New Jersey Institute of Technology

Master of Science Degree Program in Pharmaceutical Engineering

Program Website Address

- http://chemicaleng.njit.edu/academics/graduate/masters/pharmphp
- http://chemicaleng.njit.edu/academics/graduate/

Program Management

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Program Objective

The Master of Science Program in Pharmaceutical Engineering is a program developed and administered by the Otto H. York Department of Chemical, Biological and Pharmaceutical Engineering at NJIT. The primary objective of the program is to educate professionals and provide 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 pharmaceutical/medical technology industry is the largest manufacturing industry in New Jersey. New Jersey is home to the headquarters of more global pharmaceutical and medical technology companies than any other state in the country, or any single country throughout the world. NJIT's Master of Science Program in Pharmaceutical Engineering provides the intellectual climate and the necessary tools needed to prepare students for positions and career advancement within the industry, based on the rigorous technological requirements of this highly regulated work environment.

The program is designed to provide opportunities for specialization in such areas as pharmaceutical processing and manufacturing, validation and regulatory issues in the pharmaceutical industry, pharmaceutical facility design, pharmaceutical packaging technology, reaction engineering for pharmaceutical production, pharmaceutical separation processes, pharmacokinetics and drug delivery, molecular modeling for drug discovery, pharmaceutical synthesis, fluid mixing in the pharmaceutical industry, instrumental analysis, and industrial quality control.

Admission Requirements

An undergraduate degree in chemical engineering or, in most cases, mechanical engineering, with a cumulative grade point average (GPA) of at least 3.0 on a 4.0 scale is usually required. Applicants with: (1) a science degree, (2) an engineering degree in a discipline other than chemical or mechanical engineering, or (3) a GPA below 3.0 but at least 2.8, may be conditionally admitted to the program. Conditions may involve completion of a bridge program designed on a case-by-case basis, and typically requiring taking extra bridge courses, as further explained below. Depending on the background of the student, admission conditions may additionally require taking undergraduate courses (e.g., chemistry) or graduate courses. Bridge and undergraduate courses do *not* count toward degree credit; graduate level courses do.

In general, submission of Graduate Record Examination (GRE) scores is encouraged but not required. However, applicants whose last prior degree is from an institution outside the United States or who seek financial support *must* submit GRE scores. International students must also submit scores from the Test of English as a Foreign Language (TOEFL). The minimum TOEFL score requirement is 79 (Internet Based), 550 (Paper Based) or 213 (Computer Based).

The admission requirements described above can be partially relaxed for *applicants with significant industrial experience in the pharmaceutical industry (5+ years)*. The admission requirements for such candidates will be established on a case-by-case basis, and will be determined through an interview with the prospective student and the submission of letters of support attesting the level of experience attained.

Bridge Program

The Pharmaceutical Engineering program has been designed so that applicants with different backgrounds can be admitted. Nevertheless, the program is strongly oriented toward the *engineering* component of "Pharmaceutical Engineering". In addition, since

the pharmaceutical industry is a chemistry-based industry a chemical engineering background is the most appropriate to enter the program (mechanical engineers are also generally well prepared to enter the program) This implies that students who have a science background (e g , chemistry or pharmacy B S degrees) or an engineering degree in a discipline other than chemical or, possibly, mechanical engineering, may be required to take a bridge program Depending on the background of the applicant this bridge program may consist of up to (but generally speaking less, at least for students with an engineering degree) three 3-credit courses (PhEn 500, PhEn 501 and PhEn 502) specifically designed to provide non-chemical engineers with the necessary prerequisites to enter the program The bridge courses cover a variety of topics, such as differential equations (especially applied to transport phenomena), optimization and business math (PhEn 500), mass balances, thermodynamics, and chemical kinetics (PhEn 501), and fluid flow, heat transfer and mass transfer (PhEn 502)

A grade point average of at least 3.0 must be achieved in the bridge courses Students should pay special attention to the successful completion of the bridge courses, since failure to do so may preclude them from enrolling in regular PhEn courses PhEn 500 and PhEn 501 can and should be taken concurrently Successful completion of both PhEn 500 and PhEn 501 is required to enroll in PhEn 502 Students must take the bridge courses before taking any other PhEn courses, with the exception of PhEn 601 and PhEn 604, which can be taken concurrently with the bridge courses As mentioned, admission conditions may also include taking additional undergraduate or graduate courses, if needed

