YORK COLLEGE
OF
THE CITY UNIVERSITY OF NEW YORK

PROPOSAL TO ESTABLISH A GRADUATE PROGRAM IN
PHARMACEUTICAL SCIENCE AND BUSINESS
LEADING TO THE
MASTER OF SCIENCE (M.S.) DEGREE IN PHARMACEUTICAL SCIENCE
AND BUSINESS

ANTICIPATED START DATE: FALL 2016

SPONSORED BY THE DEPARTMENT OF CHEMISTRY

APPROVED BY:
York College Curriculum Committee: May 6, 2014
York College Faculty Senate: May 13, 2014

College Representative: Dr. Marcia V. Keizs, President
York College of The City University of New York

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Professor and Program Director
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Email: dchakravarti@york.cuny.edu

Provost’s Signature: ________________________________
Provost’s Name: Dr. Panayiotis Meleties
<table>
<thead>
<tr>
<th><strong>Task 1: Institution and Program Information</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Institution Information</strong></td>
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<tr>
<td><strong>Institution Name:</strong></td>
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<tr>
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<td><strong>City:</strong></td>
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Specify campus(s) of the institution where program is offered, if other than the main campus:

*The name and code of the location(s) should reflect the information found on the Inventory of Registered Programs*

Specify any other additional campus(s) where the program is offered besides the ones selected above:

If any courses will be offered off campus, indicate the location and number of courses and credits:

If the program will be registered jointly with another institution, please provide the partner institution’s name:
# Program Information for New Programs

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<tr>
<th>Program Title:</th>
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<td><strong>Number of Credits:</strong></td>
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* If the program contains multiple options or concentrations that affect the number of program credits, list the total number of program credits required for each option:

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</table>

If program is part of a dual degree program, provide the following information:

<table>
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<tr>
<td><strong>Degree Award:</strong></td>
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</table>

## Section III. Contact Information

<table>
<thead>
<tr>
<th>Name of contact person</th>
<th>Dr. Panayiotis Meleties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of contact person:</td>
<td>Provost and Senior Vice President of Academic Affairs</td>
</tr>
<tr>
<td>Telephone</td>
<td>(718) 262-2806</td>
</tr>
<tr>
<td>Fax:</td>
<td>(718) 262-2786</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:pmeleties@york.cuny.edu">pmeleties@york.cuny.edu</a></td>
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</table>
### Task 2 - Proposed Program Information

Guidance for this task can be found by clicking here: [Department Expectations: Admissions, Academic Support Services, Credit for Experience and Program Assessment and Improvement](#)

Relevant Regulations for this task can be found by clicking here: [Relevant Regulations for Task 2](#)

#### a. Program format

Check all scheduling, format, and delivery features that apply to the proposed program. Unless otherwise specified below, it is assumed the proposed program may be completed through a full-time, day schedule. Format definitions can be found by clicking here: [Format Definitions](#)

<table>
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<tr>
<th>Feature</th>
<th>Description</th>
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<tr>
<td><strong>Evening</strong></td>
<td>All requirements for the award must be offered during evening study.</td>
</tr>
<tr>
<td><strong>Weekend</strong></td>
<td>All requirements for the award must be offered during weekend study.</td>
</tr>
<tr>
<td><strong>Evening/Weekend</strong></td>
<td>All requirements for the award must be offered during a combination of evening and weekend study.</td>
</tr>
<tr>
<td><strong>Day Addition</strong></td>
<td>For programs having EVENING, WEEKEND, or EVENING/WEEEKEND formats, indicates that all requirements for the award can also be completed during traditional daytime study.</td>
</tr>
<tr>
<td><strong>Not Full-Time</strong></td>
<td>The program cannot be completed on a full-time basis, e.g., an associate degree that cannot be completed within two academic years. Such programs are not eligible for TAP payments to students.</td>
</tr>
<tr>
<td><strong>5-Year baccalaureate</strong></td>
<td>Indicates that because of the number of credits required, the program is approved as a 5-year program with five-year State student financial aid eligibility.</td>
</tr>
<tr>
<td><strong>4.5 Year baccalaureate</strong></td>
<td>Indicates that because of the number of credits required, the program is approved as a 4.5-year program with 4.5-year State student financial aid eligibility.</td>
</tr>
<tr>
<td><strong>Upper-Division</strong></td>
<td>A program comprising the final two years of a baccalaureate program. A student cannot enter such a program as a freshman. The admission level presumes prior completion of the equivalent of two years of college study and substantial prerequisites.</td>
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<tr>
<td><strong>Independent Study</strong></td>
<td>A major portion of the requirements for the award must be offered through independent study rather than through traditional classes.</td>
</tr>
<tr>
<td><strong>Cooperative</strong></td>
<td>The program requires alternating periods of study on campus and related work experience. The pattern may extend the length of the program beyond normal time expectations.</td>
</tr>
<tr>
<td><strong>Distance Education</strong></td>
<td>50% or more of the course requirements for the award can be completed through study delivered by distance education.</td>
</tr>
<tr>
<td><strong>External</strong></td>
<td>All requirements for the award must be capable of completion through examination, without formal classroom study at the institution.</td>
</tr>
<tr>
<td><strong>Accelerated</strong></td>
<td>The program is offered in an accelerated curricular pattern which provides for early completion. <a href="#">Semester hour requirements</a> in Commissioner’s Regulations for instruction and supplementary assignments apply.</td>
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<tr>
<td><strong>Standard Addition</strong></td>
<td>For programs having Independent, Distance Education, External, OR Accelerated formats, indicates that all requirements for the award can also be completed in a standard, traditional format.</td>
</tr>
<tr>
<td><strong>Bilingual</strong></td>
<td>Instruction is given in English and in another language. By program completion, students are proficient in both languages. This is not intended to be used to identify programs in foreign language study.</td>
</tr>
<tr>
<td><strong>Language Other Than English</strong></td>
<td>The program is taught in a language other than English.</td>
</tr>
<tr>
<td><strong>Other Non-Standard Feature(s)</strong></td>
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Abstract

This proposal is a request to establish a Master of Science in Pharmaceutical Science and Business at York College of The City University of New York (CUNY) in the School of Arts and Sciences.

