Fundamentals, Design and Applications of Drug Delivery Systems

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Abstract

Chemical Engineers play an important and expanding role in the exciting field of drug delivery, yet undergraduate chemical engineering students are rarely exposed to drug delivery through their coursework. Chemical Engineering faculty at Rowan University are engaged in an effort to develop and integrate applied drug delivery coursework and experiments throughout the Rowan Engineering curriculum. This paper describes a senior/graduate level elective course in drug delivery, with descriptions of the course structure, organization and content, references, experiments and projects used in this course.

Introduction

Drug Delivery is a burgeoning field that represents one of the major research and development focus areas of pharmaceutical industry today, with new drug delivery system sales exceeding 10 billion dollars per year [1]. Chemical Engineers play an important and expanding role in this exciting field, yet undergraduate chemical engineering students are rarely exposed to drug delivery through their coursework. To provide students with the skills directly relevant to the evolving needs of the pharmaceutical industry, Chemical Engineering faculty at Rowan University are engaged in an effort to develop and integrate applied drug delivery coursework and experiments throughout the Rowan Engineering curriculum.

In addition to integrating drug delivery topics throughout the core Chemical Engineering Curriculum, an elective course in Drug Delivery is offered to senior and graduate students. This course provides engineering students with knowledge and skills relevant to the field of drug delivery. After completing this course, students should be able to design, produce, characterize and analyze drug delivery systems. This paper describes the course structure, organization and content, references, experiments and projects related to the design, preparation, characterization, and analysis of drug delivery systems.

This course is one of the very few course offerings in drug delivery for Chemical Engineering undergraduate students. Examination of course offerings through Department websites reveals that drug delivery is one topic often incorporated into Chemical or Biomedical Engineering courses in biotechnology or biomaterials. Several departments of pharmaceutical sciences offer specialized courses in drug delivery, but these courses would not address the *engineering* aspects of drug delivery systems. One other undergraduate chemical engineering course in drug delivery was found at Johns Hopkins University. This course focuses on the encapsulation and delivery

of therapeutic proteins, genes and cells from polymeric systems; routes of administration; and drug pharmacokinetics.

Controlled drug delivery systems attempt to deliver a drug to the body at a controlled rate for an extended period of time. Historically, drug delivery systems were developed primarily for traditional routes of administration such as oral and intravenous. Recently, however, there has been an explosion in research on delivery by so-called non-conventional routes, such as transdermal, nasal, ocular, and pulmonary administration. Drug delivery applications have expanded from traditional drugs to therapeutic peptides, vaccines, hormones, and viral vectors for gene therapy. These systems employ a variety of rate-controlling mechanisms, including matrix diffusion, membrane diffusion, biodegradation and osmosis. To design and produce a new drug delivery system, an engineer must fully understand the drug and material properties and the processing variables that affect the release of the drug from the system. This requires a solid grasp of the fundamentals of mass transfer, reaction kinetics, thermodynamics and transport phenomena. He or she must also be skilled in characterization techniques and physical property testing of the delivery system, and practiced in the analysis of the drug release data.

Periodic administration of a drug by conventional means, such as taking a tablet every four hours, can result in constantly changing systemic drug concentrations with alternating periods of ineffectiveness and toxicity. Controlled release systems attempt to maintain a therapeutic concentration of a drug in the body for an extended time by controlling the rate of delivery of the drug. A comparison of systemic drug profiles established by conventional administration and controlled release is shown in Figure 1

