

PROPOSAL

Master of Engineering in Pharmaceutical Engineering and Science

by

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March 2007

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Degree Program Description

Master of Engineering in Pharmaceutical Engineering and Science

Goals for the Program

The Master of Engineering in Pharmaceutical Engineering and Science degree program will be administered by the Graduate School in New Brunswick (GSNB) as a joint professional degree involving Engineering and Pharmacy. The proposed degree is sponsored by the Department of Chemical and Biochemical Engineering, School of Engineering and is one of the “tracks” in the Chemical & Biochemical Engineering program. The objective of this academic program is to educate students in the engineering and science needed to design and optimize pharmaceutical products, and to design, optimize, and control the associated manufacturing processes.

New Jersey is home to a large number of global pharmaceutical and medicinal manufacturing companies and Rutgers University is located at the national epicenter of pharmaceutical research and development. The pharmaceutical industry is fast becoming a major employer and is increasingly looking for engineers and pharmaceutical scientists with advanced training in pharmaceutical engineering. The new graduate program in Pharmaceutical Engineering Science provides an ideal environment for the Master of Engineering in Pharmaceutical Engineering and Science because of its strength in pharmaceutical engineering, biotechnology, nanotechnology, biomaterials, drug delivery and its research ties with the pharmaceutical industry.

Rutgers’ Master of Engineering in Pharmaceutical Engineering and Science will provide an intellectual climate for the preparation of individuals for professional advancement and will train engineers and pharmaceutical scientists with the requisite skills to work in the rapidly evolving regulatory framework that determines pharmaceutical product design and manufacturing processes. The curriculum reflects the emphasis on “Process Understanding” and “Risk Based Regulation” that has been identified by the US FDA as the guiding principles for awarding licenses to manufacture and commercialize drug products in the 21st century.

Rutgers University does not yet have a Master of Engineering in Pharmaceutical Engineering and Science. Rutgers is centrally located in an area rich in pharmaceutical companies. The need for such a program is exemplified by the fact that one company is willing to financially support the creation of the Master of Engineering in Pharmaceutical Engineering and Science.

We are planning to launch the new Master of Engineering in Pharmaceutical Engineering and Science in the Fall of 2007. One of the new electives was already taught in the Fall of 2006, and two new courses (one core, one elective), are taught in the Spring 2007.

Resources

There are sufficient resources available to launch an effective Master of Engineering in Pharmaceutical Engineering and Science.

Faculty: There is a broad pool of available tenure-track faculty at Rutgers to teach the new core courses and electives. Additional lecturers will be brought in as adjunct faculty from Pharmaceutical companies in the surrounding area and the program has both authority and funding for further tenure and tenure track hires. The Master of Engineering in Pharmaceutical Engineering and Science ties in with the IGERT program (Integrative Graduate Education and Research Training Program in Nanopharmaceutical Engineering and Science) and the new ERC (Engineering Research Center) on Structured Organic Particulate Systems, there are also tenure track faculty available from NJIT, Purdue University, and the University of Puerto Rico at Mayaguez. These faculty members are already involved and are able to teach, mentor, give advice and help each student with his/her individual curriculum and studies.

Staff: The ERC/IGERT Program Coordinator in Pharmaceutical Engineering has experience managing Chemical Engineering and Biomedical Engineering graduate programs and will support the Master of Engineering in Pharmaceutical Engineering and Science. Another full-time staff member has been budgeted for the ERC program, and that person will also support the proposed Master of Engineering in Pharmaceutical Engineering and Science program with advertising, writing brochures, mailings and direct questions from students about the program, including admissions, registration, credits, etc. Extra efforts will be made to accommodate the additional advising burden presented by the large number of new master's students.

Location: There are classrooms and meeting rooms available on Busch campus. There is office space for students to come in and talk to the Master of Engineering in Pharmaceutical Engineering and Science program representatives.

Impact: We do not expect the program to negatively impact the Chemical and Biochemical Engineering PhD program. Students who apply to our PhD program are interested in the long-term research associated with a PhD, which is not a part of this Masters program.

