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Core Courses and Core Activities in the Pharmaceutical Engineering Program at NJIT: A Re-evaluation of What Constitutes the Core Knowledge of an Emerging Engineering Field

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ABSTRACT: *Pharmaceutical engineering is the branch of engineering devoted to the application of engineering concepts, scientific principles, and codes of practice to develop processes and scale-up criteria for drug manufacturing and pharmaceutical operations, including the operation of industrial facilities for pharmaceutical production. Pharmaceutical engineering is a new engineering area in the academic world. Because of its proximity to many pharmaceutical companies, and in order to better address the industry need for qualified engineers, in December 2001 the New Jersey Institute of Technology (NJIT) established the first official Masters Degree Program in Pharmaceutical Engineering in the State of New Jersey. The program has grown rapidly attracting a large number of students, including many professionals from local pharmaceutical companies. Because of its novelty, the program and the courses that constitute it, as well as their contents, had to be defined without the benefit of relying on previous experience from other academic institutions or a consolidated body of academic knowledge in this area. The result has been the establishment of a number of core courses that all students are required to take. This arrangement has worked well so far. However, it has become apparent that the core curriculum can be improved by reinforcing the common design components and strengthening the students' pharmacy science background, especially in areas such as pharmacokinetics and drug delivery systems. These suggestions have led to a new curriculum comprising five common core courses, two track-specific courses, and several elective courses. The discussion of what constitutes the common knowledge in the evolving area of pharmaceutical engineering in an academic curriculum is an ongoing debate, and constitutes the focus of this paper. This work provides a re-examination of the approach taken to determine the range and extent of the core knowledge and activities in pharmaceutical engineering.*

1 INTRODUCTION

Pharmaceutical engineering is emerging as a new and important discipline in the academic arena. The reason behind this development is primarily a requirement, on the part of the pharmaceutical industry, of a competent and well-trained technical workforce that can process, manufacture, and eventually bring to the market the new pharmaceutical and medical device products that have the potential to reshape to world in which we live in. The industry has always employed engineers to design, build and operate the industrial facilities required for the commercial production of drugs. However, new technical challenges are emerging, driven by the demand for lower production costs, new and more stringent production requirements (e.g., reduced batch-to-batch product variability, lower impurity profiles), new design challenges resulting from advances in chemical and drug development (e.g., fast, competitive reaction systems; asymmetric organic synthesis); technological advances (e.g., the possible use of continuous processing and microreactors for large-scale production), improved control

requirements (e.g., in-line measurement of key process variables), and new regulatory guidelines and initiatives from regulatory agencies (such as the Process Analytical Technology initiative recently launched by the US Food and Drug Administration). All these developments are forcing the industry to pay greater attention to the engineering aspects of its pharmaceutical production, starting at the development stage and going all the way up to large-scale processing and manufacturing. The challenge is now for academia to train the engineering professionals who can not only accomplish all this, but also advance the technical field so as to enable the industry to move forward and meet the newer challenges that will undoubtedly emerge as stricter requirements are imposed on drugs and processes.

The New Jersey Institute of Technology (NJIT) has already worked extensively on this concept. Pharmaceutical engineering can be defined as the branch of engineering devoted to the application of engineering concepts, scientific principles, and codes of practice to (1) develop processes and scale-up criteria for drug synthesis, drug manufacturing, and pharmaceutical operations; (2) design and construct pharmaceutical plants; and (3) operate industrial facilities for pharmaceutical production. Following this concept, in December 2001, NJIT established the first official Master of Science Degree Program in Pharmaceutical Engineering in the State of New Jersey. The program, now in its fifth semester of existence, has grown substantially in a very short period of time, rapidly attracting a large number of students as shown in Figure 1 (and even greater than initially anticipated), including a many students currently working at local pharmaceutical companies.

New Jersey is geographically at the heart of the nation's pharmaceutical industry, and NJIT is located at the national epicenter of industrial pharmaceutical research and development. In fact, NJIT's campus is located within miles of the headquarters and major facilities of 21 of the world's leading pharmaceutical companies. This greatly facilitates industrial interactions and provides a fertile ground for student career development.

The enrollment in the program of professionals working full-time at pharmaceutical companies is further evidence of the need for this type of program. It is expected that the program described here (one of a handful of such programs in the U.S.) will experience a very significant growth both in size and in its range of activities over the next few years, in response to the growing needs of the pharmaceutical industry for qualified engineering professionals.

