in the body (Truskey, Yuan, & Katz, 2009). Since the background for the design problem examined in this work involves simulating an oral dose of encapsulated medicine, the one compartment model is not accurate or appropriate. A two-compartment model that predicts the movement of the drug from a digestive system to the blood or a target organ is more relevant to this application.

"Unfortunately the two-compartment model is still a simple model used mainly to study plasma pharmacokinetics in specific regions of the body" (Truskey, Yuan, & Katz, 2009). Despite this limitation, a two compartment model illustrates many of the complexities of higher order pharmaco-kinetic models, and will be used in this project.

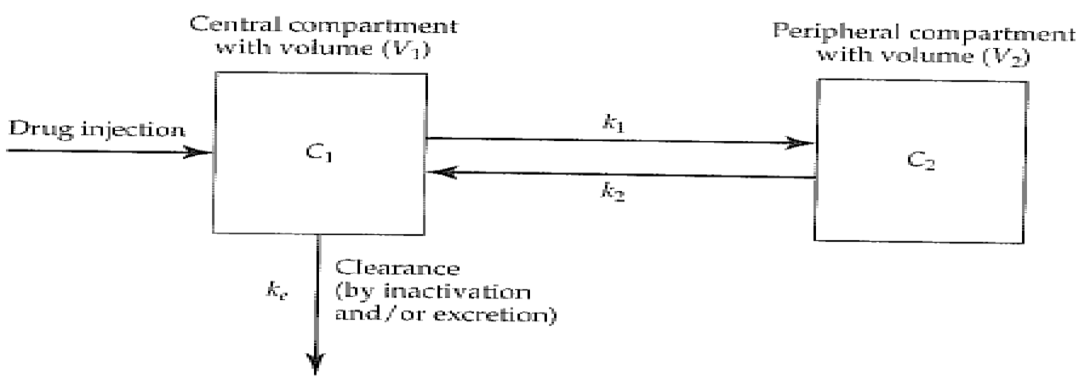

Figure 2.1 Two-Compartment Model with clearance from the central compartment only (Truskey, Yuan, & Katz, 2009)

Above, in Figure 2.1, is a two-compartment model where C represents concentrations of drugs, k_c is the rate constant of clearance, $k_1$and k_2 are the rate constants of mass transfer (Truskey, Yuan, & Katz, 2009). A basic assumption about all compartmental models is that the medicine is uniformly distributed within the compartment (Madihally 2010). Another assumption of the model shown in Figure 2.1 is that all medicine is cleared via the central compartment not taking into account the metabolism of medicine in the peripheral compartment.

This project will take a medicine design challenge currently using a one-compartment model and attempt to adapt it to a two-compartment design challenge. The current system model does not take into account the rate of absorption of medicine by the body; it only models the dissolution, a one-dimensional look at a complex process. It is important to avoid misconceptions in the students understanding of how medicine works and to provide the appropriate level of challenge for the students that will be at the end of the yearlong engineering course.

Chapter 3: Methodology and Results of Apparatus Redesign

This Chapter describes the design of an apparatus for students to use for testing their simulated medicine. A subsequent Chapter (Chapter 4) will describe a modification of the curriculum to accommodate a new testing apparatus. The process of developing the modified testing apparatus included the generation and testing of a variety of concepts (the generate, embody and test phases of the EDP found in Figure 1.1), followed by the selection of a modified system (finalize phase of the EDP).

The engineering design challenge presented to students is to design a medicine delivery system or encapsulation that provides the dose versus time behavior shown in Figure 3.1. The desired, constant rate of delivery in a modified medicine is contrasted with a more conventional delivery of medicine where the release is not effectively controlled in an unmodified medicine.

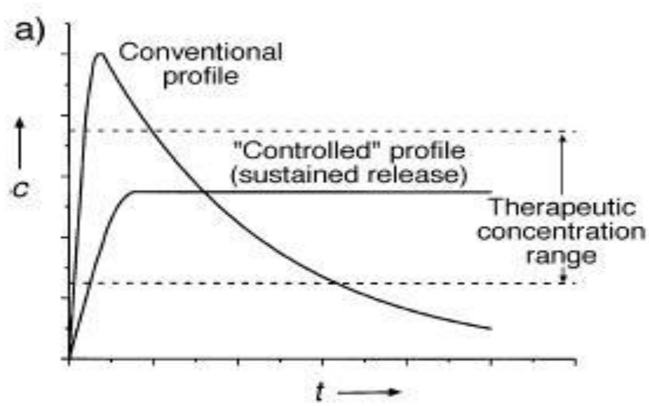

Figure 3.1 Graph of controlled release (Medicine unchanged and medicine encapsulated as concentration versus time)

DESCRIPTION OF ORIGINAL ONE-COMPARTMENT DESIGN CHALLENGE

Modeled in a one-compartment system, a constant rate of drug delivery can be converted to mass of drug remaining over time, shown in Figure 3.2. Also shown in Figure 3.2 are data collected in a one compartment experimental system via two methods.

