RESEARCH EXPERIENCE FOR TEACHERS (RET): SUMMER 2009 TEACHING MODULE:

USING THE ENGINEERING DESIGN METHOD TO MANAGE A SCIENCE OR ENGINEERING PROJECT

OVERVIEW

Projects which last longer than a day or two require planning. Students need to learn to take a longer view of their work plans. When faced with a lot of work they may want to jump right in without thinking through an overall plan. This module features lessons for teaching the creative problem solving and organizational skills needed to prepare and execute a project. It prepares a student to be able to follow through with a plan, once an initial project goal has been defined. Using engineering design method students will frame a problem, if it needs definition, brainstorm solutions, prioritize them, select tools, divide tasks for a team, and document their work.

The example projects in the lessons used in this module come from an actual pharmaceutical engineering project, shared with Project SEED students, to create gels and thin films as a new drug delivery form. The project involved many small experiments, which had to be coordinated and evaluated at each step in order to steer a proper outcome to the project. The engineering design method was used as much in planning, coordinating, and scheduling the tasks required for this project as it was in the technologies used to meet the project goal.

STANDARD(S) & INDICATOR(S):

(Note: This section should include all standards listed in the lessons.)

- 5.1.8.B1. Identify questions and make predictions that can be addressed by conducting investigations.
- 5.1.8.B2. Design and conduct investigations incorporating the use of a control.
- 5.1.8.B3. Collect, organize, and interpret the data that result from experiments.
- 5.4.6.C1. Select a technological problem and describe the criteria and constraints that are addressed in solving the problem.
- 5.4.4.C3. Use the design process to identify a problem, look for ideas, and develop and share solutions with others.
- 5.4.6.C1. Select a technological problem and describe the criteria and constraints that are addressed in solving the problem.
- 5.6.6.A3. Describe the properties of mixtures and solutions, including concentration and saturation.

OBJECTIVES:

(Note: This section should include all objectives listed in the lessons.) Students will be able to:

- 1. Define the problem to be solved.
- 2. Define the specifications, limits, constraints for the problem.
- 3. Generate design concepts that could solve the problem.
- 4. Scale this process up to a small test plant.
- 5. Develop and perform laboratory experiments to determine the properties of gelling materials that could be dried for use as thin films.
- 6. Recommend the properties of a gelling material that can be used for scale up and production.

INTRODUCTION AND BACKGROUND

Project management is very important part of any research or engineering project. The more extensive the project and complex the project goals, the greater there is a need for a good plan. The Research Experience for Teachers Project which inspired this module had a seemingly simple goal: find and characterize gelling materials that could be dried to thin films that would deliver a specific amount of an Active Pharmaceutical Ingredient, API, while maintaining the size of the particles of the API. The goal was achieved by designing and executing three subprojects and coordinating the work requirements with 4 Project SEED students who worked in teams of two. The first team of students prepared a database of gelling properties of two different edible polymers, Sodium Alginate and Hydroxypropyl methylcellulose, HPMC, at different concentrations, with and without two different plasticizers, PEG, polyethylene glycol 50-60 cps and PEG 4000 cps, with and without polymer coated particles of an API at two different concentrations, which could be milled or un-milled. Another side study this team did was to observe the effects of temperature and mixing on particle size reduction when the particles were prepared with the coatings of polymers prior to milling. The second team tried three different methods of drying, two of which proved usable for the experiments to make films of all the various gels. They also tested four different drying surface materials. In order to get to this point they had the determine the amount of gel needed to make a good test film, measure the amount of water removed and estimate the amount of API in the films. They also created a matrix of film properties with and without particles, including pictures of the films. At the end, they dissolved test films to see how easily they would dissolve if used for drug delivery, and measured the sizes of the particles they would deliver. At this point, one can see how proper project management is needed to coordinate all the tasks needed to achieve the goal of this project. Using the Engineering Design method students have a well structured process for organizing, planning, and executing projects.