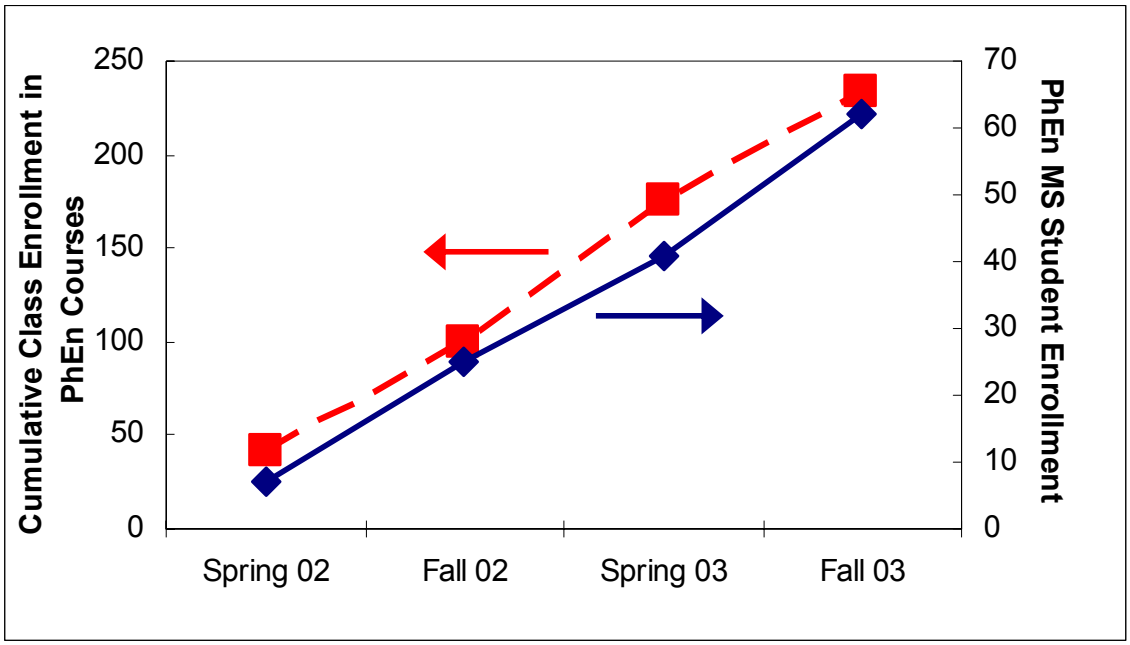

Figure 1. Cumulative class enrollment in pharmaceutical engineering courses and overall number of students enrolled in the NJIT program over time.

2 THE PROGRAM AND ITS CURRICULUM

Overview

The Master of Science (MS) Program in Pharmaceutical Engineering (PhEn) was developed with the objective of educating pharmaceutical professionals and those wishing to become pharmaceutical engineering professionals, by providing them with the skills required to work in the pharmaceutical field, with particular emphasis on the *engineering* aspects of drug manufacturing, pharmaceutical production, pharmaceutical development, and pharmaceutical operations.

The PhEn MS program is a 30-credit program structured along a central study core and two different study tracks. Students have the option of fulfilling 6 credits of electives by doing a Master's Thesis. The thesis option is primarily but not exclusively meant for full-time students. Full-time students receiving support (full or partial) must complete a Master's Thesis. Students are certified for graduation if they maintain an overall cumulative grade point average of at least 3.0 our of a maximum of 4.0, as well as a grade point average of 3.0 in the required core courses. Details about the program are also available elsewhere (Armenante and Manfredi, 2003; Armenante and Muzzio, 2003; www.njit.edu/che/pharme/; http://hex.njit.edu/cocoon/eCatalog/graduate/programs/Pharmaceutical/Pharmaceutical_S#masters).

Current Curriculum

Currently, all students must take a common 9-credit study core. Then, depending on the selected study track, the students must take an additional 9-credit track-core, as described below. Each track has 12 credits of electives and/or thesis selected by the student in consultation with, and subject to, the approval of the program advisor.