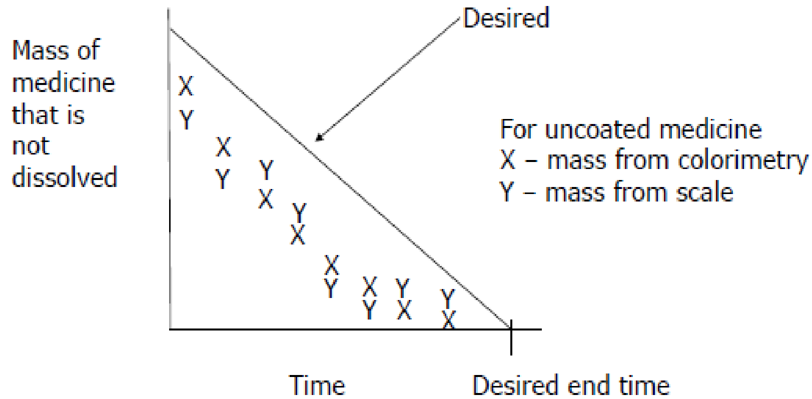

Figure 3.2 Graph of desired and actual release of medicine [2]

In the one compartment model, a piece of candy that dissolves in water is used to simulate medicine. The candy is placed in a known volume of water and the mass of candy represents medicine not yet in solution. Once the simulated medicine goes into solution with the water the determination of the concentration of solute, multiplied by the volume of water represents the amount of medicine entering the body. The mass of the candy or simulated medicine that enters the body can either be determined directly (concentration in water multiplied by

[2] This is a graph of a one-compartment system made for the original curriculum to visually represent the phenomena to students by Dr Karen High

volume of water) or indirectly, by determining the mass of candy remaining undissolved and determining the difference between the partially dissolved and initial masses of candy. This one-compartment setup involves a cup, which is the stomach compartment, to hold the solution of water and candy and is show in Figure 3.3.

Figure 3.3 One-compartment Model (candy is being weighed prior to placement in the cup)

If concentrations are used, they can be measured (for colored candies) using a colorimeter or photospectrometer. These instruments measure absorption of visible light which can be converted to concentrations after the instruments are calibrated with solutions containing known masses of dissolved candy. A set of standard solutions are prepared with a known mass of the candy dissolved in a specific amount of water. The instruments perform best when operated at the wavelength of maximum absorbance. The wavelength of maximum absorbance is determined using a standard sample of the highest concentration to be determined measuring the absorbance at various wavelengths until the wavelength that yields the greatest absorbance reading is found.

The absorbance of the prepared standards (A) described above is measured and graphed versus concentration to use as a comparison for the unknown concentrations from the simulated medicine. The relationship is generally referred to as Beer's Law, $A=\varepsilon cl$, where A is the absorbance measured with a colorimeter, ε is the molar absorptivity, a constant for the particular solute you are analyzing, c is the molar concentration of the solute, and l is path length, the distance light travels through the cuvette. Figure 3.4 shows results from a sample experiment in which A is plotted versus time.

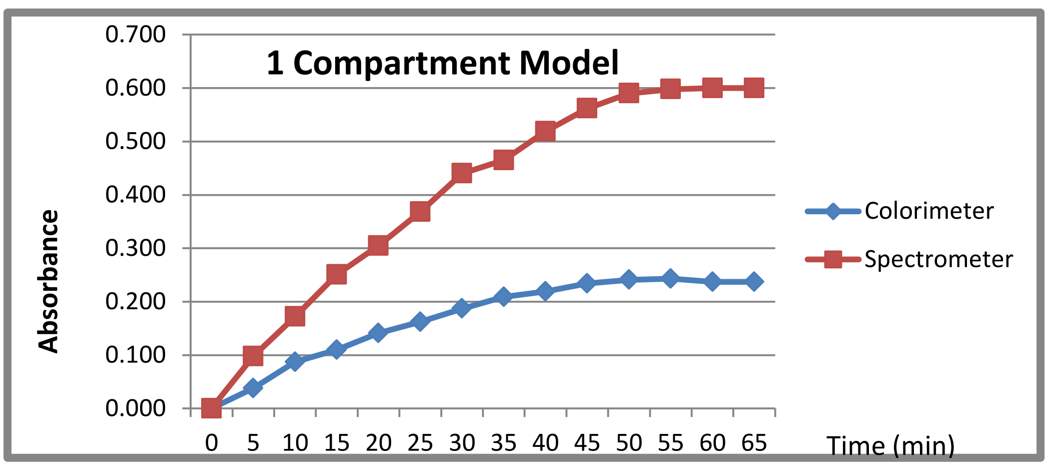

Figure 3.4 Graph of absorption for a One-Compartment Model (provided for comparison with the Two-Compartment Model)

GENERATING A TWO-COMPARTMENT MODEL APPARATUS

The engineer better medicine design challenge described in this report examines changing the original setup, described above, from a one-compartment model to a two-compartment model. Assuming a capsule around the medicine allowing the medicine to pass through the oral cavity without release, the first compartment in the model is the digestive organ, stomach, and the second compartment the simulated medicine transfers to represents the tissue in the periphery, blood. A third compartment could be included to represent the receptor cite at the cellular level, however it is not being included since the project is intended for high school students with a limited skill set and amount of time to complete the design cycle. In addition, adding a third compartment would increase the level of rigor especially due to the computations involved.