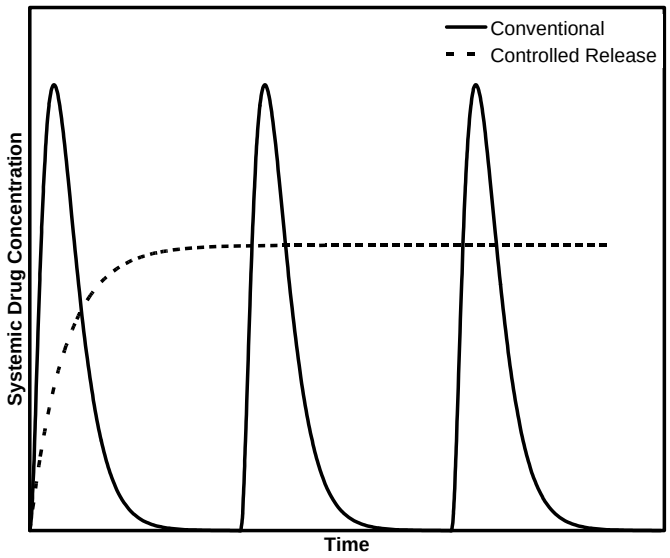

Figure 1. Controlled Release vs. Conventional Administration

Historically, drug delivery systems were developed primarily for traditional routes of administration such as oral and intravenous. Recently, however, there has been an explosion in research on delivery by so-called non-conventional routes, such as transdermal (skin), nasal, ocular (eyes), and pulmonary (lung) administration. Drug delivery applications have expanded from traditional drugs to therapeutic peptides, vaccines, hormones, and viral vectors for gene therapy. These systems employ a variety of rate-controlling mechanisms, including matrix diffusion, membrane diffusion, biodegradation and osmosis. To design and produce a new drug delivery system, an engineer must fully understand the drug and material properties and the processing variables that affect the release of the drug from the system, as well as the pharmacokinetic properties of the drug in the body.. This requires a solid grasp of the fundamentals of mass transfer, reaction kinetics, thermodynamics and transport phenomena. He or she must also be skilled in characterization

techniques and physical property testing of the delivery system, and practiced in the analysis of the drug release data.

There are two main objectives of drug delivery systems: (1) Drug targeting: to deliver a drug to the desired location in the body and (2) Controlled release: to deliver a drug at a desired rate for a desired length of time. Many drug delivery systems attempt either controlled *or* targeted delivery; some drug delivery systems attempt both.

Essential Information

The title of the undergraduate (senior level) course is "Fundamentals of Controlled Release", and the title of the graduate course is "Controlled Release Theory, Technology and Applications". Students registered for these courses meet together during a common class meeting time. To be consistent with the level of the courses, students registered for graduate credit have additional responsibilities on take-home assignments, laboratory reports, exams, and the semester project.

Both courses are three-credit courses, and meet once per week in the evening for approximately three hours.

There is no required textbook for the course. Required reading and supplemental materials are assigned periodically throughout the semester, and students obtain this material from the library.

Enrollment for elective courses is typically limited to a small number of students (10-20) to allow a high degree of in-class interaction in a seminar-style setting.

References

There are are a few excellent books on controlled release and drug delivery that were used extensively for topic readings throughout the course. None of these was chosen as a required textbook. Below is a brief description of some of the relevant texts on this subject.

Agis Kydonieus, Treatise on Controlled Drug Delivery, Dekker, 1992. ($225). This is an introductory but detailed treatment of the subject which includes many references and solved examples and end-of-chapter problems, making it useful to students and instructors. The book is written with an engineering perspective, providing development of mathematical models and methods of rate analysis for different types of drug delivery systems. Chapters are devoted to different mechanisms of rate control in controlled release systems, and delivery systems for various routes of administration. The pharmokinetics, pharmacodynamics, and biological and biopharmaceutical parameters pertinent to each route of administration (oral, parenteral, transdermal, and nasal) are also discussed. The list price of this book made it too expensive to adopt as a required text for an elective course.

Joseph Robinson and Vincent Lee (Eds.), Controlled Drug Delivery Fundamentals and Applications, 2nd ed., Dekker, 1987. ($299). This book is organized into three parts: (1) Biological considerations, (2) design and fabrication and (3) biochemical and molecular biology approaches. This book has a heavier emphasis on the pharmacy, physiologic, and biological aspects of drug delivery and provides only a modest amount of mathematical modeling in the relevant chapters. At $299, this book is also prohibitively expensive for textbook adoption.

Mark Saltzman, Drug Delivery: Engineering Principles for Drug Therapy (Topics in Chemical Engineering), Oxford University Press, 2001. ($85). While this book was not yet in print at the time the course was offered, its mention and a brief description are appropriate. The book is written from a chemical engineering perspective and is authored by a Chemical Engineering faculty member. In addition to examining drug transport in biological systems, rate control from drug delivery devices, the book also presents case studies on systemic delivery, localized delivery, and topical delivery.

