

Proposal for New Program
MS in
Pharmaceutical
Engineering

College of Engineering
Bouvé College of Health
Sciences

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EXECUTIVE SUMMARY

Northeastern University's College of Engineering (COE) and Bouvé College of Health Sciences (Bouvé) are proposing a joint Master of Science (MS) program (non-thesis) in Pharmaceutical Engineering. This jointly developed program supports the growing industry need for engineers with advanced skills in state-of-the-art pharmaceutical design, manufacturing processes, regulatory, and quality. Using the Coop expertise within COE, the proposed MS degree contributes to the University's emphasis on experiential education and interdisciplinary knowledge, preparing students for professional advancement.

A market analysis was performed and it demonstrated that we have a clear market and opportunity within the Boston area. Few programs exist across the country, and our focus on using expertise in Chemical Engineering and Pharmaceutical Sciences, as well as our experiential opportunities, distinguish our proposed program. We have met with MassBioEd, MassLifeSci, and International Society for Pharmaceutical Engineering (IPSE) representatives to discuss the program objectives and distinguishing features from other programs. In addition, we have met with the Biotechnology program director to assure distinguishing features between the programs, which primarily includes engineering analysis and control.

1. PROGRAM DESCRIPTION

Northeastern University's College of Engineering (COE) and Bouvé College of Health Sciences (Bouvé) joint Master of Science (MS) program in Pharmaceutical Engineering will be a non-thesis degree program offered by the Department of Chemical Engineering in COE and the Department of Pharmaceutical Sciences in Bouvé. The program supports the growing industry need for engineers with advanced skills in state-of-the-art pharmaceutical design, manufacturing processes, regulatory, and quality. Students additionally benefit from the close research ties and workplace connections made possible by Northeastern's experiential education model and close proximity to the Boston area biotechnology and pharmaceutical companies. COE is taking the lead on the program and will use the coop faculty currently affiliated with the Chemical Engineering department to support the student's experiential learning. The MS in Pharmaceutical Engineering will be a 1.5-2-year full time degree program. The program is intended to begin in Fall 2022, with 32 total semester hours.

2. CONTRIBUTION TO THE UNIVERSITY'S MISSION

The MS in Pharmaceutical Engineering aligns well with the missions of both COE and Bouvé, as well as the University. The proposed MS degree contributes to the University's emphasis on experiential education and interdisciplinary knowledge, preparing students for professional advancement. Faculty from COE and Bouvé are deeply committed to training future leaders in pharmaceutical engineers, and the program has a core that requires courses from both disciplines.

The primary department that will oversee the students, including advising and coop, will be the Department of Chemical Engineering. Working closely with the Department of Pharmaceutical Sciences, we have developed a curriculum that brings together the expertise of both departments. We have also met with MassBioEd, MassLifeSci, and ISPE representatives to discuss any concerns about the program objectives and distinguishing features from other programs. The focus on engineering aspects of pharmaceutical development, operations, and manufacturing are clear distinguishing features from programs such as Biotechnology, which do not present engineering aspects.

3. PROGRAM MARKET ANALYSIS

A market analysis was performed by Hanover. The entire report is attached in an appendix. The key findings noted that there is a growing student demand and the number of existing programs is low, while employment outlook is high.

Between 2015 and 2019, the number of master's degree completions in pharmaceutical sciences, pharmaceuticals and drug design, and related fields grew, in aggregate, at an annualized rate of 4.9 percent at the national level. In Boston, the number of master's conferrals grew, in aggregate, annually at a rate of 8.6 percent, more than twice as fast as all master's degree completions in the area (5.0 percent).