Some constraints to consider for the apparatus design include being economically affordable, easily obtainable materials and equipment, reasonable set up including time to build, tools needed, and skill set to build the apparatus, and the apparatus needs to be large enough to accommodate the type of encapsulation the students are likely to design. The apparatus needs to be able to be assembled and provide data in a 50 minute class period. Additional constraints such as modifying the material used for the simulated medicine, type of data to be collected, method for collecting data and materials used to engineer a coating for the medicine are outside the scope of this report.

After considering the needs and constraints for the new two-compartment apparatus and procedure, the concept of using a membrane to allow for transfer of medicine between compartments was selected. Ideas for a membrane to provide a boundary between the two compartments include dialysis tubing, sausage casing, and plastic wrap. Alternatively, if a membrane could not be identified that would selectively allow medicine to be transferred between compartments, direct flow between the compartments, for example using a tube that connects two beakers or plastic cups together, was identified as a concept. The first membrane material tested was dialysis tubing. Dialysis tubing was chosen because it has a semi-permeable membrane which closely mimics the plasma membrane of a cell. This semi-permeable membrane allows some small solutes and water to pass through the membrane via diffusion or osmosis and it inhibits larger molecules from passing through. Dialysis tubing is a common product used in high school labs to demonstrate principles governing diffusion and osmosis concepts. The product comes in a seamless roll and is made of regenerated cellulose with a typical molecular weight cutoff of 12,000 to 14,000 as indicated on the product description from the company from which it was purchased, Carolina Biological Supply Company. It is economical, easily obtainable and reasonable to set up for students and teachers. It is expected that high fructose glucose from the candy and water will have differing abilities to diffuse through the membrane which is why this material is selected to set up the prototypes of apparatus to test the dissolution of the simulated medicine.

Prototype tubing	Structure: 2 clear tubes, dialysis tubing in between held together with ring clamp.	Solutions: Compartment 1 water & candy Compartment 2 Water only	
Prototype tubing	Same as above	Compartment 1 water & candy Compartment 2 Nothing	Same setup as above
Prototype jar	Glass jar with dialysis tubing glued in the ring lid.	Solutions: Compartment 1 water & candy Compartment 2 Water only	
Prototype jar	Same as above	Compartment 1 water & candy Compartment 2 Nothing	
Prototype jar	2 Glass jars stacked on top of one another & dialysis tubing glued in the ring lid.	Compartment 1 water & candy Compartment 2 Nothing	No picture

Table 3.1 Two-compartment Prototypes (This table includes the original failed prototypes of two-compartment apparatus.)

Five different versions of two containers separated by a dialysis tubing membrane were tested with candy and water in compartment one (the stomach compartment) and the second compartment (peripheral blood) either contained water or were empty. All of these prototypes failed to show any movement of the sugar and dye from the candy.

One prototype shown in Figure 3.5 from the first iteration of prototypes included a small dialysis tube bag made of 1 ¾ inch tubing tied at both ends with string filled with water a candy for compartment one and compartment two included a beaker filled with water was successful and demonstrated movement. However, the result was that water from compartment two moved into compartment one due to osmosis. The dialysis membrane did not allow solute to move out of compartment one into the second compartment.

Figure 3.5 Two-Compartment Model Prototype (Dialysis tubing made into a bag to model the stomach which is compartment one. The dialysis tubing bag with candy and water in it is then submerged in water in a beaker where the beaker of water represent compartment two)

A second iteration of prototype apparatus was to limit osmosis by adding sugar to the second compartment. Dialysis tubing as the membrane to separate the compartments was again used making a bag suspended in the solution of compartment two. The set up involved compartment one including colored hard candy and water in a small dialysis tube bag made of 1 ¾ inch tubing tied at both ends with string and compartment two with a simulated blood plasma solution of a ratio of 50 mL of corn syrup to 150 mL water and some salt. The colored candy solution from the stomach compartment did move through the membrane into the peripheral compartment representing blood shown in Figure 3.6 but it took hours for the movement across the compartment membrane making this system impossible to use in a 50 minute class period.

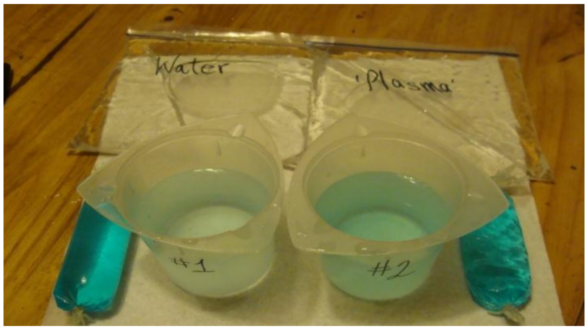

Figure 3.6 Two-compartment Model to test the encapsulation.(This is the first model to work and demonstrate proof of concept)

A third generation of prototype apparatus was then set up which intended to remove sugar from the entire apparatus as a diagnostic means to determine if the large sugar molecules are possibly clogging the membrane. The purpose of this is to determine if the removal of sugar would improve the system. This included substituting a different type of candy, sugar free colored hard candy, in compartment one and compartment two with just a saline solution. This prototype failed even though the salt continued to drive osmosis with the effect of water and solute from compartment one moving into compartment two however, the process quickly reversed with movement of water and solute back into compartment one.

