

Descriptive Information:

I. Objectives:

The focus of the MS program in Pharmaceutical Systems Management (MSPhM) is to train and educate professionals in the pharmaceutical industry by providing them with the skills required to work in careers involving the analysis, planning, implementation, project management, and evaluation of all operational components in this highly sophisticated industry. The program is designed to prepare technical managers in the pharmaceutical industry, whose professional functions involve significant levels of technology development and application in areas such as drug discovery and clinical research, manufacturing operations, packaging and distribution, quality control and regulatory compliance, validation, and product management. Offered by the Department of Industrial and Manufacturing Engineering in collaboration with the Pharmaceutical Engineering program, this degree integrates expertise in systems engineering and management methods with pharmaceutical manufacturing, validation, research, and development processes.

The MSPhM program follows a systems approach and is designed to provide graduates with the skills and abilities to analyze and manage the increasingly complex pharmaceutical industry. These will include classical engineering management approaches and methods. The program will provide the intellectual climate and the necessary tools needed to prepare students for positions and career advancement within the pharmaceutical industry based on the rigorous technological requirements of this highly regulated work environment.

II. Need

A. Need for the Program

The program is designed for technical managers in the pharmaceutical industry, whose professional functions involve significant levels of technology development and application. These include the areas of drug discovery and clinical research, manufacturing operations, packaging and distribution, quality control and regulatory compliance, and product management. Many of these managers are looking for an advanced degree that provides a combination of managerial and technical training. The dual focus of this new program on a systems engineering and management approach combined with knowledge of pharmaceutical industry process meets this need.

New Jersey has one of the largest pharma concentrations in the world, and it is the backbone of our knowledge-based, high-technology economy. According to the *Star-Ledger* J&J (14,000 jobs), BMS (7,600 jobs), and Merck (7,500 jobs) rank among the top 25 largest employers in New Jersey. In 2006 New Jersey had 14% of the nation's total employment in the pharmaceutical industry as measured by the U.S. Bureau of Labor Statistics. This is an extraordinary concentration and powerful economic presence, that is second only to California. The job opportunities for technical managers in the pharmaceutical industry continues to be very strong and this degree will certainly increase their skill base and facilitate their career growth.

Today there are many challenges facing the pharmaceutical industry ranging from the need to lower development, manufacturing and distribution costs to competition between, branded, generic and OTC products. Large Pharmacy Benefits Manager organizations (PBMs) are expecting the pharmaceutical industry to achieve the same levels of productivity and efficiency as seen in the consumer products industry. Historically the pharma industry has enjoyed relatively high profit margins, but this has been declining steadily. As a result pharma companies are becoming more focused on cost containment and productivity improvement. The MSPhM curriculum focuses on this need.

B. Describe the relationship of the program to the following: institutional master plans and priorities.

The NJIT vision is to be a preeminent technological research university known for innovation, entrepreneurship, and engagement. Within this vision the university has identified a graduate growth initiative by creating industry focused programs. The pharmaceutical industry represents a sizeable industry in the state and NJIT has specifically identified the biological and biomedical fields as strategic growth areas. The proposed MSPhM fits into this overall strategy.

The 1981 Statewide Plan for Higher Education identified NJIT as New Jersey's comprehensive technological public research university, whose role, among others, is to offer advanced instruction and research in the applied sciences. The Statewide Plan also indicates that NJIT "has a special responsibility to provide technical services and assistance to the state and local government agencies and the industrial community by providing technical programs and undertaking research applied to New Jersey's needs." The pharmaceutical industry is a critical component of the state's economy, and the MSPhM program supports this industry by creating a technically trained workforce. The program will also foster the growth of groups and companies that develop new technologies in the associated fields.

The recent *Report of the Governor's Commission on Health Science, Education, and Training* recognized NJIT's role in "increasing interactions between the fields of biology, engineering, and computer science." It is expected that the proposed MPhM would enhance this role.