Degree Requirements

The Master of Science in Pharmaceutical Engineering is a 30 credit program structured along two different tracks The two tracks have a common 15-credit core Each track has an additional 6 credit track-core, as described below Each track has 9 credits of electives selected by the student in consultation with , and subject to, the approval of the program advisor for the selected track

Students have the option of fulfilling six (6) of the nine (9) 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 *Part-time students working in the pharmaceutical industry are encouraged to pursue a Master's Thesis, possibly conducted at their site and in collaboration with their supervisor.*

Students must maintain an overall cumulative grade point average of at least 3.0 throughout their academic career Students are certified for graduation only if they:

- achieve an overall cumulative grade point average of at least 3.0; and
- achieve a grade point average of at least 3.0 in the required seven core courses; and
- achieve a grade point average of at least 3.0 in the bridge courses (if taking the bridge courses is required)

Students may not repeat a course without approval of both the Program Director *and* the Office of Graduate Studies If a student repeats more than one course, the grades received in the first two repeated courses will replace the original grades in the calculation of the cumulative grade point average, although the old grades will still appear on the transcripts However, the grades received in all repeated courses beyond the first two will count in the calculation of the cumulative grade point average Students who receive an F in a course are required to repeat the course

Program of Study

The program of study includes common core courses, track-specific core courses, elective courses, and, if the students so chooses, a thesis (in lieu of some elective courses), as specified below The common core courses cover a variety of topics ranging from drug dosage forms to drug manufacturing processes, validation and regulatory issues, design criteria and unit operations for pharmaceutical processes, pharmacokinetics and drug delivery

The program has two tracks, i e :

- *Track 1 – Process Development and Design for Drug Substance Manufacturing* This track is focused on the engineering aspects of chemical reaction and separation processes required for the manufacturing of active pharmaceutical ingredients
- *Track 2 – Process Development and Design for Drug Product Manufacturing* This track is focused on the engineering aspects of processes required for the manufacturing of final drug products

All students must take the same five (5) common core courses as well as the two (2) track-specific core courses for the track that they have selected Irrespective of the track selected, the total number of core courses (7) and the corresponding core credits (21) are the same for both tracks

Course Requirements

A. **Appropriate bridge courses, if any.** Students should check their admission conditions, as detailed in the admission letter, to determine whether they are required to take any or all of the bridge courses specified above, as well as other possible courses

B. **Five (5) core courses** common to both tracks (3 credits each ; 15 credits total), as follows:

- PhEn 601 Principles of Pharmaceutical Engineering
- PhEn 603 Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems
- PhEn 604 Validation and Regulatory Issues in the Pharmaceutical Industry
- PhEn 606 Pharmaceutical Unit Operations: Solids Processing
- PhEn 618 Principles of Pharmacokinetics and Drug Delivery

C **Two (2) track-specific core courses**, depending on the track selected (3 credits each; 6 credits total), as follows:

Track 1 – Process Development and Design for Drug Substance Manufacturing

- PhEn 612 Pharmaceutical Reaction Engineering
- PhEn 614 Pharmaceutical Separation Processes

Track 2 – Process Development and Design for Drug Product Manufacturing

- PhEn 602 Pharmaceutical Facility Design
- PhEn 605 Pharmaceutical Packaging Technology

D **Three (3) elective courses** (3 credits each; 9 credits total) Any graduate course at the 600-level or 700-level in the areas specified below is considered to be a valid elective:

- Pharmaceutical Engineering (PhEn) (such as courses in the track not chosen by the student)
- Biopharmaceutical Engineering (PhB)
- Pharmaceutical Materials Processing (PhMP)
- Chemical Engineering (ChE)
- Pharmaceutical Systems Management
- Biomedical Engineering (BME)
- Industrial Engineering (IE)
- Engineering Management (EM)
- Chemistry (CHEM)
- Biology (BIOL)
- Mathematics (MATH)

Students can also take electives in other areas (e.g., management, finance, computer science, other engineering disciplines, and others), *but only in consultation with, and with the approval of, the Program Advisor.*