Since use of a semi-permeable membrane was not entirely successful a combination of direct interconnection between compartments was constructed. This fourth generation of prototype was set up just like the previous with exception of a dialysis tubing bag of 3 inch diameter containing the original Jolly Rancher candy and water suspended in the solution of compartment two which is a beaker of water. The larger dialysis tubing is selected to allow for both the collection of samples from compartment one with a transfer pipette and to accommodate the encapsulation that the students will be designing. The previous prototypes were for proof of concept only and did not take into consideration the collection of samples for data or how the encapsulation would be placed in compartment one. Dialysis tubing is intended to mimic a cell membrane and in an actual cell glucose travels through a protein channel in the membrane via facilitated diffusion. To mimic this, a needle was used to make small holes in the membrane. Since the appropriate concentration of colored candy to water that will be detected by the photospectrometer is unknown two different concentrations are set up. Trial one in Figure 3.8 is set up as concentration of compartment one with one candy to 150 mL water and compartment two is 300 mL water and trial two in Figure 3.9 is set up as concentration of compartment one with two candies to 150 mL water and compartment two is 300 mL water. After the final embodiment of apparatus was assembled and the medicine was placed in compartment one to dissolve, samples are collected from compartment one and two at five minute intervals with a transfer pipette. A picture of the two-compartment apparatus with the transfer pipette in compartment one is shown in Figure 3.7.

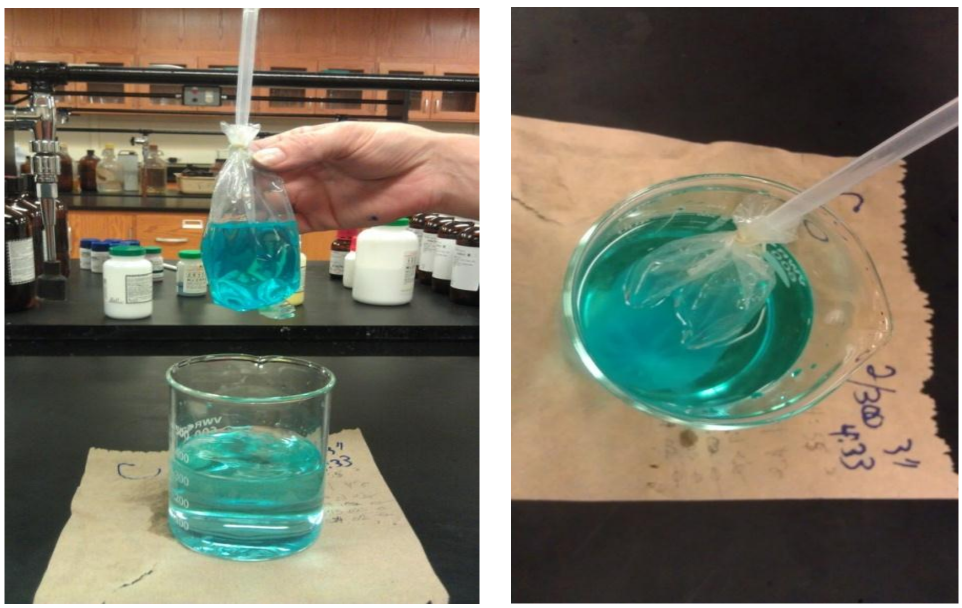

Figure 3.7 Modified Two-Compartment Model (dialysis tubing with needle size holes which represent protein channels in the cell membrane and a plastic transfer pipette to collect samples that meets all constraints)

To compare the data and results from the final design setup of two-compartment apparatus with the data and results from original set up graphs of the data are found in figures 3.4 for one-compartment only and 3.8 and 3.9 below. Trial one shows a greater lag time before the appearance of the solute in compartment two due to a lesser concentration of candy in compartment one. In comparison both trial show a similar pattern of appearance of solute in compartment one prior to the appearance in compartment two. More trials should be run prior to implementation to determine the ideal concentration of colored candy and the number of holes to put in the membrane to gather the most meaningful data.

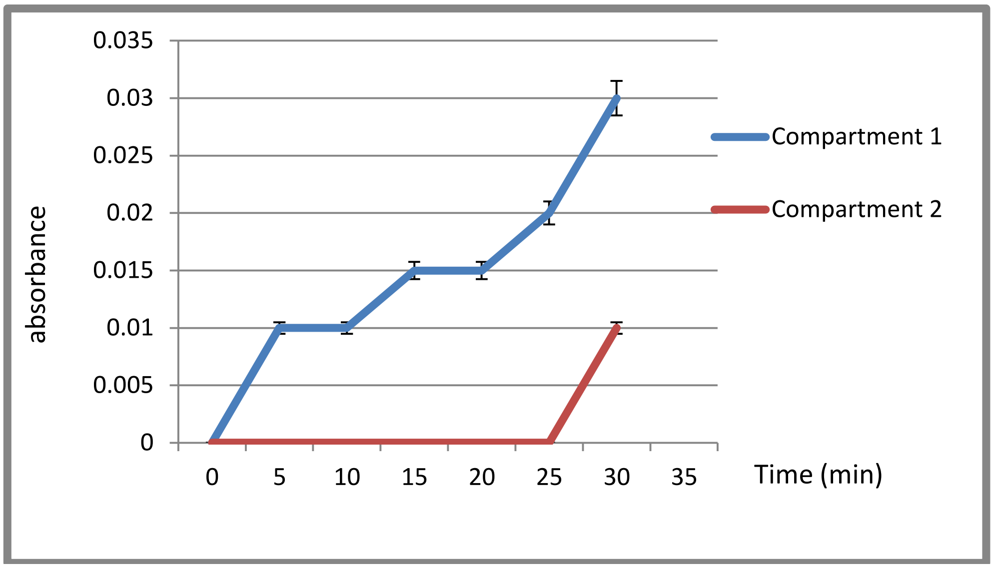

Figure 3.8 Trial one data of Two-compartment Model with holes in membrane (concentration of compartment one is 1 candy to 150 mL water and compartment two is 300 mL water).