More specifically, all students who do *not* elect to do a thesis must satisfy the following requirement to complete the MS degree:

• Three (3) core courses (3 credits each) common to both tracks	9
• Three (3) additional core courses (3 credits each) specific to the track selected	9
• Four (4) additional elective courses (3 credits each) selected from the list of available courses	12
• *Total Credits*	*30*

Those students who select the thesis option have the following requirements:

• Three (3) core courses (3 credits each) common to both tracks	9
• Three (3) additional core courses (3 credits each) specific to the track selected	9
• Two (2) additional elective courses (3 credits each) selected from the list of available courses	6
• Thesis (6 credits)	6
• *Total Credits*	*30*

At the moment, the program has two study tracks, i.e.:

1. Pharmaceutical Production and Development Track
2. Pharmaceutical Operations Track

The emphasis of the first track is on the operations associated with the development and production of the *drug substance*, or Active Pharmaceutical Ingredient (API), i.e., the ingredient that is responsible for the therapeutic effect of the drug on the patient. The second study track is oriented toward the development and manufacturing of the *drug product*, such as a tablet or capsule, i.e., the dosage form in which the drug is eventually administered to the patient. A drug product contains not only the drug substance, but also a variety of excipients, i.e., non-active ingredients, added for a number of reasons and

necessary to deliver the drug to the right organ (e.g., the enteric coating applied to an acid-sensitive drug substance, protecting the API as the drug product travels through the stomach to reach the intestine where absorption can take place).

Figure 2 shows a schematic of the current program of study. The specific courses that the student must complete to get the degree are currently as follows:

- Three (3) core courses (3 credits each) common to both tracks (9 credits total), as follows:
  - PhEn 601 Principles of Pharmaceutical Engineering
  - PhEn 603 Pharmaceutical Processing and Manufacturing
  - PhEn 604 Validation & Regulatory Issues in the Pharmaceutical Industry
- Three (3) additional core courses (3 credits each) specific to the track selected (9 credits total), as follows:

  Pharmaceutical Production and Development Track
  - PhEn 612 Pharmaceutical Reaction Engineering
  - PhEn 614 Pharmaceutical Separation Processes
  - PhEn 618 Principles of Pharmacokinetics and Drug Delivery

  Pharmaceutical Operations Track
  - EM 602 Management Science
  - PhEn 602 Pharmaceutical Facility Design
  - PhEn 605 Pharmaceutical Packaging Technology
- Four (4) additional elective courses (3 credits each) selected from the list of available courses (12 credits total), of which 2 courses (6 credits) can be substituted with Thesis work.

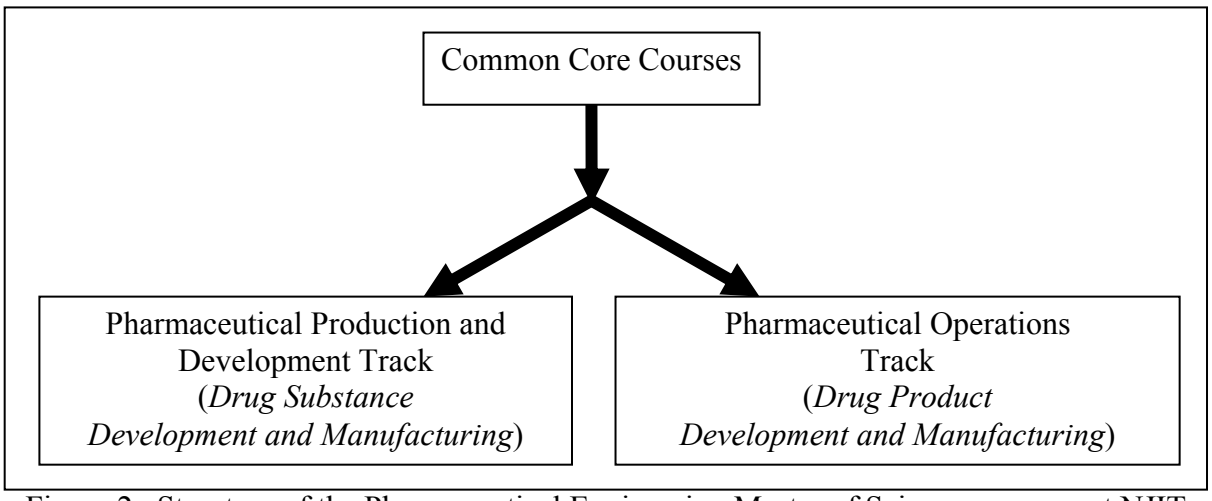

Figure 2. Structure of the Pharmaceutical Engineering Master of Science program at NJIT