Learning Outcomes

The Master of Engineering in Pharmaceutical Engineering and Science will graduate students who are proficient in using the modern tools of engineering analysis, built on a strong background in the mathematical, physical, chemical and biological sciences, for the design of pharmaceutical processes. Graduates will know how to apply engineering principles to interdisciplinary applications and work effectively in teams with other engineers and/or scientists. Our graduates will also know that it is important to engage in life-long learning in order to adapt to the constantly changing nature of cutting-edge technology. To this end, we teach students how to do critical, as well as thorough, objective-driven design exercises. Graduates are expected to be proficient in oral and written communication skills, to be team players and leaders. Graduates will have a good understanding of contemporary culture and issues necessary for good citizenship in our society and in the world.

The faculty in the Pharmaceutical Engineering Program, which is part of the Department of Chemical and Biochemical Engineering, is deeply committed to the development and education of future leaders in the pharmaceutical engineering field. They will create a mutually supportive stimulating environment to promote the individual and professional growth of the student community. For this reason, The Master of Engineering in Pharmaceutical Engineering and Science curriculum is designed to

1. provide graduates with skills and tools to be innovative, competent, contributing engineers in the pharmaceutical industry;
2. train our graduate students to meet the constantly changing needs of industry for state-of-the-art research/manufacturing practices and protocols
3. give graduates the training and experience to further their career in industry.

Specifically, the Master of Engineering in Pharmaceutical Engineering and Science ensures that its graduates will have acquired:

- the ability to apply knowledge of mathematics, science and engineering to pharmaceutical processes;
- the ability to design a system, component, or process to meet desired needs;
- the ability to function on multidisciplinary teams;
- the ability to identify, formulate, and solve pharmaceutical engineering problems;
- the understanding of professional and ethical responsibility;
- the ability to communicate effectively;
- the broad education necessary to understand the impact of engineering solutions in a global/societal context;
- a recognition of the need for an ability to engage in lifelong learning; and
- a knowledge of contemporary issues.

Measures, Tools and Assessments

The Assessment tools used in The Master of Engineering in Pharmaceutical Engineering and Science are the same as used in the MS in Chemical and Biochemical Engineering. The same high standards of teaching used in the School of Engineering are also applied to the Master of Engineering in Pharmaceutical Engineering and Science. Specifically, assessment of learning outcomes and educational quality will include:

1. In classes, the students' achievement of the program's learning outcomes will be assessed using:
 - grading of homework assignments
 - quizzes
 - midterms
 - individual and/or group projects
 - research papers
 - final exams
2. A capstone experience as described on page 6 (Degree Requirements) of the proposal will be implemented in order to further assess students' achievement of the program's learning outcomes.
3. Student evaluations of teaching experience:

The Center for the Advancement of Teaching at Rutgers administers and compiles the student evaluations of all courses taught in the university. This information is reviewed by the Director of the Program and recommendations and adjustments to the courses are implemented, if necessary.

Outcomes

A student's progress is tracked by the Program's Coordinator. Since the majority of these classes will be taught in the evening, the Program Coordinator is available for the students before classes start, so that students from industry, who work during the day, still manage to feel "connected" to the academic environment and have their questions answered. The Program Coordinator will ensure that every graduating student fills out an exit survey, which will provide contact and employment information. These statistics, compiled over a period of years, will provide valuable information on the outcomes of the program.

Budget

Resources for The Master of Engineering in Pharmaceutical Engineering and Science are adequate and discussed on page 3 and 4 of the proposal. Assessments will be an integral part of the teaching of classes and day-to-day running of the program, and is thus not budgeted separately from other activities.

Admission Requirements

An undergraduate degree in Chemical, Mechanical, or Industrial Engineering, Materials Science, Materials Engineering, Chemistry, or Pharmacy, with a cumulative grade point average of at least 3.0 on a 4.0 scale is expected. Foundation courses will be offered every summer to support applicants who may need refresher training in mathematics, statistics and other engineering tools. International students (and students from Puerto Rico) must also submit scores from the Test of English as a Foreign Language (TOEFL).

Admission into the program will be administered by the Chemical and Biochemical Engineering Graduate Program and will be subject to its rules and regulations; preferred consideration for admission will be given to applicants with significant experience in the pharmaceutical industry (at least 5 years).