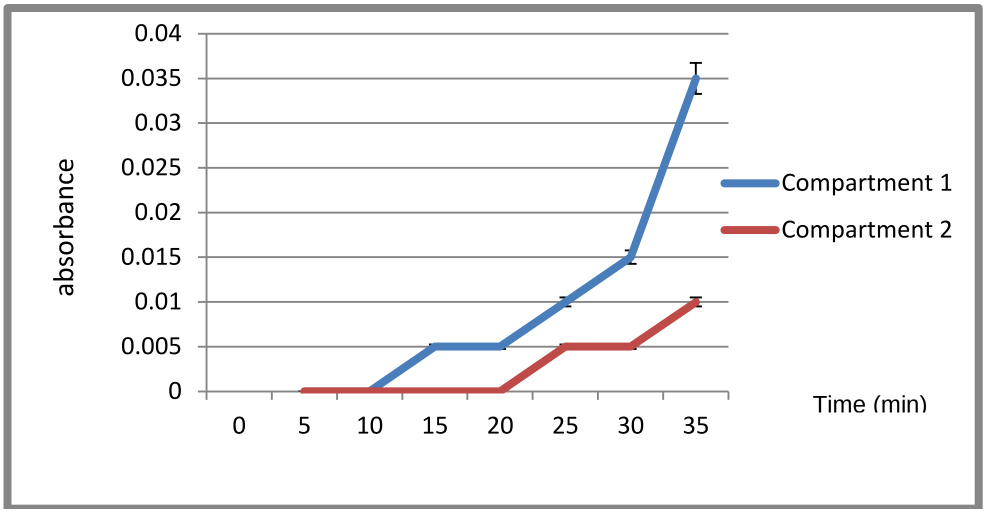

Figure 3.9 Trial two data of Two-compartment Model with holes in membrane (concentration of compartment one is 2 candies to 150 mL water and compartment two is 300 mL water).

In conclusion, a prototype for a two-compartment functional model to replicate the human digestive system was designed, built, tested then incorporated into the new version of the curriculum for the free design project. Chapter 4 now describes how this revised model can be incorporated into a curriculum.

Chapter 4: Methodology of Curriculum Modification

After designing the two-compartment experimental apparatus as described in Chapter 3, the existing curriculum that supports the one-compartment model was revised. Table 4.1 described the curriculum based on the one-compartment model. As will be described in this Chapter, two lessons were changed to incorporate the two-compartment model into the curriculum. Additional modifications were made to address the revision of the pedagogical approach to a PBL format. This was accomplished by modifying the beginning and the end of the original curriculum to a more student-centered, teacher-facilitated project approach.

To begin the revision of the curriculum the content and format of individual lessons, sequence of all prepared lessons, resources, teachers' notes, and all other miscellaneous materials were examined. There are two objectives for updating the curriculum. First, the procedure for modifying the curriculum includes removing specific lessons relating to the one-compartment model in isolation and replacing them with new lessons relevant to the two-compartment functional model. Second, the overall format for the entire six-week free design unit is modified to incorporate the PBL format. This is accomplished by adding specific documents that facilitate key elements of PBL.

One- Compartment Model Lessons Day 1 **Uncoated Lesson 1- Project Specifics** Introduction to Unit/ Uncoated Medicine	**Two- Compartment Model Lessons** PBL curriculum modification to launch project with a well defined problem, Entry Document, Know & Need to Knows, Group Contract
Day 2 **Uncoated Lesson 2- Better Medicine Requirements** How medicine is made	Same
Day 3 **Uncoated Lesson 3- Gathering Data** Students working in lab /Beer's Law	Same
Day 4 & 5 **Uncoated Lesson 3- Gathering Data continued** Students working in lab/Modeling and diagrams	Modeling and diagrams include two-compartment functional model
Day 6 **Uncoated Lesson 4- Functional Modeling** Students working in lab/linear regression	Same
Day 7 & 8 **Uncoated Lesson 5- Modeling Using Technology**	Same
Day 9 & 10 **Uncoated Lesson 6- Improving Medicine** FDA ethics In Vitro Careers Review project specifics	In Vitro lesson modified to incorporate the relevance of using the two-compartment model representing human digestive system for testing apparatus
Lesson Set 2- Creating and Analyzing Coated Medicines	
Day 11 & 12 **Coated Lesson 1- Planning the Project**	Same
Day 13 & 14 **Coated Lesson 2- Prior Solutions and External Justification**	Same
Day 15 & 16 **Coated Lesson 3- Choosing Test Coatings Students in Lab**	Same
Day 17 through Day 20 **Coated Lesson 4- Evaluating Solutions**	Provide time for Reiteration of the encapsulation
Lesson Set 3- Presenting Results	
Day 21 through Day 25 **Presentation Lesson 1- Developing Presentations** Day 26 through Day 30 Presentation Lesson 2- Delivering Presentations	Same

Table 4.1 Curriculum comparison of one and two compartment models

Pedagogical Approach Revision

The current pedagogical style of the engineering challenge is traditional in that students receive instruction through a predetermined set of lessons and agendas before students have the opportunity to explore and design. For example, there is no student choice incorporated in the curriculum until the last phase of the challenge (Days 16-20) in which four 50 minute classes are allotted to choosing, manufacturing, testing and evaluating a coating, then reiterating as time permits. Based on the review of the literature in chapter 2, science and engineering needs to be integrated and placed in the context of a real world project. Design challenges should be introduced to students from the beginning.