Proposed New Curriculum

Because of its novelty, the program and the courses that constitute it, as well as their contents, had to be defined without the benefit of relying on previous experience from other academic institutions, or a consolidated body of academic knowledge in this area. Before the program was established, an *ad hoc* Industrial Advisory Group including representatives from both the pharmaceutical industry and support organizations was formed to provide feedback and guidance. However, the final determination of the course contents was largely based on the work carried out by a more restricted group of faculty members and industrial representatives, all involved in the actual teaching of the courses. The result has been the establishment of the above-mentioned program, including and a number of core courses that all students are required to take.

This arrangement has worked well so far. However, it has become apparent to the instructors involved in the program that the core curriculum can be improved by strengthening the common design component and introducing a course providing the students with a common pharmacy science background, especially in areas such as pharmacokinetics and drug delivery systems. These suggestions

have led to a proposal for a new curriculum, which comprises five common core courses and two track-specific courses, as follows:

- Five (5) core courses (3 credits each) common to both tracks (15 credits total), as follows:
  - PhEn 601 Principles of Pharmaceutical Engineering
  - PhEn 603 Pharmaceutical Unit Operations: Processing of Liquid and Dispersed Systems
  - PhEn 604 Validation & Regulatory Issues in the Pharmaceutical Industry
  - PhEn 606 Pharmaceutical Unit Operations: Solids Processing
  - PhEn 618 Principles of Pharmacokinetics and Drug Delivery
- Two (2) additional core courses (3 credits each) specific to the track selected (6 credits total), as follows:

  Drug Substance Development and Manufacturing Track
  - PhEn 612 Pharmaceutical Reaction Engineering
  - PhEn 614 Pharmaceutical Separation Processes

  Drug Product Development and Manufacturing Track
  - PhEn 602 Pharmaceutical Facility Design
  - PhEn 605 Pharmaceutical Packaging Technology
- Four (4) additional elective courses (3 credits each) selected from the list of available courses (12 credits total), of which 2 courses (6 credits) can be substituted with Thesis work.

3 RATIONALE FOR CURRICULUM MODIFICATIONS/ADDITIONS

Required Student Background

Initially, applicants with different types of engineering background had the possibility of being unconditionally admitted to the program. However, applicants are now typically admitted unconditionally only if they possess an undergraduate degree in chemical engineering and have an undergraduate cumulative grade point average (GPA) of at least 3.0 on a 4.0 scale. Students with a mechanical engineering degree are also typically admitted without other conditions, although some may be required to take a graduate level course in transport phenomena, which counts towards the total number of credits necessary to receive the MS degree. Students with backgrounds in other engineering disciplines are also admitted to the program, although they may be required to take one or possibly two bridge courses described below (which do not count toward degree credits), or the corresponding graduate level courses, (which instead count toward degree credits).

The current program is strongly oriented toward the *engineering* component of "Pharmaceutical Engineering". In addition, the pharmaceutical industry is a chemistry-based, process industry. This is why a chemical engineering background was deemed to be the most appropriate to enter the program. However, the general question was raised of whether to admit students with background in disciplines other than engineering in general, or chemical engineering in particular. This question is especially relevant for a pharmaceutical engineering program since the industry is heavily populated with scientists, such as chemists, pharmacists, and microbiologists, who have traditionally played a dominant role within the industry, and who occupy key positions even in areas (such as development groups) in which engineers are traditionally predominant in other industries. In the end, it was decided that the program would ultimately benefit from the presence of students with diversified backgrounds, provided that non-engineering students and engineering students with an engineering degree that did not offer courses in some of the areas critical to the program would be adequately prepared before entering the program. This was accomplished by establishing a bridge program that provides such students with the prerequisites required to enter the pharmaceutical engineering graduate program.