Welling, Peter G., Pharmacokinetics, Processes, Mathematics, and Applications, 2nd ed., ACS, Washington, D.C., 1997. ($85) Pharmacokinetics is the study of the absorption, distribution, metabolism, and excretion of drugs in humans. This bookaddresses the basic principles of pharmacokinetics including drug transport, parenteral and enteral routes of drug administration, and factors affecting drug absorption, distribution, and metabolism. Mathematics of pharmacokinetics with various single- and multi-compartment models are described. It also describes drug metabolism, renal and hepatic drug clearance, and the influence of kidney and liver impairment on these functions. This book was used as the primary source for pharmacokinetics lectures.

Course Organization and Structure
Part I: Rate Control. Drug delivery systems are often categorized according to their rate controlling mechanism, of which there are three basic types: matrix systems, membrane (or reservoir) systems, and osmotic systems. In the first part of the course these different types of controlled release systems were examined, with an emphasis on development of mathematical modeling for each type of system. Approximately one week was spent on each of the topics below:

1. Introduction to Controlled Release
2. Factors influencing design.
3. Monolith Systems
4. Membrane Systems
5. Erodible Systems
6. Osmotic Systems

The next part of the course focused on pharmacokinetics and biological factors. Approximately three weeks was devoted to this topic.

7. Pharmacokinetics
8. Pharmacokinetics
9. Biological factors and drug properties

The third part of the course focused on routes of administration of drugs, and design of the associated drug delivery systems. Approximately one week was spent on each of the topics below.

10. Transdermal Delivery

11. Oral Delivery

12. Parenteral Delivery (Injectables)

The emphasis up to this point in the course has been on controlled release systems. In the last two weeks of the course, topics of drug targeting, fabrication techniques and regulatory issues are addressed:

13. Targeting

14. Fabrication Techniques and Regulatory Issues

Experiments

Several experiments have been developed for use in this course. Some of the experiments have already been implemented in the course; others were developed by a team of students as their semester project in this course. The project requirements are described in the "Assignments" section later in this paper. Below is a brief description of the experiment that have been developed for use in this course. These experiments expose students to the fabrication and analysis of release rates from a variety of drug delivery systems: tablets, membrane systems, ointments, and microspheres; additional experiments examine drug stability testing and the use of supercritical fluid technology for the "green" production of drug delivery systems. More detail on each experiment is provided in [2]

Experiment #1: Drug release from a solid tablet

Oral ingestion has long been the most convenient and commonly used route of drug delivery. For this reason, design and manufacture of oral formulations such as tablets and capsules is a very important aspect of drug delivery in the pharmaceutical industry. To prepare a sustained release tablet of a water-soluble drug, the drug is mixed with a hydrophobic matrix, and compressed into tablet form using a standard method such as the direct compression method or dry granulation method. Drug, matrix, and process parameters affect the tablet's physical properties which include hardness, disintegration and dissolution. These properties can be evaluated using standard methods commonly taught in Pharmaceutical Science courses and widely used by scientists and engineers in the pharmaceutical industry. Drug release kinetics from tablet matrices commonly follow a square-root-of-time dependence first described by Higuchi [3] and shown in Figure 2.

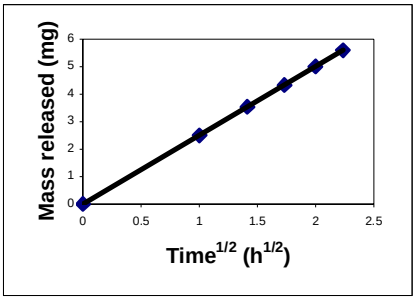

Figure 2. Higuchi drug release follows a square-root of time dependence.

In this experiment, students produce drug matrices in tablet

form for caffeine delivery. The objectives of this experiment are to (1) prepare tablet dosage forms, (2) investigate how drug concentration, matrix material and particle size, and tableting pressure effect a tablet's physical properties [4], (4) investigate the release kinetics of the drug from the matrix and to determine whether Higuchi kinetics [3] are followed. Drug release profiles are be determined by analysis of drug concentration using UV spectrophotometry.