LESSONS IN THIS MODULE:

When faced with a multitask project some students might not know where to start. The three lessons in this module are meant to address this dilemma, using the Engineering Design Method. The first lesson teaches students how to get a good start on a project. This means framing the problem or goal, brainstorming, setting priorities, making lists of required tasks, and putting them in a logical order so the project can proceed smoothly. The second lesson is a classic engineering challenge. It gives students a goal and a set of ground rules. They must calculate requirements, plan a schedule, and order tasks in series or parallel to make optimal use of time and materials. The second lesson can be extended to include identification of critical path items and ergonomic design of work space for more advanced students. The third lesson is a laboratory exercise in which students repeat parts of the actual RET project creating then films with other gelling materials. This lesson teaches students what it means to design their own experiments to achieve a research goal. This lesson can be extended to process resulting data with statistical tools.

RESEARCH EXPERIENCE FOR TEACHERS (RET) LESSON #1 USING THE ENGINEERING DESIGN PROCESS

DESCRIPTION

Starting the Engineering Design Process – 1-3 hours

This lesson is an exercise for students to learn to frame a problem, define limits and specifications, brain storm solutions, and prioritize their ideas. This exercise should get students to Step 4 in the Engineering Design Process, "Prototyping".

This exercise should be evaluated with the following criteria:

- Did the students frame or define the problem or goal at the start?
- Did they work as a team and record everything?
- Did they propose questions to learn more about the challenge?
- Did they consider practical details for each situation, especially cost?
- Did they prioritize their ideas?
- Can they take the challenge idea to next step?

STANDARD(S) & INDICATOR(S):

(Note: This section should include all standards listed in the lessons.)

5.4.6.C1. Select a technological problem and describe the criteria and constraints that are addressed in solving the problem.

5.4.4.C3. Use the design process to identify a problem, look for ideas, and develop and share solutions with others.

OBJECTIVES: Students will be able to:

- 7. Define the problem to be solved.
- 8. Define the specifications, limits, constraints for the problem.
- 9. Generate design concepts that could solve the problem.

CLASSROOM ACTIVITY DESCRIPTION:

Engineering Design Process Practice

An important aspect of the Engineering Design Process is simply learning how to ask the right questions to start. In this exercise you will try out the first 3 to 4 steps in the Engineering Design Process. You will use brainstorming techniques to both gather the information you need to start, and to prioritize it for prototyping.

You will

- Define a problem or goal
- Brainstorm for ideas to get started.
- Evaluate the ideas

Your tasks:

- 1. Select a scribe to record all ideas, and rotate this job among team members.
- 2. Select one or more challenges from the list below.
- 3. Define the problem as you would like to solve it
- 4. Build a check list of things you need to know about this problem in order to solve it. Engineers always build lists.
- 5. Order the items on the list from what you think are most important to least important in helping you meet the goal. This will get you to the "prototyping" stage of the design process.

Challenge Ideas – select one at a time for brainstorming

- 1) A friend has a new business making really awesome chocolate chip cookies. She asks you to design packaging for them that keeps them fresh and unbroken for shipment to supermarkets. How will you do it?
- 2) You work for a company that manufactures ink-jet printer technology. You find out that there are many unconventional uses for it, such as "printing" pharmaceuticals into skin patches. You would like to learn about some of these, and make a proposal to your management to try it.
- 3) You work for a sports equipment company that has decided to sponsor the Para-Olympics. What specialized items can your company make for them?
- 4) Your company will design an oil and fuels pipeline from the port at the Italian Riviera to just outside Milan. Your two main concerns are security and the environment. How would you address them?
- 5) You've just developed a new fabric that's wrinkle and stain resistant, and you would like to propose uses for it. Where would you start?
- 6) The plastic housing of a new electronic game has a tendency to crack and break. The high number of returns is costing your company too much. What would you do about it?