To modify the curriculum, an essential open-ended question to launch the project and the collection of artifacts is added to conclude the project (Blumenfeld, Soloway, Marx, Krajcik, Guzdial, & Palincsar, 1991) (Thomas, 2000).

An entry document was added that includes a problem statement that summarizes the challenge and role of the students that fits into a format similar to "How do we, as ____ , do _____ so that ______?" For this project the problem statement added was (see Appendix A4): "How do we, as biochemical engineers, design a capsule so that it releases the medicine in the stomach, in a controlled way, in order to be absorbed into the blood?" This launch leads students to need to know the content objectives and allowing the teacher to provide instruction of those objectives (Buck Institute for Education, 2012).

This launch statement has students take on the role of a biochemical engineer. This provides them an authentic opportunity to explore the profession of biochemical engineering. The only change this makes from the original curriculum is adding the problem statement to the launch document placing students in that role from the beginning and throughout the project rather than just experience a single career lesson. There is also a shift from chemical engineering to biochemical engineering.

The launch causes students to create a set of “knows” and “need to knows” (an example is provided in Appendix A3). Students identify everything they know in detail followed by producing an exhaustive list of what they need to know in order to successfully complete the project. It is this exhaustive list of need to know items produced either individually, by teams, or as an entire class, at the discretion of the teacher, which drives the instruction provided to the students. (Buck Institute for Education, 2012). The teacher controls instruction through a process often described as leaving a trail of breadcrumbs. Students follow the “need to know” breadcrumbs until they reach the final destination of mastery of course objectives and the final product. The know and need to know activity is also an effective pre-assessment tool for the instructor to ascertain knowledge of specific terminology, concepts and even skills that the students either possess or lack as well as identify misconceptions that allow the teacher to facilitate instruction throughout the remainder of the project.

The next item added to existing curriculum was a group contract for the team of student engineers. A group contract is an essential tool to hold students accountable in a PBL class context however; it also needs to be equipped for an engineering class environment. This is accomplished by incorporating the periphrasis of engineering habits of mind into a group contract template that allows for students to be held accountable while reinforcing engineering standards. The habits of mind mesh well with the group contract. For example, team roles are now lead communicator, manager of ethical considerations, collaboration manager and initiator of creativity. In addition, it helps model the engineering professional environment. A copy of the engineering group contract with the habits of mind incorporated can be found in Appendix A4.

Incorporating Biological and Chemical Sciences

Incorporating biological and chemical sciences into the engineering design module increases the potential level of engagement of female students in general and groups of students from underrepresented categories of engineering professionals. Adding the context of biological science via the human body maximizes engagement and supports core engineering concepts. Two modifications to the curriculum are made that incorporate both anatomy and physiology of the human body. First, is the addition of a two-compartment model that represents the interaction of the digestive and blood systems. Second, is a lesson regarding ethical engineering practice through utilizing in vitro rather than in vivo testing. The adjustment to the curriculum is to highlight the two-compartment functional model that represents the human system in context as an example of practicing in vitro testing.

EMBRACING THE ENGINEERING DESIGN PROCESS

The final stage of the EDP is to embody the concept. Students finalize the prototype and then are ready to share the design. As stated in the beginning of Chapter 4, the end of a project in PBL format requires a collection of artifacts along with the final product. This is already accounted for in the original curriculum including a list of student artifacts to produce throughout along with the presentation. Changes needed include redistributing the number of days dedicated to prepare their presentations, providing and receiving feedback from peers in order to improve the quality of their work, presenting final products and providing an authentic audience for students to present. Also the content rubric needs to be given to students when the project is initiated. This helps the teacher facilitate the instruction of course objectives without having to lead and prescribe every lesson in a specific sequence for every student. If only half of the students need a lesson on one-compartment functional models and only five students need a lesson on in vitro testing, the rest of the students can continue working with their team to research, learn and produce what they need A complete the project according to the rigorous standards in the rubric.

An additional change is to have students learn to give and receive feedback responses "I likes" which are strengths, "I wonders" which are things that are unclear, and "next steps" which are suggestions, ideas and resources.

Finally, student teams present to an authentic audience of professionals from the community that are invited and arranged by the teacher.

Chapter 5: Analysis of Project Needs

The goal of this project was to produce an engaging, pedagogically sound curriculum that is successful in providing a diverse group of students, both male and female, of all socioeconomic backgrounds as well as ethnic and cultural groups with a positive engineering experience.   Four needs were identified in the literature review that were addressed by producing a testing apparatus based on a functional two-compartment model to include the context of the human body and modifying curriculum to incorporate both the two-compartment model and project based learning pedagogy.