Experiment #2: Drug release from a membrane system

Membrane-based drug delivery devices are another commonly used system available in a variety of forms such as microbeads, transdermal patches and oral formulations. In a membrane system, the drug is contained in a reservoir which is surrounded by a coating (membrane) that controls the rate of release of the drug. Membrane systems are capable of achieving a constant rate of drug delivery for an extended time [5, 6, 7,8]. One of the first membrane systems for controlled release was the Transderm-Scop® patch developed by Ciba (Woodbridge, NJ) for the control of motion sickness (Figure 3)[9]. Alza Corp (Palo Alto, CA) developed the Ocusert® system for 7-day ocular delivery of pilocarpine in the treatment of glaucoma[10, 11].

The release rate from a membrane device is related to the drug concentration in the reservoir (C_r), and the permeabilities (P) in the different layers: $\frac{dM}{dt} = \frac{C_r}{\frac{1}{P_1} + \frac{1}{P_2}}$

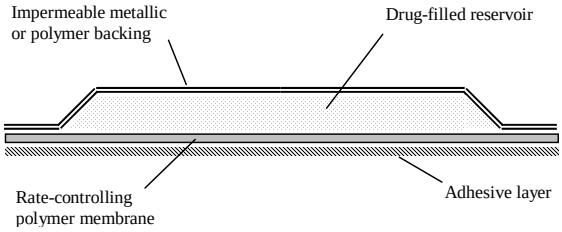

Figure 3. Transderm-Scop® system. Adapted from [7]

In this experiment, students explore some of the drug and membrane properties that affect the rate of release from a membrane-based drug delivery system. They produce their own membrane systems for release of nicotine. The objectives are (1) to build a system to test the release kinetics from a membrane system (2) to investigate drug properties that affect the release rate of the drug (3) to investigate membrane properties that affect the release rate (4) to investigate the hydrodynamic effects of the test system on the release rate (5) to introduce students to mathematical modeling of membrane systems and (6) to analyze release rate data and test the validity of the mathematical model.

Experiment #3: Ointments: Preparation and evaluation of drug release

Ointments are used for topical delivery of agents such as antiseptics, antibiotics, and corticosteroids. Release of drugs from ointment bases occurs by diffusion from a matrix type system. The kinetics of drug release follow the Higuchi square-root of time dependence [3].

In this experiment, students prepare an ointment formulations containing salycilic acid, and evaluate the drug release kinetics from this system. The objectives are (1) to investigate the variables that affect the release rate of a drug from an ointment: the type of ointment base, the drug solubility in the base, and the drug concentration, (2) to perform drug release studies on the drug from the ointment, (3) to investigate the release kinetics of the drug from the ointment matrix and to determine whether Higuchi kinetics [3] are followed.

Experiment #4: Drug delivery using an osmotic pump

The osmotic pump developed by Alza exploits osmosis to achieve a constant release rate of drug for an extended time. This technology has been applied to implant systems for delivery of many drugs for treatment of diseases such as Parkinson's and Alzheimer's, cancer, diabetes, and cardiovascular disorders. Efidac® 24 hour nasal decongestants are an example of an oral system that uses the same technology.

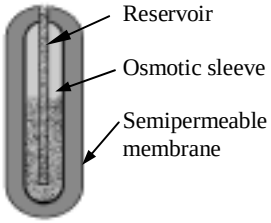

Figure 4. The Osmotic Pump

The osmotic pump comprises three concentric layers: an innermost drug reservoir contained within an impermeable membrane, an osmotic solution, and a rigid outer layer of a rate-controlling semi-permeable membrane (Figure 4). As water from the body permeates through the outermost membrane and into the osmotic "sleeve", the sleeve expands and compresses the innermost drug reservoir. This squeezes the drug out of the reservoir through a delivery portal [12]. The rate of drug release is proportional to the rate at which water flows into the "osmotic sleeve" due to an osmotic imbalance $\Delta\pi$ [13]:

$$\frac{dV}{dt} = \frac{Ak}{h}(\Delta\pi)$$

where A, k and h are the membrane area, permeability and thickness, respectively.