Quality of the Program and its Offerings:

Degree Requirements

The Master of Engineering in Pharmaceutical Engineering and Science is a 30-credit degree program. Students are to complete five core courses (15 credits), and five elective courses (15 credits). The elective courses include 3 credits of supervised/independent research. At the conclusion of the program, students will make a presentation to a committee of 3 faculty approved by the Graduate Program Director of Chemical and Biochemical Engineering, will provide a written

report similar to a Plan B Master's of Science requirement and will answer questions by their committee. The project can be the results of a three credit independent study that the student conducts in a semester.

Basic requirements for the completion of the degree are the completion of 30 credits of courses, including:

- 15 credits of core courses
- 15 credits of elective courses (to be selected from established engineering and science graduate courses – listing appended).
- Maintaining an overall cumulative grade point average of at least 3.0.
- Maintaining a grade point average of at least 3.0 in the core courses.
- Students receiving more than three (3) grades below B will be recommended for dismissal to the Graduate School.

Core courses (five required courses)

- 155:545 Pharmaceutical Process Design I (Synthesis, Separation and Sterile Processing in the Pharmaceutical Industry)
- 155:546 Pharmaceutical Process Design II (Pharmaceutical Unit Operations)
- 155:547 Statistical Analysis and Design of Pharmaceutical Operations
- 155:549 Advanced Engineering Pharmacokinetics
- 155:541 Design of Pharmaceuticals

Electives (five courses)

- 150:521 Intro to Packaging Engineering
- 150:575 Packaging Regulatory Aspects
- 155:501 Advanced Transport Phenomena I: Momentum Transfer
- 155:502 Advanced Transport Phenomena II : Heat and Mass Transfer
- 155:506 Fluid Particle Granular Flow
- 155:507 Analytical Methods in Chem. & Biochem. Engineering
- 155:511 Advanced Chemical Engineering Thermodynamics
- 155:514 Kinetics, Catalysis, and Reactor Design
- 155:532 Topics in Biochemical Engineering
- 155:542 Chemical Processing of Drugs and Fine Chemicals
- 155:543 Industrial Chemistry of Drugs and Fine Chemicals
- 155:544 Pharmaceutical Organic Nanotechnology
- 155:548 Advanced Topics in Pharmaceutical Engineering
- 650:554 Mechanics of Continua
- 663:501 Advanced Medicinal Chemistry
- 663:502 Principles of Drug Design
- 663:505 Drugs Structure and Function

- 720:507 Advanced Pharmaceutics I
- 720:509 Advanced Pharmaceutics II
- 720:550 Nanotechnology-based Drug Delivery
- 155:586/587 Independent Study in Pharmaceutical Engineering

Course Descriptions

Core courses (Five Required Courses)

155:545 *Pharmaceutical Process Design I (Synthesis, Separations & Sterile Processing)*

- The course provides an introduction to synthesis, separation, and sterile processing and their applications to designing and optimizing pharmaceutical processes. Fundamentals of drug synthesis will be discussed using industrial pharmaceutical examples including separation, distillation, crystallization, filtration, lyophilization, and drying processes.

155:546 *Pharmaceutical Process Design II (Unit Operations)*

- The course provides an introduction to the essential operations used in the manufacture of pharmaceutical products. The course discusses the pharmaceutical product life-cycle, variability, testing, and specifications of pharmaceutical ingredients. Unit operations including blending, granulation, fluidized bed operations, milling, capsule filling, compaction, tablet coating and other processes will be addressed. Students learn to recognize how the output of one process is the input to the next process, and how deviations can cascade along the production sequence until they cause process failures. The course emphasizes design, scale-up, trouble-shooting, and optimization.

155:547 *Statistical Analysis and Design of Pharmaceutical Operations*

- The course provides an introduction to statistical analysis and experimental design methods and their applications to designing and optimizing pharmaceutical processes. Classic statistical concepts and methods will be discussed using pharmaceutical examples including product/process development scenarios, routine in-process and finished product testing, and failure investigations. Regulatory requirements for test of samples, sampling plans, tablet and capsule assay, content uniformity, hardness, friability, dissolution and bioavailability tests will be discussed in detail.

155:549 *Advanced Engineering Pharmacokinetics*

- The course reviews concepts from transport phenomena, thermodynamics, and reaction engineering, as well as basic physiology, to provide students with an understanding of the fundamentals of drug delivery: kinetics of drug absorption, distribution, and elimination; clearance concepts; compartmental, noncompartmental, and physiological models. Fundamental issues relevant to the design of drug products having immediate release, delayed release, sustained release, and extended release profiles are reviewed. Generation and fate of metabolites is discussed.

