

New Jersey Institute of Technology

Master of Science Degree Program in Biopharmaceutical Engineering

Program Website Address

- <http://chemicaleng.njit.edu/academics/graduate/masters/pharmbioprocessing/index.php>

Program Management

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Program Objective

The Master of Science Program in Biopharmaceutical Engineering (PhB) 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 by providing them with the skills required to work in the bioprocessing and biopharmaceutical field, with particular emphasis on the *engineering* aspects of industrial bioprocessing and biomanufacturing, biopharmaceutical production, and biological/biochemical development.

New Jersey is considered a “hot bed” for pharmaceutical, health care, and bioscience companies, and examples of large and small companies having major facilities in New Jersey abound. The use of microbial/biological systems and the manipulation of biological systems for the production of pharmaceutical products and therapeutic agents are becoming increasingly important for these companies and for the health care industry as a whole. The Biopharmaceutical Engineering program is designed to address the engineering component of the educational needs in this area: students are trained in areas such as microbial and cell growth operations, bioreactor and bioprocess design, fermentation and cell culture processing, recovery and bioseparation processes, and validation and regulatory issues for biological production. Since this program is strongly tied to the pharmaceutical engineering and chemical engineering programs, pharmaceutical bioprocessing students are able to benefit from the use of basic chemical/pharmaceutical engineering approaches, such as transport phenomena, (bio)reaction engineering and unit-operations principles, to understand and design bioprocesses for new biotherapeutics.

NJIT’s M.S. program in Biopharmaceutical 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.

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 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 courses and undergraduate courses do *not* count toward degree credit; graduate-level courses do.

Submission of Graduate Record Examination (GRE) scores is encouraged in all cases, but it required of those seeking financial support and those whose last prior degree is from an institution outside the United States. International students must also submit scores from the Test of English as a Foreign Language (TOEFL). According to university policy, a minimum score of 79 (Internet-based TOEFL), 550 (paper-based TOEFL) or 213 (computer-based TOEFL) is required for all international applicants.

Bridge Program

The Biopharmaceutical Engineering program has been designed so that applicants with different backgrounds can be admitted. Nevertheless, the program is strongly oriented toward the *engineering and processing* components of “Biopharmaceutical

Engineering". In addition, since the biopharmaceutical industry is a chemistry/biology-based industry a chemical or biochemical engineering background is the most appropriate to enter the program. This implies that students who have a science background (e.g., a chemistry or pharmacy B.S. degree) or an engineering degree in a discipline other than chemical, biochemical 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 than, at least for students with engineering degrees) 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, statistics 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/PhB courses, with the exception of PhB 610, 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 Biopharmaceutical Engineering is a 30-credit program, including 21 credits worth of core courses. 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 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 courses, 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

A minimum of 30 credits is required for degree completion. Of these, 21 credits must be obtained by taking seven (7) prescribed Core Courses, which include Biopharmaceutical Engineering (PhB) courses as well as Pharmaceutical Engineering (PhEn) courses. In addition, engineering applicants with little or no biology background, but not biology or pharmacy applicants, may be required to take an additional Foundation Course (PhB 505 - Principles of Pharmaceutical Microbiology and Biochemistry), which *will* count toward the 30 credits required to complete the PhB program. The remaining credits needed to achieve the required 30 credits may be obtained by taking either elective courses only or a combination of an elective course and M.S. Thesis credits. As already indicated, applicants with a science background or an engineering degree in a discipline other than chemical engineering may be required to *additionally* take one or more bridge courses. Bridge courses do *not* count toward the 30 credits required to complete the program.