In this experiment students fill pre-made osmotic pump devices with a drug (caffeine solution), and measure the rate of release of the drug from the device. The objectives of the experiments are (1) to investigate the release rate of drug from the device and to compare the release rate to the manufacturers specifications, (2) to compare the release profile to that predicted by the mathematical model described above and (3) to study the effects of temperature and osmolality on the release rate of the drug, and to compare with the model given by Theeuwes [12]:

$$Q_t = Q_0\left(0.135e^{(0.054T)} - (.0.004\pi) + 0.3\right)$$

where Q_t and Q_0 are pumping rates at temperature T and 37°C respectively.

Experiment #5: Microcapsules: preparation and evaluation of drug release

Microencapsulation is one of the most intriguing fields in the area of drug delivery. It is an interdisciplinary field that requires knowledge of the field of polymer science, familiarity with emulsion technology, and an understanding of drug and protein behavior [14]. Testing of microcapsule release rates requires knowledge of the behavior and modeling of membrane diffusion systems. Pharmaceutical applications of microencapsulation technology include theophylline, heparin, anti-tumor drugs, gene therapy vectors, and vitamins, and current research is being done on such exciting applications as artificial red blood cells, and for treatment of acute kidney failure and other life-threatening conditions [15].

In this experiment students prepare microcapsules containing theophylline, a drug used in the treatment of asthma, and they study the release rate of drug into simulated gastric fluid. The objectives are (1) to prepare theophylline-containing microcapsules of water-insoluble whey based protein, (2) to study the effect of microcapsule size, type of simulated digestive fluid, and

extent of cross linking on the drug release (3) to determine whether the system is membrane-controlled or matrix diffusion-controlled by comparing the release profile to the appropriate models (the system is matrix diffusion controlled and follows Higuchi kinetics [16].

Experiment #6: Chemical kinetics: Drug stability

The chemical stability of a drug in a dosage form is of great interest since a drug may become therapeutically ineffective as it degrades. Additionally, drug decomposition may yield toxic by-products that are harmful to the patient.

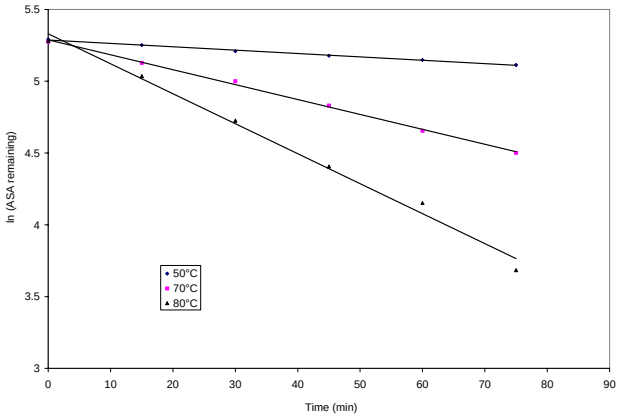

Figure 5. Aspirin degradation kinetics (student data)

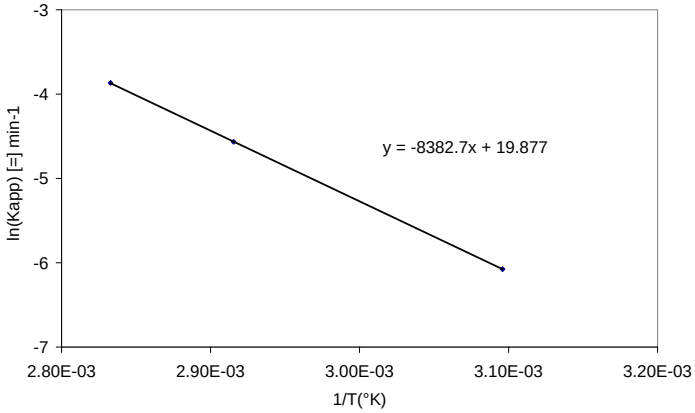

Figure 6. Arrhenius Plot is used to determine the shelf life.