C. List similar programs within the state and in neighboring states. How does this program compare to those currently being offered?

There are three graduate programs in the Pharmaceutical Management area in NJ. Two of these (Rutgers and FDU) are MBA specializations while the third is in a school of technology. Brief descriptions of exemplary programs in pharmaceutical management that were evaluated in preparing the proposed program include the following:

- Rutgers University - MBA in Pharmaceutical Management - Provides MBA students with a specialization in either operations management or marketing specific to the pharmaceutical industry. The program is quite successful and is sponsored by at least 4 of the big pharma companies in NJ
- Stevens Institute of Technology – MS in Pharmaceutical Management offered by the Howe School of Technology Management. On the management side this program overlaps the proposed programs, but lacks the technology and processing content of the NJIT program.
- Drexel University – MBA in Pharmaceutical Management is designed to focus on the medical science and health policies subjects specific to the pharmaceutical industry.
- Boston University – MS in Pharmaceutical Management program focuses on policy issues and brings together expertise in infectious diseases, public health, demography, epidemiology, economics, and social sciences in an effort to improve the use of medicines.

Of these, the Stevens program is most closely aligned with the program proposed here, in that it has strong emphasis on systems engineering analysis and tools. The MBA based programs focus primarily on preparing graduates for advancement in a management track and the technology focus is quite limited. Our program is designed for individuals who are progressing in a technical management track. A key strength of MPhM will be its association with the Pharmaceutical Engineering (PHEN) program at NJIT. Appropriate technical curricula from PHEN is combined with our engineering management strengths to create a program that is distinguishable from the existing programs.

III. Students

A wide variety of jobs titles can be related to the MSPhM program. Typically these would be prefixed with titles such as Project Leader, Manager/Senior Manager, Associate Director or Scientist. The pharma industry is, by nature, a knowledge intensive place and most jobs have a creative and innovative component to them. The target student population would be individuals who have been working in a pharmaceutical related organization for two or more years, and are now looking for additional skills to further their progress their careers in the industry. Individuals working in a managerial track involved in functions that require a strong analytical and technical background would be candidates for this program.

Admission requirements will be a Bachelor's degree in an engineering, science, or some other technical discipline. The enrollment is expected to be a mixture of part-time and full-time students.

IV. Resources to Support the Program

A. Course Development

The program will require the development of at least two new courses. One of these is EM 6H1 Introduction to Healthcare Delivery Systems which is being developed for the MS Healthcare Systems Management program. In addition one of our existing courses (EM635) will be modified to better fit this program, and will be cross listed with PhEn. One new course (EM6P1) is planned specifically for this program. Brief descriptions of the new and modified courses are as follows:

EM 6H1 Introduction to Healthcare Delivery Systems – Definitions of the key healthcare entities; the healthcare workforce; facilities, problems, and costs of delivery; health planning, finance, role of government, alternative delivery models, and health policy. Presentations on healthcare service delivery from individual providers to complex financing and delivery organizations.

EM 6P1 Pharmaceutical Product Management –This course covers a number of product management topics as related to the pharmaceutical industry. Topics covered included market analysis, new product launches, sales forecasting, and supply chain and distribution planning. The interaction between all stages of the pharmaceutical value chain and their relationship to system efficiency and costs are examined in detail. The integration of regulatory issues including labeling and quality control are studied.

EM/PhEn 635 Management of Pharmaceutical Technology R&D – A systems approach to management of resources, and tasks needed for

pharmaceutical technology research and development. Identification, analysis, and evaluation of the operational characteristics and structure of the research laboratory and engineering office; functions of planning, organizing, staffing, direction, control, innovation, and representation; and planning and control theories, techniques, and current practices in R&D management.

B. Faculty

The department of Industrial and Manufacturing Engineering expects to add at least one new faculty member in the Engineering Management area. This faculty member would be active both in the existing MSEM program and the proposed MSpHM program. The program will also require the recruitment of qualified adjunct faculty who have practical experience in the pharmaceutical management field.