Project and Problem Based Learning in Engineering Education

The first need identified for the engineer medicine design challenge was to use project based learning as a preferred pedagogical approach. Implementation of PBL begins with a well defined open-ended problem for students to solve (Blumenfeld, Soloway, Marx, Krajcik, Guzdial, & Palincsar, 1991) (Buck Institute for Education, 2012)**.** This is addressed in the entry document, located in the Appendix A2, which not only outlines the problem but puts it in a real world scenario for the students.   According to Blumenfeld, Soloway, Marx, Krajcik, Guzdial, & Palincsar (1991) students construct knowledge by learning in a social context and by working in teams. This need is addressed specifically in project based learning and students are held accountable for the social aspect of learning while working in teams through the group contract found in the appendix A4.

INTEGRATING SCIENTIFIC AND ENGINEERING PEDAGOGICAL APPROACHES

The next need was integrating scientific and engineering pedagogical approaches. As discussed in the literature review, (1) design challenges engage students and therefore should be introduced to students from the beginning not saved for the end, (2) the use of models can help students represent and interpret the problem and (3) time should be allowed for students to iterate and refine (Schunn, 2009) This advice was incorporated into the modified curriculum via introducing the design challenge from day one in the entry document found in the Appendix A2. More time was allowed for students to spend on iteration and reiteration of their designs. In addition, the use of a physical two-compartment functional model was incorporated into the curriculum.

ATTRACTING DIVERSE STUDENTS TO ENGINEERING

Statistics from the Census Bureau described in the literature review shows that women and other minority groups of students are completing biological and chemical science degrees at higher percentages than engineering degrees. Therefore use of a medicine design challenge should cause this project to have an appeal to broader range of students.

ENGINEERING CAREER AWARENESS

Engineering career awareness was the third need discussed in the literature review.   Emphasizing that engineers can make a difference in the world as in improving medicine for humanity has an appeal and is an effective strategy in attracting a broad range of students (Changing the Conversation, 2008). Bringing real engineers into the classroom for project presentations to represent an authentic audience, throughout the project having students contact engineers to ask questions are all methods brought into the modified curriculum that raise career awareness and are listed in the table of lessons in Appendix A1.

Core Engineering Concepts

Based on another need from the literature review, core engineering concepts were incorporated into the curriculum modifications as well as used to develop the two-compartment apparatus. Engineering habits of mind are embedded into the group contract which is in the Appendix A3. Learning in a social context is an integral part of both a PBL classroom and an engineering class (Schunn, 2009). It is critical to hold students accountable for their group interactions as well as their individual learning which is the purpose for the group contract and a great way to review the habits of mind on an ongoing basis throughout the project.

The curriculum modifications to the engineer better medicine design challenge also include appropriate adjustment to incorporate a more realistic two-compartment functional model which reinforces key concepts in pharmaco-kinetic modeling.

Chapter 6: Applications for Future Practice

There is a huge barrier for science teachers in Texas to include engineering in their curriculum due to the fact that there is no engineering mentioned in any science courses. There is only one engineering course in which students can receive a science credit which is engineering design and problem solving course. Moreover, a typical science teacher is not prepared to incorporate engineering into a science course by their traditional teacher preparation programs or district professional development focused on preparing teachers to prepare students for state assessments. Only teachers prepared by programs such as the UTeach engineering program could be adequately prepared to incorporate engineering into the science courses in addition to the science TEKS on which the students are assessed.

Engineering habits of mind are not exclusive to engineering courses. The habits of mind include skills such as communication, collaboration, creativity, verification and systems thinking. These skills are deemed 21st century skills and are required of students in project based learning classroom environments. Students are held accountable for these skills as learning outcomes by which students are graded. In addition, these skills are beneficial in being prepared for careers other than engineering for example teaching. It behooves educators and students alike to encourage these skills in all courses not just engineering.

Through this Master's report which is based on an assignment that is both to complete an engineering and an education design, it provides the opportunity to apply what was learned from both disciplines and should be considered for requirement of every Masters student in the UTeach Engineering program (MASEE). The UTeach engineering MASEE program itself is a one size fits all program that lacks student accountability and teacher feedback in the majority of the courses within the program therefore, a student in this program gets out of it what they put into it. In the end, a project and report such as this that utilizes the engineering design cycle to produce a modified curriculum that incorporates an apparatus based on a two-compartment functional model and is an original creation is evidence of success in learning with the UTeach science and engineering education Master of Arts program.

Appendix

A1: Lessons for Engineer Better Medicine Design Challenge

Phase of: EDP	**Lessons In Original Curriculum**	**Lessons In Modified PBL Curriculum**
	Project Specifics (1 Day)	Project Launch: Entry Document, Know/Need to Know Chart, Group Contract
Describe: Describe Need Characterize & Analyze the system	Explain how medicine is made Describe the customer needs Identify constraints	
Generate: Generate Concept	[redacted]	[redacted]
	Better Medicine Requirements (1 Day)	
	Gathering Data (3 Days)	
	Functional Modeling (1 Day)	Functional Modeling of 2-compartment system
		Modeling applied to Human System; In Vitro
	Modeling Using Technology (2 Days)	
	Improving Medicine (2 Days)	
Generate: Select Concept	[redacted]	[redacted]
	Planning the Project (2 days)	
	Prior Solutions and External Justification (2 Days)	
Embody: Test and Evaluate	Choosing Test Coatings (2 Days)	Test Coatings (2-4 days)
	Evaluating Solutions (4 Days)	Evaluating Solutions (4 days) Reiterate (2 days)
Finalize & Share the Design	[redacted]	[redacted]
	Developing Presentations (5 Days)	Develop presentations (3-5 days depending on the format required) Critic Friends (1 day)
	Delivering Presentations (5 Days)	Presentations to panel of authentic professionals or experts from the community. (1-2 days)