Applicants with: (1) a science degree, (2) an engineering degree in a discipline other than chemical or, possibly, mechanical engineering (as indicated above), or (3) a GPA below 3.0 but at least 2.8, may be conditionally admitted to the program. Conditions involve completion of a bridge program designed on a case-by-case basis, and typically requiring taking extra bridge courses, as further explained below. These courses are not counted toward degree credit. Depending on the background of the applicant this bridge

program may consist of up to three (but generally speaking less, at least for students with engineering degrees) 3-credit courses (PhEn 500, PhEn 501 and PhEn 502) specifically designed to provide the students who need them with the necessary prerequisites to enter the program. Each bridge course covers a variety of subjects, but none of them counts toward degree credit. Currently the following three bridge courses are available:

- *Pharmaceutical Engineering Fundamentals I (PhEn 500).* This course is intended for those students who do not have a background in differential equations, probability and statistics, and finance business mathematics. The course includes a review of calculus, and covers the fundamentals of ordinary differential equations (first order, linear, non-linear, second order, homogeneous and non-homogeneous), probability and statistics (probability models, normal distribution, statistical estimation, expected value; measures of dispersion; measures of central tendency, application of sampling distribution theory, determination of sample size, linear regression analysis, least square method; estimation of parameters, statistical inference), and finance business mathematics (interest/compound interest, annuities, sinking funds, amortization, leasing and capital expenditure). All these topics are applied to pharmaceutical engineering problems and illustrated through pharmaceutical engineering examples, such as drug excretion and AUC.
- *Pharmaceutical Engineering Fundamentals II (PhEn 501).* This course covers the fundamentals of pharmaceutical engineering calculations related to material and energy balances (for steady and unsteady, non-reactive and reactive systems) applied to pharmaceutical facilities and systems; estimation of thermophysical properties, phase and reaction equilibrium; and chemical kinetics and basic reactor design.
- *Pharmaceutical Engineering Fundamentals III (PhEn 502).* The course covers the fundamentals of fluid mechanics (fluid statics, viscosity, continuity equation; equation of motion; equation of energy, laminar flow, turbulent flow; Reynolds number; *f* factor, average velocity, pumps and hydraulic systems, flow past immersed objects), heat transfer (conductive, convective, and radiative heat transfer, energy balances, heat exchangers), mass transfer (diffusion, convective mass transfer; mass transfer coefficients, mass transfer applications to vapor-liquid, liquid-liquid and solid-fluid separation processes and equipment) and the design of unit operations involving these principles.

Rationale for Changes to the Core Courses

The discussion of what constitutes the core knowledge of the academic curriculum in the evolving area of pharmaceutical engineering is an ongoing debate. As far as the NJIT PhEn program is concerned, the three areas that were initially considered to constitute the core of the program were the pharmaceutical "unit operations", the practical and often peculiar aspects of pharmaceutical production and manufacturing, and the regulatory issues. In addition, since the students entering the program were not always familiar with the industry in general (and even when they were, their knowledge was very limited and incomplete), additional "core" knowledge had to be provided for the students to understand the framework in which the specific material had to be arranged. For this reason, three common core courses were developed, i.e., Principles of Pharmaceutical Engineering (PhEn 601); Pharmaceutical Processing and Manufacturing (PhEn 603); and Validation and Regulatory Issues in the Pharmaceutical Industry (PhEn 604). These courses proved to be very effective not only to provide the students with knowledge in the specific areas that they covered, but also to create the foundations on which the material covered in other track-specific or elective courses could be added. This was especially true for the introductory PhEn 601 course and the PhEn 604 "validation" course. Although these courses have been revamped and modified since they were first offered in the spring of 2002, their structure has remained relatively intact. However, two important issues became apparent. The first was the fact that the number of unit operations commonly used in the pharmaceutical industry (and hence to be covered in the program) is large. To make matter worse, many of these operations are rarely covered in undergraduate engineering courses (e.g., liquid and multiphase mixing, milling, granulation, tableting and coating), which implies that the students were exposed to them for the first time only in the PhEn program. Therefore, it became apparent that a single course (PhEn 603) was insufficient to cover the fundamentals and applications of all these

unit operations. A second, separate issue was associated with the lack of any pharmaceutical science background by the vast majority of students, especially when it came to basic physiology, pharmacology (including pharmacokinetics and pharmacodynamics), and drug delivery principles. To address all these issues a new core curriculum has been developed and already partially implemented, as described specifically in the next section.