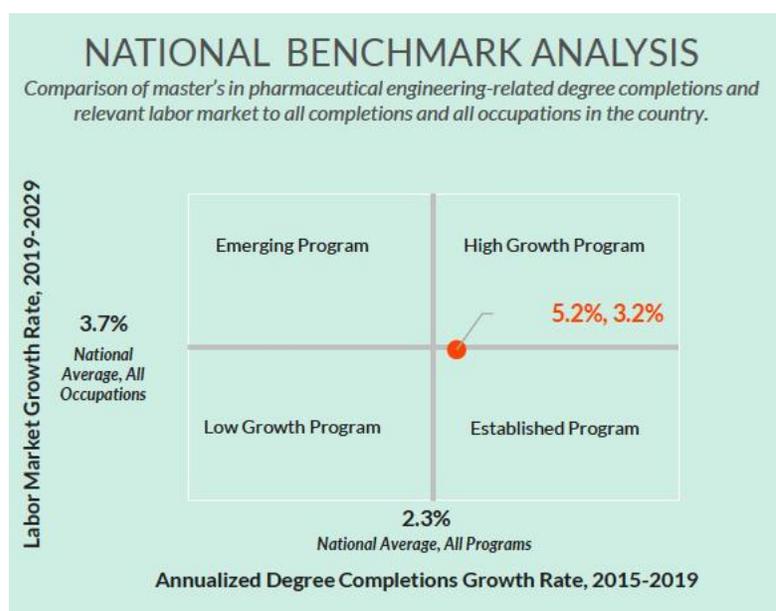


Figure 1: From Hanover Market Analysis, growth rate for programs focused in pharmaceutical engineering.

Please see Hanover's recommendations and key findings pasted in below:

- Offer a professional master's degree in pharmaceutical engineering
Student demand in closely related engineering and pharmaceutical sciences fields has grown at all geographic levels, while the employment outlook is positive. The low number of comparable programs would allow a program at Northeastern University to stand out nationwide.
- Clearly message the benefits of a degree in pharmaceutical engineering
Prospective students may be accustomed to considering traditional programs, such as chemical engineering or industrial pharmacy, when researching academic programs aligned with careers in the pharmaceutical industry. It will be essential that Northeastern illustrate the specific advantages and benefits of a professional master's degree in pharmaceutical engineering with concrete examples of industry applications, professional roles, or career advancement opportunities that might facilitate students'

decision-making process.

- Consider prioritizing marketing efforts in California and Massachusetts first
California and Massachusetts are national leaders in (bio-)pharmaceutical industries and both states indicate robust labor demand for related professionals. If Northeastern were to move forward with the proposed master's degree program, it should prioritize marketing efforts to these two states first before launching a nationwide campaign.

Demand for more programs

The market analysis highlighted the need for more programs in this area:

Researchers have demanded more pharmaceutical engineering programs for almost 20 years

Around the mid 2000 s, industry experts and academics started demanding an overhaul of industrial pharmacy training programs and a shift towards pharmaceutical engineering. They suggested that there was a need for broader, crossfunctional training covering pharmaceutical/clinical development and manufacturing, discovery, early stage development operations, and a 'more rigorous quantitative approach.'

In 2008 faculty from New Jersey Institute of Technology and Rutgers University launched graduate level pharmaceutical engineering programs at their institutions and highlighted the incorporation of 'structured organic particulate systems into the existing engineering curriculum.'

Other researchers have also identified 'an urgent need of both innovative technological solutions and fundamental scientific work, enabling the production of highly engineered drug products.' In addition to chemical and biomedical engineering observers see strong potential in systems process facility and automation engineering to improve drug development and manufacturing.

Recently launched graduate degree programs also indicate growing demand

In 2019 the Illinois Institute of Technology launched a new master's degree program in pharmaceutical engineering Illinois Tech reportedly tailored this new offering specifically to meet "growing demand for specialized talent throughout the Midwest and across the globe." The same year, Virginia Commonwealth University started offering a new PhD program in pharmaceutical engineering, allegedly the first in the United States. In 2020 Carnegie Mellon University launched a new master's degree program in biotechnology and pharmaceutical engineering.

Competition from other programs

The proposed program offers this rigorous and quantitative approach using chemical engineering fundamentals at its core through a newly designed pharmaceutical engineering course sequence. By requiring the pharmaceutical sciences courses, the program will allow those engineers with little background in biology and pharmaceuticals to develop a core

knowledge in pharmaceutical sciences while evaluating development, operations, and manufacturing processes from an engineering point of view. With integration of a coop, laboratories, and project courses, graduates of the program will have integrated their classwork and hands-on knowledge to problems in industry.