A2: Entry Document Engineer Better Medicine

Better Medicine Pharmaceuticals

Greetings engineering students and teachers,

Out team of pharmaceutical research scientists are busy formulating a new medicine to prevent acne safely and effectively. We have discovered that the medicine requires direct absorption into the bloodstream to be the most effective yet needs to be administered orally based on consumer preference.

We need your help as biochemical engineer consultants to design a capsule to encase the medicine. This capsule needs to be safely developed with in vitro testing, follow engineering ethics, effective and affordable allowing the medicine to skip the orally cavity, break down in the stomach only to be absorbed into the blood without moving through the intestine where specific enzymes cause the medicine to become ineffective.

It is also crucial that the coating you engineer does not violate any existing patents; so the encapsulation your team designs must be original. The final product prototype, along with data to support the effectiveness of the design will be presented to a panel of experts in six weeks. The team that engineers the capsule that meets all of the specs mentioned previously will earn a scholarship to the engineering college of their choice. Good luck and may the best design win.

Sincerely,

A:3 KNOW AND NEED TO KNOW CHART

Know	Need to Know
Content: (Examples are from entry document in A2) Medicine dissolves in stomach. Medicine skips the oral cavity/mouth. Medicine will be absorbed into the bloodstream. Enzymes can make the medicine not work. Data will be collected.	Content: (Examples are from entry document in A2) Where does medicine go after stomach? What is in vitro testing? What will the prototype be made out of? What kind of medicine will be tested? Will it be real medicine tested?
Logistics: Ex: The due date is 12/12/12 in six weeks. We are presenting to experts. We will be working in teams.	Logistics: Ex: How long is the presentation? Do we get to pick our teams? Are we in the same teams the whole time?

A4: ENGINEERING GROUP CONTRACT

Section 1: Engineering Habits of Mind (HOM)

We will demonstrate the following engineering habits of mind:

a. *Systems thinking*
b. System understanding and quantification
c. Understanding/application of engineering tools and techniques
d. *Creativity*
e. *Collaboration*
f. *Communication*
g. *Attention to ethical considerations*
h. Safety and reliability

As a group to demonstrate communication HOM, we agree to keep in contact with each other on throughout the entire project.

Name	Phone	Email

Section 2: Expectations for Group Behavior.

I. We will display the following values especially when faced with challenges through the design process or struggling to meet deadlines:

a. Respect: The following are ways in which we will be respectful:

b. Reliability (HOM): The following are ways in which we will show responsibility:

c. Perseverance: The following are ways in which we will persevere.

II. We will share responsibility for our task.

a. If a team member is taking too much control of our project, we will:

b. If a team member is not contributing enough to the project, we will:

III. Another problem we anticipate is:
We will solve this problem by:

Section 3: Getting the Work Done.

I. Group Roles. We will perform the following roles in our group. Not only will we be responsible for our own role, but we will also be responsible for all research and rubric requirements.

a. **Group Lead Communicator (HOM):** ______________________
This person will be responsible for organizing group communications to include: communicating group questions, concerns, and progress to the teacher, and for communicating teacher comments and instructions to the team.

b. **Manager of Ethical Considerations (HOM)**: ____________________
This person will take responsibility for holding their group to the norms and core values of the classroom. When norms are violated, this group member should speak up and remind his/her group of the norm.

c. **Collaboration Manager (HOM)**: ___________________________
This person will take responsibility for maintaining teamwork and cooperation through enforcing group contract, and monitoring group mood and atmosphere whenever a problem arises or group energy lags.

d. **Initiator-Contributor of Creativity (HOM)** : _____________________
This person will take responsibility for offering new ideas and avenues of research, proposing solutions and new directions for creative expression, and creating a plan for completion and setting deadlines for the group to follow.

II. Dividing up the Work.

a. Our plan for dividing the work fairly is:

b. If someone does not have a computer at home, we will make sure he/she can still contribute by:

c. If someone is not doing work and/or doing work of poor quality, we will:

Section 4: Firing Procedure

Should a group member repeatedly choose not to uphold this contract, we will follow this procedure in order to fire him or her from our group.

I. The group member will receive 2 warnings from their group. The group member should be told verbally that they are being warned, AND the warning will be logged on the contract.
II. On the third violation of the contract, the group will meet with the teacher to discuss the difficulties.
III. On the fourth violation, the group will notify the teacher and fire the group member.

Section 5: Agreement

We have read this group contract and agree to uphold the standards that we have set for ourselves. We will monitor not only our own behavior, but also that of our group members. We understand that it is our responsibility to enforce this contract.

Signed:

_____________________________ _____________________________
_____________________________ _____________________________

Group Member Warning Log:

Date	Person Being Warned	Reason for Warning	Signature

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