4 SPECIFIC CORE COURSE MODIFICATIONS/ADDITIONS IN THE PROPOSED NEW CURRICULUM

To address the above-mentioned issues two steps were taken. The first consisted of proposing an expansion of the number of common core courses from the current three, i.e., PhEn 601, PhEn 603, and PhEn 604, to five, i.e., the previous three core courses plus a new unit operations course focused on processing of solids and solid dosage forms (PhEn 606), and another course on pharmacokinetics and drug delivery systems (PhEn 618). The second step was a re-examination of the content of the existing core courses to update them and, especially, to distribute better the material among different courses. This was particularly relevant to the unit operations material.

The specific modifications, additions, and improvements are now discussed in some detail by examining the specific core courses in the proposed new curriculum.

Principles of Pharmaceutical Engineering (PhEn 601)

This is the first course that most students in the program typically take or are strongly encouraged to take. This is done on purpose since this course is designed to provide the students with a greater understanding of the overall pharmaceutical industry. The course begins by providing a historical perspective of drug products, including a detailed discussion of critical successes and failures from the past, and numerous important legislative and regulatory actions. In addition, students are made aware of the extensiveness of the drug discovery and development process including pre-clinical research, human clinical trials and regulatory requirements through post-marketing. Review of dosage form design and manufacture familiarizes students with the unique equipment, processing technology, facility design issues, microbiologic control, packaging and labelling, as well as omnipresent regulatory and validation oversight.

The effect of drugs on human beings remains a continuous thread throughout the course work to ensure students recognize both the design requirements and the impact issues. A qualitative understanding of pharmacology provides valuable insight into the physiological nature of treatment. Safety is a major emphasis including discussions of toxicology, dose regimes, and the issues of bioequivalence and therapeutic equivalence, often driven by competition with generic drug manufacturers.

Extensive discussions regarding granulation, tableting and encapsulation provide a basic understanding of oral solid dosage forms, which account for approximately 70% of all drug sales. However, other forms ranging from oral liquids to topical semi-solids to radiopharmaceuticals are also covered in detail along with various dose delivery technologies. Reviewed delivery technologies range from the more traditional, such as transdermal and parenteral routes of administration, to the more exotic and novel, such as iontophoresis, phonophoresis and implanted devices.

Students learn that biologics and biotechnology products require additional consideration beyond that of traditional pharmaceuticals and must meet specialized requirements in various aspects of development, manufacture and handling, packaging and compliance.

An introduction to facilities and equipment is also very important and allows the students to understand the extreme uniqueness and specialization of the pharmaceutical production environment. Drug manufacture in clean rooms, the use of fluid bed processing and cell culture technology are just a few of the many sophisticated methods employed that must be clearly understood and correctly applied by engineers and other technical individuals.

Noted industrial experts are scheduled as guest speakers providing a validation of the materials covered, while facility tours and research opportunities supplement class lectures, notes, and the text to provide a complete and comprehensive industry overview.

Throughout the course, the quality and criticality of pharmaceutical products is emphasized and directly correlated to human administration, safety, efficacy and biological activity with the goal of providing an industry overview prior to student advancement into more topic specific courses necessary to complete the program.

Pharmaceutical Unit Operations: Processing of Liquid and Dispersed Systems (PhEn 603)

Initially this course was supposed to cover *all* unit operations encountered in the pharmaceutical industry. Although this could be done in a very superficial fashion, it was decided to divide the original content of course into two courses i.e., PhEn 603 and PhEn 606 (as explained below), in order to provide a more in-depth analysis of each process. PhEn 603 is now dedicated exclusively to unit operations involving liquids or dispersed systems, whereas PhEn 606 is fully focused on operations involving solids and solid dosage forms.

The main objective of PhEn 603 is to examine methodologies, both applied and fundamental, to scale up manufacturing processes for a variety of pharmaceutical dosage forms. The emphasis of the course is primarily on the engineering aspects of the pharmaceutical processes examined in the course. The course covers state-of-the-art pharmaceutical processing, identifying underlying chemical process engineering principles, and providing quantitative approaches to drug product manufacturing process design and optimization.

The course covers topics such as processing of liquid systems, mixers and agitated vessels, liquid mixing fundamentals, power, flow and blend time in agitated liquid systems, solid-liquid suspensions, solid dissolution and mass transfer, liquid-liquid dispersions, emulsification and high-shear processing of pharmaceutical dispersed systems, gas-liquid systems, equipment and scale-up criteria for dispersed systems, sterilization processes, aseptic manufacturing, drying, freeze-drying and lyophilization, sedimentation, filtration, centrifugation, and fluidization.