Institution	Academic Unit(s)	Program	Tuition Per Credit†	Modality	Curricular Structure	Notable Features
Carnegie Mellon University Pittsburgh, PA	Biological Sciences and Chemical Engineering	MS, Biotechnology and Pharmaceutical Engineering	\$1,917*	On-campus	<p>108 units total (=36 credits)</p> <ul style="list-style-type: none"> 0-18 units in background 39 units in foundation 24 units in biology electives 24 units in chemical engineering electives 12-21 units in depth courses 	<ul style="list-style-type: none"> Thesis optional Launched in 2020 Suggest program length of 1.5 years
Drexel University Philadelphia, PA	Chemical and Biological Engineering	MS, Chemical Engineering with specialization in Pharmaceutical Engineering	\$2,013^	On-campus	<p>45 credits total (=30 credits)</p> <ul style="list-style-type: none"> 15 credits core courses 15 credits technical electives 6 credits free electives 9 credits non-thesis (=additional technical electives) 	<ul style="list-style-type: none"> Thesis optional
Illinois Institute of Technology Chicago, IL	Chemical and Biological Engineering	Master of Pharmaceutical Engineering	\$1,614	On-campus	<p>30 credits total</p> <ul style="list-style-type: none"> 12 credits in core courses 18 credits in elective courses 	<ul style="list-style-type: none"> Announced in 2019 Claim to be first program of its kind in Chicago area, addressing "growing industry demands"
New Jersey Institute of Technology Newark, NJ	Chemical and Materials Engineering	MS, Pharmaceutical Engineering	\$1,375**	On-campus	<p>30 credits total</p> <ul style="list-style-type: none"> 15 credits in core courses 6 credits in courses 9 credits in electives 	<ul style="list-style-type: none"> Thesis optional Tracks in process development and design for either drug substance manufacturing or drug product manufacturing Can be completed in full-time or part-time study Established in 2001

Institution	Academic Unit(s)	Program	Tuition Per Credit†	Modality	Curricular Structure	Notable Features
Purdue University West Lafayette, IN	Chemical Engineering	Professional MS, Chemical Engineering with concentration in Pharmaceutical Engineering	\$463	On-campus	<p>30 credits total</p> <ul style="list-style-type: none"> 6 credits on chemical engineering core 9 credits in concentration 9 credits in management 6 credits directed capstone 	<ul style="list-style-type: none"> Suggest program length of 1 calendar year Target students with and without undergraduate background in chemical engineering
Rutgers University Piscataway, NJ	Chemical and Biochemical Engineering	Master of Engineering in Pharmaceutical Engineering and Science	\$772*	On-campus	<p>30 credits total</p> <ul style="list-style-type: none"> 15 credits in pharmaceutical engineering 15 credits in electives 	<ul style="list-style-type: none"> Non-Thesis Industrial internships available ERC for Structured Organic Particulate Systems
University of Rhode Island Kingston, RI	Chemical Engineering	MS, Chemical Engineering with specialization in Pharmaceutical Engineering	\$940*	On-campus	<p>30 credits total (curriculum n/a)</p>	<ul style="list-style-type: none"> Thesis optional Non-thesis program for part-time students
University of Washington Seattle, WA	Bioengineering	Master of Pharmaceutical Bioengineering	\$1,245^	Online	<p>38 credits total (=25.3 credits)</p> <ul style="list-style-type: none"> 16 credits in basic bioscience 10 credits in track (drug discovery and design or translational pharmaceuticals) 12 credits clinical development/capstone (6) and seminars (6) 	<ul style="list-style-type: none"> Targets working engineers, scientists, researchers, and professionals in biotechnology, pharmaceutical, and related industries

Institution	Program	Career Outcomes and Industry Connections	Related Offerings
Carnegie Mellon University Pittsburgh, PA	MS, Biotechnology and Pharmaceutical Engineering	<ul style="list-style-type: none"> Suggest careers in "pharmaceutical companies, academic labs, federal and state governments, hospital labs, genomics core facilities, biotechnology companies, and software development companies" Networking opportunities 	<ul style="list-style-type: none"> MS, Computational Biology MS, Colloids, Polymers and Surfaces MS, Polymer Science MS, Biomedical Engineering Master, Chemical Engineering
Drexel University Philadelphia, PA	MS, Chemical Engineering with specialization in Pharmaceutical Engineering	<ul style="list-style-type: none"> Co-op programs 	<ul style="list-style-type: none"> Certificate, Pharmaceutical & Medical Device Manufacturing
Illinois Institute of Technology Chicago, IL	Master of Pharmaceutical Engineering	<ul style="list-style-type: none"> Suggest roles, such as industrial engineer, product development engineer, and pharmaceutical project manager 	<ul style="list-style-type: none"> MS, Biomedical Engineering MS, Chemical Engineering More
New Jersey Institute of Technology Newark, NJ	MS, Pharmaceutical Engineering	<ul style="list-style-type: none"> Work in pharmaceutical field, "with particular emphasis on the engineering aspects of drug manufacturing, pharmaceutical production, pharmaceutical development, and pharmaceutical operations." Suggest students will learn "a wide range of leadership and management skills" 	<ul style="list-style-type: none"> MS, Biomedical Engineering MS, Chemical Engineering MS, Pharmaceutical Chemistry MS, Pharmaceutical Systems Management
Purdue University West Lafayette, IN	Professional MS, Chemical Engineering with concentration in Pharmaceutical Engineering	<ul style="list-style-type: none"> Suggest careers in "academia, national laboratories, government and policy roles, private consulting corporations, and in chemical industry." Capstone project: students work with industry leaders 	<ul style="list-style-type: none"> Concentrations in Biochemical Engineering, Polymer Science and Engineering, more
Rutgers University Piscataway, NJ	Master of Engineering in Pharmaceutical Engineering and Science	<ul style="list-style-type: none"> "Students [...] benefit from the close research ties and connections made possible by Rutgers' location in the heart of New Jersey's pharmaceutical corridor." 	<ul style="list-style-type: none"> Professional Science Master/Master of Business and Science with concentration in Pharmaceutical Engineering Master's in Chemical Engineering
University of Rhode Island Kingston, RI	MS, Chemical Engineering with specialization in Pharmaceutical Engineering	<ul style="list-style-type: none"> Mention hands-on learning 	--
University of Washington Seattle, WA	Master of Pharmaceutical Bioengineering	<ul style="list-style-type: none"> Suggest opportunity to "gain an edge in your current job, or receive training to transition to a new career in the biotechnology or pharmaceutical industry." 	<ul style="list-style-type: none"> Master of Applied Bioengineering Certificate in Basic Bioscience More