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. *Bridge Courses do not* count toward the 30 credits required to complete the PhB program). The typical bridge courses (3 credits each; 9 credits total; typically required for non-engineering applicants only) are as follows:
 - PhEn 500 — Pharmaceutical Engineering Fundamentals I
 - PhEn 501 — Pharmaceutical Engineering Fundamentals II
 - PhEn 502 — Pharmaceutical Engineering Fundamentals III
- B. *Foundation Course (3 Credits);*** required for engineering applicants with little or no biology background, but not for biology or pharmacy applicants. This course counts toward the 30 credits required to complete the PhB program:
 - PhB 505 — Principles of Pharmaceutical Microbiology and Biochemistry
- C. *Seven (7) Core Courses (3 credits each; 21 credits total),*** as follows:
 - PhEn 601 — Introduction to 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 618 — Principles of Pharmacokinetics and Drug Delivery
- PhB 610 — Biotechnology/Biopharmaceutical Processes and Products
- PhB 615 — Bioseparation Processes
- PhB 630 — Pharmaceutical Bioprocess Engineering

D. Three (3) Elective Courses (3 credits each; 9 credits total or as appropriate to achieve the required total number of credits).

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)
- Pharmaceutical Bioprocessing (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.

- 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 PhB 701 (Master's Thesis) in lieu of 6 credits of elective courses [Remark: two PhB 701 courses exist, i.e., PhB 701B (3 credits) and PhB 701C (6 credits). Students are strongly encouraged to register for PhB 701B for two different semesters rather than take PhB 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 additional 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

Many PhEn/PhB courses 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).

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. The course covers the fundamentals of calculus, differential equations, probability and statistics, and finance business mathematics applied to pharmaceutical engineering problems and illustrated through 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 603 – Pharmaceutical Unit Operations: Processing of Liquid and Dispersed-Phase Systems. Prerequisites: PhEn 601; 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 618 – Principles of Pharmacokinetics and Drug Delivery. Prerequisites: PhEn 601; 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.

PhB 505 – Principles of Pharmaceutical Microbiology and Biochemistry. Prerequisite: graduate standing. This is a course that students who do not have a background in biological sciences will be required to take. This course covers the major concepts of cell biology, from both a structural and a functional perspective, including cell physiology and structure, molecular biology, genetics, and evolution. The fundamentals of cellular chemistry, life cycles, and regulation will also be discussed. In addition, this course covers the fundamentals of biochemistry related to physical organic chemistry, including buffers, blood, proteins, enzymes, carbohydrates, fats, and nucleic acids.

PhB 610 – Biotechnology/Biopharmaceutical Processes and Products. Prerequisites: PhEn 601 and PhB 505 (if required). This course will cover the different biological processes currently used in the pharmaceutical and biotechnology industry to produce molecules used in pharmaceutical products or of relevance to the pharmaceutical industry. The processes examined here will include long-established biochemical processes such as those used for antibiotic production and peptide extraction, as well as biopharmaceutical processes to obtain recombinant proteins, monoclonal antibodies, cytokines, hormone and blood products, therapeutic enzymes, antibodies, vaccines, and nucleic acid therapeutics.

PhB 615 – Bioseparation Processes. Prerequisites: PhEn 601; completion of bridge courses (if required as admission condition) and PhB 505 (if required). This course will cover the principles, methods, and unit operations required for the separation and recovery of biologically obtained molecules and especially proteins. Also studied here is the relationship between the chemistry of biological molecules and efficient separation and preservation of biological activity. Processes covered in this course will include extraction, liquid chromatography, adsorption, precipitation, crystallization, electrophoresis, drying and others, where, in each case special emphasis is placed on separation of biomolecules.

PhB 630 – Pharmaceutical Bioprocess Engineering. Prerequisites: PhEn 601; completion of bridge courses (if required as admission condition) and PhB 505 (if required). This course covers the principles, methods and approaches required for the development and operation of bioprocess engineering system, with special emphasis on pharmaceutical bioprocessing in which living organisms or enzymes are used to obtain products of therapeutic values. The course is focused primarily on the application of chemical engineering principles to the production of pharmaceutical products. Topics include a review of biological basics (including basic structures of prokaryotic and eukaryotic cells, microbial metabolism, enzyme activity, cell cycles, and genetics), cell line selection, genetically engineered cells and cell banking, kinetics of cell growth, substrate utilization and product formation, metabolic stoichiometry, transport phenomena in bioprocess systems, design and analysis of suspended-biomass bioreactors and immobilized-cell bioreactors, and bioreactor scale-up/scale-down.

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. *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.*