Both a qualitative and a quantitative approach are used in the course. For each topic, the equipment, operations, and their purpose and relevance in a pharmaceutical process are first described. Then, the same topic is covered quantitatively using the appropriate mathematical models to design, scale up, and predict the operation of a specific apparatus or process.

Although the pharmaceutical industry is very scientifically advanced (especially for all aspects pertaining to drug discovery and drug synthesis), it is, relatively speaking, technologically weak, relying on processes that are robust but labor-intensive and dated. The main reason for this is cultural and historical, since the industry is heavily regulated (thus leaving little margin to technological innovation), and dominated by drug discovery.

PhEn 603 is one of the few available courses in which pharmaceutical processing is examined and described quantitatively, using, whenever possible, a unit operation approach similar to the approach that has been successfully used in other disciplines, such as chemical engineering, to analyze industrial processes. The objective of the course is to produce engineers who can analyze and design pharmaceutical processes relying not only on previous experience, but also on tested, quantitative, predictive tools.

Validation and Regulatory Issues in the Pharmaceutical Industry (PhEn 604)

Validation is a key component of all pharmaceutical and medical device manufacturing. It is a legal requirement, according to the US Code of Federal Regulations. The purpose of validation is to produce a product that is expected to meet its predetermined specifications. For example, a pharmaceutical manufacturer needs to have specific conditions met before a product can be considered effective. The process of validation is the means that assures the manufacturer and the government that the product can and does meet all of the manufacturing and production expectations. The new version of the course developed at NJIT covers both major areas to a validation program: equipment qualification and the process validation.

This course is designed to teach the students about all phases of the validation program. It is expected that at the end of the course the student will have a working knowledge of both validation and qualification. Since all pharmaceutical and medical device operations require compliance to the current "Good Manufacturing Procedures" (cGMPs), the student is given examples of real situations, an

opportunity to explore the ways and means of developing a program that will meet the test of the regulatory agencies, and the chance to learn all aspects of validation.

Even students working in the validation department at an operating company will learn only a small portion of the full requirements. This course gives the student a full understanding of the process of developing a program, implementing the program and correcting problems in their own work environments. This will ultimately lead to better, safer, and cheaper pharmaceutical products to the consumer.

Pharmaceutical Unit Operations: Solids Processing (PhEn 606)

Solid dosage forms, being either compressed tablets or encapsulations, continue to be the most widely administered drug delivery systems for both over-the-counter and prescription drugs. Although there have been many advances in the technology of wet granulation and direct compression methods, these processes consist of fundamental unit operations involving liquid-solid and dry solid systems. The objective of this course is to examine the chemical engineering principles involved in tablet formulation, granulation and direct compression methods, as well as other solid dosage operations, in order to predict and optimize scale-up performance from the laboratory and pilot plant to the manufacturing scale.

Tablet product design has undergone rapid changes in the past few decades with the advent of advanced direct compression materials and technologies, as well as changes in federal regulations involving bioavailability, bioequivalence, and formulation validation. Furthermore, tablets must be designed to function in a wide variety of ways. Examples include sustained or dual release products, targeted intestinal release, or slow dissolution in the mouth or under the tongue. With this in mind, the course in constructed to cover all engineering aspects involved in tablet production, with emphasis on current technologies and recent advancements.

Part I of the course systematically covers product formulation and design involving preformulation testing of the Active Pharmaceutical Ingredient (API), selection of excipients, formulation optimization, tablet design and encapsulation. Part II of the course examines in detail the unit operations and equipment selection involved in wet and dry granulation versus direct compression methods. Unit operations include particle size reduction by milling, solid-solid and liquid-solid blending, fluidized bed granulation, solids drying, coating operations and tablet compression. As in PhEn 603, a qualitative and quantitative approach is taken to develop engineering models and methodology to design and scale up a process from the bulk API to final solid dosage form. Finally, Part III of the course deals with the engineering aspects of the pharmaceutical pilot and manufacturing plant design, tablet production and quality assurance considerations.

PhEn 606 is a comprehensive course covering all aspects of solid dosage form processing. The course has been specifically designed to complement the PhEn 603 curriculum in order to provide students with an in-depth analysis of both the solid and liquid-dispersed systems in two core courses. Industrial experts in the field are invited to speak to the class to provide an industrial perspective on the topics covered. As in PhEn 603, the objective of the course is to provide students with predictive engineering models, based on fundamental chemical engineering principles, for analyzing and designing pharmaceutical processes and selecting appropriate equipment for scale-up.