Impact on existing programs at Northeastern

Chemical engineering may lose MS applicants if they are particularly interested in pharmaceutical engineering, but the focus is sufficiently different that it is not clear if the loss might be substantial. In addition, Bioengineering may see a loss in applicants for their MS program for those specifically interested in pharmaceutical-based engineering, but it is not clear that there is a substantial number of applicants as Bioengineering's program areas include cell and tissue engineering, biomechanics, and biomedical devices and bioimaging, which do not cross over into pharmaceutical engineering. We do not anticipate any loss of interest in Pharmaceutical Sciences or Biotechnology, as those programs do not have an engineering focus, and therefore have a sufficiently different market and program outcomes. However, these programs may see increased interest as students determine how their background and interests are aligned with engineering or the sciences.

4. EDUCATIONAL OBJECTIVES AND CURRICULUM

This section discusses educational objectives, course curriculum, admission criteria, and other requirements of the proposed MS program.

Admissions criteria and process

The admission criteria are:

- Differential equations or equivalent mathematics coursework
- BS degree in engineering, science, mathematics, or equivalent experience

- TOEFL for international students (Minimum 79)
- 3 letters of recommendation
- Personal statement

Applications for the program will be processed by the Graduate School of Engineering. The program director will review the applications and admit those that fulfill the admission standards. The admissions requirements of the program will be defined within the framework of policies set forth by the College of Engineering and the University Graduate Council.

Degree requirements

Credit hour requirements

The program requires a minimum of 32 SH, with 18 SH of core courses and 14 SH of group electives. The electives are grouped to allow for flexibility and depth. Of the elective courses, at least 3 SH must be from the approved engineering courses and at least 3 SH must be from the approved pharmaceutical sciences courses.

Degree Requirements	Semester Hours
Core courses	18 SH
Restricted Electives- Regulatory	3 SH
Restricted Electives- Quality/Statistics	4 SH
Restricted Electives - Depth	7 SH
Minimum semester hours required	32 SH

Core Courses

Students are required to take the following core courses (18 SH):

- **CHME 7600** Pharmaceutical Engineering I, 4 SH (new)
- **CHME 7601** Pharmaceutical Engineering II, 4 SH (new)
- **CHME 7602** Pharmaceutical Engineering Lab, 2 SH (new)
- **PHSC 5100** Concepts in Pharmaceutical Sciences I, 2 SH
- **PHSC 5102** Concepts in Pharmaceutical Sciences II, 2 SH
- **PHSC 7010** Pharmaceutical Sciences Laboratory, 4 SH

Restricted Elective Courses

At least 4 credits of courses in total of electives are required from Pharmaceutical Sciences (PHSC, PMST) and from Chemical Engineering (CHME). These course credits could come from any elective group, as appropriate.

Elective Group 1 - Regulatory (3 SH):

- **RGA 6000** Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation
- **RGA 6002** Introduction to Regulatory Compliance and Practice.