In this experiment students test the stability of aspirin , which undergoes hydrolysis to form products of salicylic acid and acetic acid. Aspirin hydrolysis is a second order reaction, but in buffered solution follows apparent first-order kinetics [17]. The objectives of this experiment are to (1) use accelerated stability testing at elevated temperatures to predict the shelf life of the drug room temperature (25°C). (2) to investigate temperature and pH dependence of aspirin degradation (3) to distinguish between zero, first and second order reactions and rates (4) to use drug degradation data to construct an Arrhenius plot and determine activation energy, first order rate constant at room temperature, and shelf life at room temperature.

Experiment #7: Supercritical Fluid Technology in Drug Delivery

Supercritical fluid technology (SFT) using environmentally benign agents such as CO_2 is an emerging technology in the field of drug delivery. SFT has been used to prepare drug delivery systems of various types: polymeric particles, plain drug particles, drug-containing liposomes, and inclusion complexes of drug and carrier. In comparison with traditional techniques for preparation of these types of systems, SFT enables more control over formulation, thereby allowing more precise control of drug release from delivery systems [18].

According to Kompella [18], “scant literature is available on the solubility of drugs in supercritical carbon dioxide”. In this experiment, students determine the solubility of a drug in CO_2. and also use a supercritical fluid process to obtain plain drug particles. In determining the drug solubility in supercritical CO_2 a phase monitor is used for direct visual observation of the supercritical fluid

solution, and to ensure there is no liquid phase present. The objectives of this experiment are (1) to determine the solubility of vitamins in supercritical CO_2 and (2) to investigate the effect of SFT process variables such as flow rate, temperature and pressure on the mean drug particle size.

Assignments

Weekly assignments: In the absence of a regular textbook on controlled drug delivery, the development of weekly homework assignments was a challenge. Some calculation-based homework problems were developed based on the mathematical models developed for each type of drug delivery system. The emphaisis, however, for weekly assignments was on the critical review of journal articles. A single paper was assigned to the class, and teams of students were assigned the primary responsibility for certain sections. The following week, each team made an oral presentation of its section of the paper (typically introduction and background; experimental; modeling; results and conclusions). Students were required to present a critical analysis of each section, and students in the audience ware graded on their effort to stimulate discussion. In the case that there were more teams than (logical) sections of the paper, some teams were assigned a literature search for new applications of the relevant technology.

Project: A semester project was assigned about one third of the way into the semester. The project involved the design of an experiment related to drug delivery intended for use our laboratory at Rowan. The following constraints for the project were chosen to make the project practical and adaptable for use in courses at the University:

- Timeframe: the experimental timeframe should be consistent with a standard three-hour laboratory or a six-hour unit operations laboratory.
- Economics: The materials and supplies should be reasonably inexpensive.
- Equipment: If major equipment is needed for the drug formulation, an equipment description as well as vendor information and price quotes should be included.
- Analysis: Use standard methods of analysis such as gravimetric, spectrophotometer, conductivity, etc. Indicate the specific analytical method that will be used, and include a reference from literature.
- Modeling: The experimental data must be compared with a mathematical model. Fitting data to an empirical correlation is also acceptable.

The Deliverables: The deliverables for the project included a report, a copy of the literature cited, a list of materials and supplies with pricing, and an oral presentation.

- A report complete with introduction, literature review, objectives, theory & modeling, experimental methods, and results including data analysis. Hypothetical results, or results from literature should be used to illustrate how to present/analyze data.
- A copy of all literature cited.
- A list of materials and supplies, including vendor information and pricing.
- A presentation

Results

As mentioned previously, the objectives for this course were for students to acquire the knowledge and skills necessary design, produce, characterize and analyze drug delivery systems.

The critical analyses presented by students for the weekly journal article reviews were an overall success. For undergraduate students, this was their first exposure to critique and analyze journal articles, and the results were surprisingly good for this initial experience. All students benefited from discovering flaws in models and experimental procedures and proposing improvements or corrections. All of the students believed that the journal article analysis improved their understanding of drug delivery systems and their critical thinking skills. In addition to demonstrating an understanding of the work described in the articles, students were able to identify errors in modeling equations, flaws in experimental procedure, conceptual flaws in analysis of results, and instances in which essential information was not provided.