Engineering Design Process

The Steps of Engineering Design Method (Similar to Scientific Method)

- 1. Identify the want or need, define the problem, frame the problem
 - 1. Refine the definition of the "problem"
 - 2. Avoid any "perceived problems" and ask all the "what ifs"
- 2. Define/Generate Specifications, limits, constraints
 - 1. Start asking all the right questions
 - 2. Make lists and prioritize requirements
- 3. Generate Design Concepts
 - 1. Brainstorm all ideas for all nuances
 - 2. Use Critical thinking go for quality and quantity
 - 3. Record all ideas without prejudice no idea is too silly
- 4. Prototyping: test the ideas
 - 1. First models can be crude, but should be functional
 - 2. Do "back of envelope" type calculations to compare ideas
 - 3. Sort results based on pros and cons for each
- 5. Select the Best Concepts
 - 1. Select the three most elegant solutions based on the design requirements and limits. Good solutions are usually "elegant". Buckminster Fuller said that if it's not beautiful, it's wrong.
 - 2. Save all unused ideas for future reference.
- 6. Detailed Design for best concepts
 - 1. Draw it first
 - 2. Estimate and measure materials
 - 3. Build the working model
- 7. Manufacture and Implement
 - 1. This can only be done with real designs, when the working model works.
- 8. Test and Refine
 - 1. Analyze results and compare to specifications.
 - 2. Return to step 5, 6 or 7 depending on test results, return to the "drawing board" if needed.
- 9. Release

In a nutshell: Design – Break – Redesign - Repeat

Lesson #2 The Engineering Pilot Plant Challenge - 3-5 days

Many engineering projects start with a goal or challenge. A very typical engineering project in the chemical industry requires an engineer to take a chemist's bench scale operation and scale it up to some level of production. This challenge is based directly on the RET project's hypothetical next steps.

In this exercise the teacher should allow the students to try to define the requirements as much as possible by themselves, adding ideas only to guide and extend the students critical thinking process.

STANDARD(S) & INDICATOR(S):

5.4.6.C1. Select a technological problem and describe the criteria and constraints that are addressed in solving the problem.

OBJECTIVES: Students will be able to:

1. Scale this process up to a small test plant.

CLASSROOM ACTIVITY DESCRIPTION:

Teacher's notes to guide students

One of the first steps is to scale up the quantities from 100ml to 50L. Because this is a suspension instead of a solution the term "wt%" is defined as a weight ratio, 2 wt% means 2 grams of API per 100 g of water. Calculating the amount of additional gelling material needed is greatly simplified without water present. Some students might observe that when scaled to 50L the suspended particles and gel might change the overall volume to where it might not fit in the mixer. If so, you can presume that the mixing vessel can handle the increased volume.

In order to create a schedule of how many batches they can create in a day students need to define the length of a "work day", and understand that they cannot ask the same workers to do a 24 hour shift.

In optimizing this process students should identify the slowest step in the series, for example, the time in the dryer over, and maximize its use, or minimize its downtime.

For the floor plan students should use graph paper and create a proportional scale. They should estimate the sizes of the mixer and oven, based on their volume. Comparing the mixer to an industrial sized kitchen mixer might help. There might be one in the school cafeteria. Advanced students could actually size the mixer and oven based on the volume requirements of the mixture, and estimate the number of films produced per 50L batch.

Rubric for grading:

- 1) Did students properly scale up the process? Is it mathematically correct?
- 2) Did the students include a scaled floor plan?
- 3) Did the students give as reasonable estimate of a one day's schedule and production?
- 4) Did the students consider worker safety in the floor plan?
- 5) Did the students document all of the above in an orderly fashion?
- 6) Did the students work as a team, divide tasks and coordinate their efforts?
- 7) Did the students include a neat summary cover letter to plant manager?

Advanced

8) Did the students optimize use of the equipment and consider ergonomics in the design of the plant?