Remark: Students who are required to take either PhEn 612 or PhEn 614, as detailed in their admission letters, can use this course either as a track-specific core course (if they choose Track 1) or as an elective (if they choose Track 2)

E **Master Thesis (Optional)** Students can opt to do a Master Thesis, if they so choose Students who choose to do a thesis must take 6 credits worth of PhEn 701 (Master's Thesis) in lieu of 6 credits of elective courses [Remark: two PhEn 701 courses exist, i.e., PhEn 701B (3 credits) and PhEn 701C (6 credits) Students are strongly encouraged to register for PhEn 701B for two different semesters rather than take PhEn 701C in one semester] Students who want to do a thesis must first select a project and a Thesis Advisor who will supervise them through their thesis work To do so, students should discuss available research topics and projects with different faculty members in order to finally select a Thesis Advisor They must also receive the Program Advisor approval for their selection of Thesis Advisor, and they must also complete a form indicating the three (3) faculty members composing their Master Thesis Committee, to be selected in consultation with their Thesis Advisor NJIT requires that students who elect to do a thesis must register for thesis during the semester in which they will graduate, even if this requires taking addition thesis credits beyond the required six (6) credits Completion of the thesis requirements also includes: (a) writing the thesis document, to be approved by the Thesis Committee and the Office of Graduate Studies, and (b) making a final oral presentation to the Thesis Committee

Full-time students receiving full or partial financial support must complete a Master Thesis Part-time students can also complete a Master Thesis if they so choose. *Part-time students working in industry are also eligible, and encouraged, to pursue the thesis option, possibly even conducted at their site and in collaboration with their supervisor.*

Distance Learning Students

All PhEn courses, with only one exception (at least for the time being), can be taken by distance learning (DL) students These courses are offered either as *asynchronous* courses (students follow courses by independently downloading recorded course lectures, notes, homework, and other course material) or as *synchronous* remote courses (students follow courses by joining "live" classes via a WebEx web link at the same time the same class is offered, face-to-face, to students in a classroom)

PhEn Course Description

PhEn 500 - Pharmaceutical Engineering Fundamentals I. Prerequisite: undergraduate calculus This is a required bridge course for those students who are admitted to the Pharmaceutical Engineering MS program without an undergraduate engineering degree This course is not counted toward degree credit related to the Pharmaceutical Engineering MS program Material covered in the course includes an introductory review of calculus, methods of applied mathematics, differential equations (especially applied to fluid flow, mass, and heat transfer phenomena in pharmaceutical engineering), numerical methods, and optimization and business mathematics needed to solve pharmaceutical engineering problems The concepts introduced are illustrated through several pharmaceutical engineering examples

PhEn 501 - Pharmaceutical Engineering Fundamentals II. Prerequisite: If needed, PhEn 500 (which can also be taken concurrently with this course), as well as an undergraduate course in physical chemistry This course is a required bridge course for those students who are admitted to the Pharmaceutical Engineering MS program without an undergraduate engineering degree or with an engineering

background that did not include the topics covered in this course. The course is not counted toward degree credit related to the Pharmaceutical Engineering MS program. The course covers the fundamentals of pharmaceutical engineering calculations related to material and energy balances applied to pharmaceutical facilities and systems; estimation of thermophysical properties, phase and reaction equilibrium; and chemical kinetics and basic reactor design.

PhEn 502 - Pharmaceutical Engineering Fundamentals III. Prerequisite: If needed, PhEn 500 and PhEn 501, as well as undergraduate course in physical chemistry. This is a required bridge course for those students who are admitted to the Pharmaceutical Engineering MS program without an undergraduate engineering degree or with an engineering background that did not include the topics covered in this course. The course is not counted toward degree credit related to the Pharmaceutical Engineering MS program. The course covers the fundamentals of fluid mechanics, heat transfer, mass transfer and the design of unit operations involving these principles.

PhEn 601 – Principles of Pharmaceutical Engineering. Prerequisite: graduate standing. This course provides an overview of the pharmaceutical industry, including basic information about drug discovery and development, FDA requirements and approval processes, drug dosage forms, and the role of key operational units in drug manufacturing processes. This course enables the students to understand the role of the pharmaceutical industry in the global market and its implications, learn the fundamentals of the drug development cycle and the investment required to bring a drug to market, and learn the most important drug manufacturing processes and the key elements of dosage formulation.