155:541 *Design of Pharmaceuticals*

- Chemical and physical compatibility. Micromeritics. Hygroscopicity. Solid dose formulations. Bulk properties of blends and mixing rules. Flow properties. Compressibility.

Carr index. Segregation tendency. Tablet hardness, dissolution, thickness, friability. Bioequivalence. Specifications. Formulation methods for immediate release, controlled release, delayed release, burst release. Lung delivery products. Cascade impactors. Parenteral products. Semi-solid products.

Electives (Five Courses)

150:571 Intro to Packaging Engineering

- Materials science, engineering, design, development and testing, packaging machinery, package production, distribution, marketing and resource utilization.

150:575 Packaging Regulatory Aspects

- State and federal regulation of packaging and labeling for consumer environmental protection. Regulations for engineers and scientists to design and fabricate legal containers. Forecasting and aiding in development of future trends in regulatory action.

155:532 Topics in Biochemical Engineering (3)

- Advanced course devoted to current topics of interest in biochemical and enzyme engineering. Topics include production, isolation, and purification of enzymes; downstream processing; design and analysis of bioreactors; bioprocess economics; modeling, optimization, and scale-up of biochemical systems.

155:542 Chemical Processing of Drugs and Fine Chemicals

- Chemical process operations and engineering methods used in the development, scale-up, and manufacture of drugs and fine chemicals; design and regulatory compliance methods for batch multiproduct plants.

155:543 Industrial Chemistry of Drugs and Fine Chemicals

- Chemical process development, scale-up, and regulatory environment of drugs and fine chemicals; strategies and technologies for the synthesis and semisynthesis of drugs. Transition from the bench to the FDA-approved plant.

155:544 Pharmaceutical Organic Nanotechnology

- The course provides an introduction to organic nanotechnology and its application to manufacturing drug products. Fundamentals of organic nanotechnology will be discussed using industrial pharmaceutical examples including nanoparticle and nanocomposite synthesis.

155:548 Advanced Topics in Pharmaceutical Engineering

- Thermochemical process safety; physicochemical methods at the bulk/dosage form interface; and surface chemistry of crystallization, extraction, and adsorption.

155:586/587 Independent Study in Pharmaceutical Engineering

- Independent supervised research with an advisor and/or committee. Only one semester of supervised research is allowed as an elective.

650:554 Mechanics of Continua (Solid Mechanics I)

- Introduction to the fundamental concepts of continuum mechanics, including stress and strain, kinematics, balance laws, and material symmetry. Theories of elasticity, plasticity, fracture, viscoelasticity, and classical fluid dynamics.

663:501 Medicinal Chemistry: Research Techniques and Principles

- Basic course for students preparing to do research in medicinal chemistry. Information management, computer methods, basic laboratory techniques, and principles of medicinal chemistry.

663:502 Principles of Drug Design

- Identifying new drug leads, drug absorption and distribution, pharmacomodulation, enzymes and receptors as targets, peptidomimetics, computer-aided drug design, and combinatorial chemistry.

663:505 Drugs: Structure and Function

- A survey of the major pharmaceutical agents in clinical use. Emphasis on the influence of chemical structure in the elicitation of pharmacological effects.

720:507 Advanced Pharmaceutics I

- Application of physical-chemical principles to the study and evaluation of pharmaceutical systems: solubility phenomena, equilibria, complexation, phase transitions, and pharmaceutical stability, and the fundamentals of pharmacokinetics.

720:509 Advanced Pharmaceutics II

- Kinetics aspects of the pharmaceutical sciences. Quantitative and mechanistic approaches to pharmacokinetics, dissolution rate, and chemical kinetics. Kong. Prerequisites: Ordinary differential equations (or equivalent) and pharmacokinetics.

720:550 Nanotechnology-based Drug Delivery

- Nanotechbased Drug Delivery: A multidisciplinary course covering nanotechnology based drug delivery, materials and processes for novel drug delivery systems, sythesis of biocompatible nano particles for healthcare, product design, products today and regulatory issues.