Pharmaceutical Pilot Plant Project

Introduction: A research scientist has perfected a new process for creating a thin film containing Class 2 (low solubility, high bioavailability) Active Pharmaceutical Ingredients, APIs. The scientist did the work with very small quantities at a laboratory bench scale, but has a well documented recipe. It starts with a 2 wt% aqueous suspension of the API which has been coated with 0.25 wt% of an edible polymer. The edible polymer also makes a gel that can be dried to a thin film.

The scientist defines the proportions for the 2 wt% suspension as follows:

- $100g H_2O + 2g API$ coated with 0.25 g of polymer

The scientist's recipe and proportions are as follows:

- The suspension is gelled at 60C in a stirred vessel with additional polymer so that the API is 25 wt% of the API and polymer mix when the gel is dried to a film.

Your manager would like you to scale this process up to a small test plant for the clinical trials. You have use of some plant space and equipment near the lab. In your pilot plant you have a 50 liter capacity heated stirring vessel. It can create one batch of gel in about one hour. You also have a drier oven that can be set to the required low drying temperature of 40C. Each batch from the mixing vessel can be poured into film molds and dried in 2 hours. You will need balances to weigh all the materials, storage drums to hold supplies, film molds, and utensils. You'll also need some safety gear and special clothing for the workers. Brainstorm ideas to determine what else you need to know before you start.

Design the small plant and create a report for your boss. Include the following

- Scale the recipe up to the size of the equipment you have and determine the quantity, in kilograms that you will need per batch of the edible polymer.
- Determine the maximum daily production of your little plant, or at least what you would recommend as the maximum daily production.
- Draw a floor plan for the equipment.
- Describe the tasks for the workers. Estimate how many workers are needed.
- Identify any "critical path" items, and analyze the importance of each step in the process. What step takes the most time or effort?
- Add a cover letter to the report containing a short summary of all the parts of the assignment.

Lesson #3 Designing New Laboratory Experiments - 1-2 weeks

Introduction and Background

Most school laboratory experiments are old tried and true procedures which teach students both the fundamentals of following proper lab and safety procedures, and a particular scientific principle. The results of these experiments are reliably predictable. Students can easily measure how well they perform based on these expected results.

For students who have mastered the basics of safety and lab technique, this experiment is the next step. The outcome is not known. Students must evaluate results based a desired outcome that they set, and design experiments to achieve it. The will use the existing recipes for gelatins as a starting point. They will then vary the recipes to measure the effects, quantify these effects, and then create new recipes to capture characteristics that would make good thin films. This project is based on an actual exercise done by Project SEED students working with my RET project, and their plans for future work during the school year in my research class.

Students performing this lab must use proper laboratory safety procedures, wear goggles and gloves, and log all their procedures and data in a proper lab notebook.

Rubric for grading

- 1) Did the students use and use proper lab and safety procedures?
- 2) Did the students keep neat and orderly laboratory notebooks?
- 3) Did the students set goals for desired outcomes?
- 4) Did the students plan new recipes and procedures in an orderly logical fashion?
- 5) Did the students document their work in an appropriate reporting form?

Advanced

Can any form of statistical analysis be performed on the students' data? Is the report in a form that could be presented or published?

STANDARD(S) & INDICATOR(S):

- 5.1.8.B1. Identify questions and make predictions that can be addressed by conducting investigations.
- 5.1.8.B2. Design and conduct investigations incorporating the use of a control.
- 5.1.8.B3. Collect, organize, and interpret the data that result from experiments.
- 5.6.6.A3. Describe the properties of mixtures and solutions, including concentration and saturation.

OBJECTIVES: Students will be able to:

- 1. Develop and perform laboratory experiments to determine the properties of gelling materials that could be dried for use as thin films.
- 2. Recommend the properties of a gelling material that can be used for scale up and production.

Designing New Laboratory Experiments

INTRODUCTION:

Thin film drug delivery is considered the wave for the future. Listerine Strips© are an early version of this, but they do not contain the prescription drugs that are envisioned by future versions. Determining recipes for delivery films is a new chemistry and engineering exercise.