Principles of Pharmacokinetics and Drug Delivery (PhEn 618)

Most of the students in the program have strong engineering background but very limited knowledge of pharmacology and drug delivery system design. Although most engineers in the pharmaceutical industry will not be directly involved in the pharmacological aspect of drug development, they will likely interact with pharmacists and other life science professionals during process development and manufacturing. Therefore, it is critical that engineers are familiar with the pharmacological concepts that determine the final product formulation and impact on product development and manufacturing.

The main objectives of this course are to provide the students with the rudiments of pre-formulation and formulation design, examine the different drug delivery systems currently used in pharmaceutical practice, present the different pharmacokinetics principles affecting drug adsorption, distribution, metabolism and excretion, and quantitatively study and apply mathematical models used to describe these phenomena.

The first one-third of the course is focused on the pre-formulation, formulation and drug delivery aspects of different drug delivery systems and dosage forms (parenterals, oral liquids, oral solids, inhalation products, transdermal, etc.). The second two-thirds of the course are focused on pharmacokinetics and pharmacodynamics. The basic principles of pharmacokinetics, including absorption, transport distribution, metabolism, and excretion of drugs and metabolites in the human body, drug transport, parenteral and enteral routes of drug administration, and factors affecting drug absorption, distribution, and metabolism are covered. Mathematical pharmacokinetic models and drug delivery processes are also presented and quantitatively studied.

The specific topics, covered both qualitatively and quantitatively, are as follows: role of pharmacokinetics, drug absorption, transport, distribution, metabolism, and excretion (ADME); bioavailability/pharmacokinetics of pharmaceutical dosage forms; principles of drug delivery, and pre-formulation and formulation design of parenteral formulations; parenteral drug delivery systems; disperse systems; targeted delivery and other delivery systems; oral solid and oral liquid delivery systems; inhalation delivery systems; transdermal delivery systems; diffusion and drug dispersion; drug permeation; drug transport distribution and metabolism; renal excretion, liver effect on drugs under normal and pathological conditions; dosage regimens; one-compartment open models and data analysis; multiple-dose kinetics and metabolite pharmacokinetics; two-compartment open models; physiological pharmacokinetic models; nonlinear pharmacokinetics; bioavailability and bioequivalence evaluation; pharmacokinetic-pharmacodynamic modeling.

This course not only gives the engineering students an appreciation for the metabolic processes involved in ADME, but also provides them with quantitative tools to understand ADME processes, especially when interfacing with pharmacy and life science professionals within the company.

5 CONCLUSION

A new Master Degree Program in Pharmaceutical Engineering has been recently developed at NJIT to educate engineering professionals who will work at pharmaceutical companies, and provide them with the skills required to work in the pharmaceutical engineering field. This program is unique in that it provides a rigorous engineering training to students who are expected to constitute the future engineering workforce of one of the most innovative and research driven industries in the country. Because of its novelty in the academic world, this program was developed relying exclusively on the experience of the faculty and industrial participants who contributed to its development and its ongoing expansion, as well as on the advice from industry. After the first two years of operation, it was decided to revise the curriculum originally developed in order to improve it and provide the students with an even stronger preparation for their future professional life. A re-examination of what constitutes the core of "pharmaceutical engineering" has been the driving force in this ongoing process. The result is a new curriculum which, when implemented, will contribute to reinforce NJIT's role as a premier, public, technological, research university.

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REFERENCES

ARMENANTE, P. M. and MANFREDI, J. J. *The Pharmaceutical Engineering Program at NJIT: a Working Example of Industry-University Collaboration in a Novel and Fast-Growing Engineering Field.* Paper presented at the ICEE 2003 Conference (International Conference on Engineering Education), Valencia, Spain, July 21–25, 2003.

ARMENANTE, P. M. and MUZZIO, F. J. *The Pharmaceutical Engineering Programs at New Jersey Institute of Technology and Rutgers University: Education and Research Opportunities for the Pharmaceutical Industry and its Engineering Workforce*. Paper presented at the 2003 AIChE Annual Meeting, San Francisco, CA, Nov. 16-21, 2003.