Elective Group 2 – Quality/Statistics (4 SH)

- **CHME 5185** Design of Experiments and Ethical Research
- **IE 6200** Engineering Probability & Statistics
- **IE 7280** Statistical Methods in Engineering
- **IE 7285** Statistical Quality Control
- **PHSC 6214** Experimental Design and Biostatistics

Elective Group 3 – Depth (7 SH)

- **CHME 5101** Fundamentals of Chemical Engineering Analysis
- **CHME 5160** Drug Delivery: Engineering Analysis
- **CHME 5179** Complex Fluids and Everyday Materials
- **CHME 5185** Design of Experiments and Ethical Research (if not selected above)
- **CHME 5631** Biomaterials Principles and Applications
- **CHME 5632** Advanced Topics in Biomaterials
- **CHME 5683** Introduction to Polymer Science
- **CHME 7330** Chemical Engineering Thermodynamics
- **CHME 7350** Transport Phenomena
- **PHSC 5300** Pharmaceutical Biochemistry
- **PHSC 5310** Cellular Physiology
- **PHSC 5500** Repurposing Drugs for Cancer Immunotherapies
- **PHSC 5555** Pharmaceutical Toxicology
- **PHSC 5560** Nanotoxicity
- **PHSC 5619** Mass Spectrometry in Drug Development
- **PMST 6250** Advanced Physical Pharmacy
- **PMST 6252** Pharmacokinetics and Drug Metabolism
- **PMST 6254** Advanced Drug Delivery Systems
- **PMST 6258** Advanced Pharmacokinetics and Toxicology

Minimum academic standards

There are no academic standards required in addition to the university requirements.

Requirements as applicable

All students in the program must complete a minimum of 32 semester hours of approved course work (exclusive of any preparatory courses) with a minimum GPA of 3.000.

Program assessment

Graduates of the program will have the knowledge and skillset required to work in the

pharmaceutical field, including the ability to:

- Analyze and design the engineering aspects of pharmaceutical development, operations and manufacturing processes.
- Describe the regulations and good manufacturing practices that are specific to the pharmaceutical industry.
- Communicate effectively within pharmaceutical engineering, in multidisciplinary teams, and between relevant regulatory and quality programs.

These outcomes will be assessed through coursework in the following courses, utilizing the University’s AEFIS accreditation management system:

Program Outcome	Supporting Courses
Analyze and design the engineering aspects of pharmaceutical development, operations and manufacturing processes.	CHME 5633 Pharmaceutical Engineering I, 4 SH (new) CHME 7634 Pharmaceutical Engineering II, 4 SH (new) CHME 7633 Pharmaceutical Engineering Lab, 2 SH (new)
Describe the regulations and good manufacturing practices that are specific to the pharmaceutical industry.	PHSC 7010 Pharmaceutical Sciences Laboratory, 4 SH CHME 7633 Pharmaceutical Engineering Lab, 2 SH (new) RGA 6000 Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation
Communicate effectively within pharmaceutical engineering, in multidisciplinary teams, and between relevant regulatory and quality programs.	CHME 7634 Pharmaceutical Engineering Lab, 2 SH (new) CHME 7633 Pharmaceutical Engineering II, 4 SH (new)

The program director, or designee, will review the assessment data and provide a summary of the feedback and suggested revisions to the faculty and the external advisory board. The faculty will vote on suggested changes to the program and these changes will go to the advisory board with the feedback for review. The external advisory board will review the feedback and suggestions for changes and provide further assessment of the proposed changes for consideration by the faculty.

5. RESOURCES

Faculty resources

There are faculty currently within Chemical Engineering and Pharmaceutical Sciences that are teaching substantively similar or the required core courses. The Chemical Engineering core Pharmaceutical Engineering courses must be developed and the expertise exists within the faculty to lead this initiative. Non-tenure track faculty or part time instructors from industry may also instruct the courses and develop appropriate content.

The elective courses are currently available in Pharmaceutical Sciences and Chemical Engineering. The courses from CPS and MIE were included with knowledge and approval of the college and department.

If the program grows beyond 1 section of courses, additional instructors may be needed, particularly for the labs, which is why the current cohort size is ~20 students per year.

Laboratory Space

The laboratory space in Chemical Engineering has needs for addition of equipment and potential modifications as the program grows. The current teaching laboratory in 001 Mugar has ample space for the addition of specialized equipment for the Pharmaceutical Engineering program, such as bioreactors and quality/characterization equipment. If the program grows beyond what can be done in the laboratory (~20 students per session), the laboratory may need to be expanded as 001 Mugar currently houses all teaching laboratories for the undergraduate Chemical Engineering program, so available time is limited.