Students were able to develop experimental procedures for the production and analysis of drug delivery systems. The experiments proposed by the students via their semester project were turned directly into a proposal, and funding was granted by NSF to develop the experiments for use in the Rowan curriculum. Not only did the students convince the instructor that they could design and analyze drug delivery systems, but they convinced an NSF review panel of the merit of their work.

Course and teacher evaluations were extremely positive; students provided favorable comments regarding the departure from traditional course structure, and the overall course ratings were 5.0/5.0.

Summary

Chemical Engineers play an important and expanding role the field of drug delivery, yet undergraduate chemical engineering students are rarely exposed to drug delivery through their coursework. To provide students with the skills directly relevant to the evolving needs of the pharmaceutical industry, an elective course in drug delivery has been developed. This course addresses fundamentals and applications of drug delivery from a chemical engineering point of view. Critical analyses of journal articles and a project in which students designed hands-on experiments were important components of the course.

Acknowledgment

This work was funded through a grant from the National Science Foundation's Course, Curriculum and Laboratory Improvement Program under grant DUE-0126902.

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Biographical Information

Stephanie Farrell is Associate Professor of Chemical Engineering at Rowan University. She received her B.S. in 1986 from the University of Pennsylvania, her MS in 1992 from Stevens Institute of Technology, and her Ph.D. in 1996 from New Jersey Institute of Technology. Prior to joining Rowan in September, 1998, she was a faculty member in Chemical Engineering at Louisiana Tech University. Stephanie has research expertise in the field of drug delivery and controlled release, and she is currently focusing efforts on developing laboratory experiments related to membrane separations, biochemical engineering, and biomedical systems. Stephanie won the Dow Outstanding Young Faculty Award in 2000, the Joseph J. Martin Award in 2001, and the Ray W. Fahien Award in 2002. .

Robert Hesketh is Associate Professor of Chemical Engineering at Rowan University. He received his B.S. in 1982 from the University of Illinois and his Ph.D. from the University of Delaware in 1987. After his Ph.D. he conducted

research at the University of Cambridge, England, and joined the faculty at the University of Tulsa in 1996. Robert's teaching experience ranges from graduate level courses to 9th grade students in an Engineering Summer Camp funded by the NSF. Robert employs innovative methods such as cooperative learning and inductive teaching techniques in his classes His dedication to teaching has been rewarded by receiving several educational awards including the 1999 Ray W. Fahien Award, 1998 Dow Outstanding New Faculty Award, the 1999 and 1998 Joseph J. Martin Award, and four teaching awards.

Mariano J Savelski is Assistant Professor of Chemical Engineering at Rowan University. He received his B.S. in 1991 from the University of Buenos Aires, his ME in 1994 from the University of Tulsa and his Ph.D. in 1999 from the University of Oklahoma. His technical research is in the area of process design and optimization with over seven years of industrial experience. His prior academic experience includes two years as Assistant Professor in the Mathematics Department at the University of Buenos Aires.

C. Stewart Slater is Professor and Chair of the Department of Chemical Engineering at Rowan University. He received his B.S., M.S. and Ph.D. from Rutgers University. Prior to joining Rowan, he was Professor of Chemical Engineering at Manhattan College. Dr. Slater's research and teaching interests are in separation and purification technology, laboratory development, and investigating novel processes for fields such as bio/pharmaceutical/food engineering and specialty chemical manufacture. He has authored over 100 papers and several book chapters. Dr. Slater has been active in ASEE, currently serving as Chair-Elect of the Chemical Engineering Division and previously Program Chair and Director of the Chemical Engineering Division. He has held every office in the DELOS Division. Dr. Slater has received numerous national awards including the 1999 Chester Carslon Award, 1999 and 1998 Joseph J. Martin Award, 1996 George Westinghouse Award, 1992 John Fluke Award, 1992 DELOS Best Paper Award and 1989 Dow Outstanding Young Faculty Award.