Finding the recipe to create a proper thin film from a gelling agent is done by trial and error, but a good starting point is the instructions that come with the gelling materials, starting with ordinary unflavored gelatin. In this exercise you will design experiments to build a database of properties of gelling materials that could be dried for use as thin films. The outcomes of the exercise are not known. This is real science. From the results you can recommend a recipe for scale up and production use with an Active Pharmaceutical Ingredient, API, added to it.

MATERIALS:

- 1) Unflavored Gelatin
- 2) Food grade pectin, agar flakes, and gums, such as xantham and guar gum
- 3) Glassware, 300 or 400ml beakers
- 4) 1 Hot Plate/Stirrer
- 5) Safety goggles and disposable gloves
- 6) Balance for weighing materials
- 7) Distilled water source
- 8) Aluminum Foil and/or foil or silicone cup cake cups.

PROCEDURE:

The first step is to measure the amounts of materials used in the basic recipe for unflavored gelatin.

- 1) Measure the mass of the contents of one of the gelatin packets.
- 2) Measure the mass of volume of water required for one packet
- 3) Calculate the ratio of grams of gelatin to grams of water in the basic recipe, it should be about 3-4 g of gelatin to 100g of water.
- 4) Make a small batch of gelatin according to the recipe, but instead of allowing it to gel in a container, pour it in a thin layer on the aluminum, or in the cup cake cups.
- 5) Use the hot plate/stirrer to heat and mix the water and gelatin.
- 6) Allow the gelatin to dry out and observe it.
- 7) Based on the drying behavior of the gel, decide if the next batches should have a lesser or greater concentration of the gelatin.
- 8) Create a series of small batches different concentrations of gelatin in water then dry the gels to thin films in the cupcake cups and observe their behavior.
- 9) One by one repeat this process with each of the gelling materials.
- 10) Observe the film properties of all substances that successfully dry thin,
- 11) Decide if a combination of different gelling materials might yield a film with a combination of desirable properties. If yes, create a recipe and test it.

When experimentation is finished evaluate your results. Prepare a report describing your laboratory techniques and outcomes. Imagine you are proposing your thin films as new product for the market, Describe characteristics of successful recipes that produce films that you think will work with new products. Include nutritional the information for your recipes.

References and Additional Resources

Try Engineering

http://www.tryengineering.org/lesson.php

"Engineering Your Future", A.G Gomez, W.C Oakes, L.L Leone, Great Lakes Press, Inc. 2006

"Engineering Design, An Introduction", J.R. Karsnitz, S. O'Brien, J.P. Hutchinson, Delmar Cengage Learning, 2009.

All about Gums

http://www.gumtech.com/gumbasics/GumsareGood.php

Learn about Listerine Strips©

http://www.aragonproducts.com/theproducts.cfm?master=5549

"Suspension and Dispersion of Particles in Gels ",Micaela Caramellino and Piero M. Armenante, Otto H. York Dept. of Chemical Engineering, New Jersey Institute of Technology, 323 King Blvd., Newark, NJ 07102

http://aiche.confex.com/aiche/2007/preliminaryprogram/abstract_98236.htm

Drug Delivery Technology Online, June 2008 – Pharmaceutical Films – "Castable Edible Films", Chen Tirol, Bass, Corniello, Watson, and Sanchez, http://www.drugdeliverytech-online.com/drugdelivery/200806/?pg=34

This material is based upon work supported by the National Science Foundation under Grant Nos. EEC-0552587 & EEC-0540855

Copyright © 2009 by New Jersey Institute of Technology

All Rights Reserved

Supporting Program: Center for Pre-College Programs, at the New Jersey Institute of Technology

Contributors

Marie Aloia (Bayonne High School, Bayonne, NJ), Primary Author

Howard Kimmel, Levelle Burr-Alexander, John Carpinelli - Center for pre-College Programs, NJIT.

Christian Beck, Yueyang Shen, Daniel Lepak, Raj Dave - C-SOPS, NJIT