C. Libraries and Computing Facilities

This program will draw upon existing courses and upon the same supplemental literature that supports them and other related NJIT programs. Since healthcare management will be a relatively new topic at NJIT some new books and journals will need to be acquired, NJIT's Van Houten Library has a collection of more than 150,000 books and subscribes to more than 1,000 print periodicals and about 8,000 electronic journals.

The library has an adequate number of networked microcomputers that provide access to many bibliographical databases and full-text electronics journals. Workstations/computers are available for searching the World Wide Web as well as the library's on-line catalog; access to CD-ROM based databases and a variety of on-line journal databases. Journal and conference literature in engineering, science, management, architecture, and other subject areas is accessible through a variety of indexing and abstracting publications in both print and electronic format. Among the databases available on line are CompendexWeb (Engineering Index); Proquest Direct (articles on business, management and industry); Applied Science and Technology Index; and UnCover, a document delivery service that faxes articles within 48 hours.

As a technological research university, NJIT has excellent computing systems, networks and software to support this program. The campus' ATM network backbone connects more than 3,900 nodes in classrooms, laboratories, residence halls, faculty and staff offices, the library, and student organization offices. The network provides access to a wealth of shared information services. Some of these include high-performance computer servers providing CPU cycles for simulation and computational research, disks and data base management

systems for storage of large data sets, communications servers for electronic mail and document exchange, databases, digital journal subscriptions and a virtual "Help Desk." A virtual private network combined with Internet access, plus a large ISDN modem bank extend access to campus information resources to faculty, staff and students at home, work, or at any of the university's extension sites or elsewhere.

D. Classrooms and Laboratories

No new classrooms would be needed for this program.

V. Curriculum

MASTER OF SCIENCE IN PHARMACEUTICAL SYSTEMS MANAGEMENT (MSPhM)

Department of Industrial & Manufacturing Engineering

Requirements for the Program:

Admission Requirements:

- 4 year baccalaureate degree
Students applying for admission to this program will have a BS in an engineering discipline, science, or some other technical discipline.
- Undergraduate GPA of at least 2.80 on a 4.0 scale or equivalent

Bridge Program: Students who do not satisfy the admission requirements may take a suitable bridge program of appropriate courses. Such courses do not count towards the graduate degree.

Degree Requirements:

A minimum of 30 credits is required for the degree. Bridge courses, if any, will not count toward degree credits. The graduate curriculum consists of six core courses and four electives, as described in the curriculum below. The program relies significantly on knowledge and courses taught in the existing Engineering Management (EM) and Pharmaceutical Engineering (PhEn) programs at NJIT. The proposed curriculum is as follows: The electives may include a 3 credit masters project.

Curriculum:

Suggested Curriculum for MSPhM

Core Courses: (18 Credits)

EM 602	Management Science
EM 636	Project Management
IE 673	Total Quality Management
IE 618	Engineering Costs & Production Economics
PhEn 601	Principles of Pharmaceutical Engineering
PhEn 604	Validation and Regulatory Issues in the Pharma Industry

Technical Electives: (12 Credits – Select 4 from 11)

EM 634	Legal, Ethical and Intellectual Property Issues for Engg Mgrs
EM 635	Management of Pharmaceutical Technology R&D (to be cross listed as PhEn 635)

EM 637	Project Control
EM 6P1	Pharmaceutical Product Management
EM 6H1	Introduction to Healthcare Delivery Systems
IE 621	Systems Analysis and Simulation
IE 659	Supply Chain Engineering
MNE 601	Manufacturing Systems
PhEn 602	Pharmaceutical Facility Design
PhEn 605	Pharmaceutical Packaging Technology
HRM 601	Organization Behavior

With advisor approval, students will be able to select electives outside of the specified list, including a project or thesis option.