PhEn 602 – Pharmaceutical Facility Design. Prerequisite: PhEn601. This course provides instruction in design of state-of-the-art pharmaceutical facilities for both manufacturing and R&D, by identifying key functional requires and design concepts necessary to pharmaceutical processes. Interdisciplinary training will be provided in appropriate areas of facility design.

PhEn 603 – Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems. Prerequisites: PhEn601; completion of bridge courses (if required as admission condition). This course examines methodologies, both applied and fundamental, to analyze and scale up manufacturing pharmaceutical processes involving liquid and dispersed-phase systems, such as liquid and multiphase mixing, sterilization and sanitation, lyophilization, filtration, centrifugation and others. The emphasis is primarily on the engineering aspects of the pharmaceutical processes examined in the course.

PhEn 604 – Validation and Regulatory Issues in the Pharmaceutical Industry. Prerequisite: graduate standing. This course is focused on the development of a working knowledge of the Federal Code of Regulations and its impact on the pharmaceutical and allied industries. The history of the Federal Government's regulation of the pharmaceutical industry is studied. Also covered are the industry's response and the methodologies it uses to comply with these regulations.

PhEn 605 – Pharmaceutical Packaging Technology. Prerequisite: PhEn601. This course focuses on developing a working knowledge of the machinery and unit operations used in transferring a drug substance in the bulk final form to a finished product ready for sale to the consuming public. Packaging of both liquid and solid forms in various types of delivery containers such as vials/ampoules, blister packs, individual packets, bottles, pouches and syringes is examined. The cleaning, sterilization and scaling/capping required for each dosage form is discussed, as well as freeze drying, tableting, capsule filling, and form/fill/seal, and the proper labeling of final drug forms.

PhEn 606 – Pharmaceutical Unit Operations: Solids Processing. Prerequisites: PhEn601; completion of bridge courses (if required as admission condition; PhEn502 can be a co-requisite). This course examines methodologies, both applied and fundamental, to analyze and scale up manufacturing pharmaceutical processes involving solids processing, such as solids characterization, blending, milling, granulation, tableting, coating, and others. The emphasis is primarily on the engineering aspects of the pharmaceutical processes examined in the course.

PhEn 612 – Pharmaceutical Reaction Engineering. Prerequisites: PhEn601; completion of bridge courses (if required as admission condition). This course examines a variety of reactions typically encountered in the pharmaceutical industry, including single/multiple phase (e.g. crystallization), fine chemical synthesis, enzymatic, bio-reactions (fermentation), and others. The course then focuses on quantitative pharmaceutical reactor design and scale-up issues.

PhEn 614 – Pharmaceutical Separation Processes. Prerequisites: PhEn601; completion of bridge courses (if required as admission condition). This course covers separation processes in general and pharmaceutical separations in particular. Specific processes to be studied include distillation, extraction, crystallization, adsorption, ion exchange, chromatography, moving bed processes, electrophoresis, freeze drying, microfiltration/ultrafiltration, reverse osmosis, and pervaporation.

PhEn 618 – Principles of Pharmacokinetics and Drug Delivery. Prerequisites: PhEn601; completion of bridge courses (if required as admission condition). The course covers the basic principles of pharmacokinetics, including drug transport, parenteral and enteral routes of drug administration, and factors affecting drug absorption, distribution, metabolism, and excretion. Mathematical pharmacokinetic models and drug delivery processes are also presented and quantitatively studied.

Student Involvement in Research

In addition to taking courses, students have the opportunity to work, one-on-one, with faculty members on research projects in areas of common interest, allowing maximum flexibility for independent work, and providing students with valuable research experience. Students have the option to complete a Master's thesis, as mentioned above. *Part-time students working in the pharmaceutical industry are encouraged to pursue a Master's Thesis, possibly conducted at their site and in collaboration with their supervisor.*

Qualified and research oriented students have the option of continuing their studies at NJIT by pursuing a Ph. D in chemical engineering, industrial engineering, chemistry, or related disciplines. The NJIT-Industry Collaborative Ph. D Program allows greater flexibility to industrial students *who are interested in pursuing their Ph.D. while working full-time in industry.*