York College’s B.S. in Pharmaceutical Science launched in 2008 has over 150 majors. Graduates of the program have found employment opportunities in the regional pharmaceutical, cosmetics and related industries, federal and other government agencies or have been admitted to graduate and professional schools to continue their education. Complementing the B.S. in Pharmaceutical Science is the B.S. in Biotechnology and the traditional sciences (Biology and Chemistry) launched earlier with comparable numbers of majors and similar students’ employment and educational successes. Responding to educational and professional needs to graduates of these programs as well as regional and even global needs of the pharmaceutical and related industries and the government regulating agencies, York College is proposing a graduate program leading to the M.S. in Pharmaceutical Science and Business. The M.S. in Pharmaceutical Science and Business program has 36 graduate credits of which 24 credits represent the program common core and 12 credits are to be chosen from a menu of elective courses allowing students to tailor the program to their specific educational and professional needs. Creative and flexible scheduling will include evening, weekend and online courses to facilitate and support students already employed who are seeking to enhance opportunities for career advancement. Summer and winter courses will be offered as needed to promote timely completion of the program.

Executive Summary

Overview

York College of The City University of New York (CUNY) is proposing a program in Pharmaceutical Science and Business leading to a Master of Science (M.S.) degree. York is unique among CUNY colleges for offering a B.S. degree in Pharmaceutical Science. The undergraduate program launched in 2008 has been very successful with current enrollment of over 150 students. The proposed interdisciplinary M.S. program covering applied pharmaceutical science and business will be the first one in CUNY and one of the few in the tri-state area that would train students specifically for employment and career advancement in pharmaceutical and related industries. The business component will provide additional skill sets to support individuals in reaching and succeeding in managerial positions. With this program both CUNY and non-CUNY New York City metropolitan and regional students will have opportunities to enhance their professional careers in a field requiring highly educated workforce. This program will increase the collaboration between York College/CUNY and the Northeast Regional Laboratory of the U.S. Food and Drug Administration (FDA) located on the college’s campus. This program will provide students and graduates with educational pathways and career opportunities in a highly competitive global industry. Diverse employment opportunities exist for students graduating from the proposed graduate degree program.
This program is also in support of the NY Startup and CUNY 2020 initiatives by introducing a graduate degree, educational and professional opportunities in direct support of the targeted high technology regional industries.

Need for the Graduate Degree and Employment Opportunities

The U.S. Bureau of Labor Statistics has projected that around 30,000 new positions will be created for pharmaceutical scientists with M.S. degrees during the decade of 2008 to 2018. For the first time in the pharmaceutical industry’s history, the consensus forecast of worldwide prescription drug sales is set to exceed one trillion dollars by 2020, with an average growth of 5.1% per year from 2013 to 2020. The economic impact reflecting such growth is enormous for New York State where a large number of pharmaceutical manufacturing industries are located. Recent scientific and technological advances have introduced very sophisticated manufacturing, testing and analytical procedures which require highly skilled trained workforce that must also be educated on current federal and state laws and regulations applicable to the field, as well as the ethical issues involved.

Students with the proposed M.S. degree in Pharmaceutical Science and Business will have the knowledge and skills to seek and enhance their employment opportunities in the local, regional, national and global pharmaceutical, cosmetics, chemicals and related industries. Graduates of the program will have opportunities to be employed in areas such as drug discovery research; pharmaceutical formulations; package development; chemistry and manufacturing process improvement; physicochemical analysis of drugs, pharmaceuticals and cosmetics; clinical research; pharmacology and metabolism of drugs; drug safety and surveillance; regulatory affairs; quality control; quality assurance; validation; compliance; licensing; business development; etc. In addition, graduates of the M.S. program will be able to pursue further studies leading to M.D., D.D.S., Pharm.D., as well as other professional or Ph.D. degrees.

Key Curriculum and Admission Requirement

In this proposed two-year graduate program, students will complete a total of 36 credits toward the degree, of which 24 will be from the common Core Courses and 12 from the optional Elective Courses. Students are expected to choose elective courses based on their career goals, such as: Pharmaceutical Research and Development, Regulation of Pharmaceuticals, Pharmaceutical Management, etc. Full time students are expected to take 12 credits per semester. Courses in regulatory science and business administration will be offered online (WEB based) during the regular academic terms and the Summer and the Winter sessions as needed. Whenever possible, classes will be offered in the evening, weekend or on a single or two day(s) per week for the benefit of individuals working in the pharmaceutical and biotech industry in the New York metropolitan area.
Admission to the M.S. in Pharmaceutical Science and Business will be administered by a Graduate Admissions Faculty Committee. Applications for admission to the program will be consistent with the general CUNY graduate program application policy.

Faculty and Resources Needed

Appointment of two full time tenure track faculty members in the first five years will help meet increased instructional demands of the new program. Adjunct faculty will also be recruited as needed to meet the needs of the program and the academic departments. Instructional, laboratory and library resources are sufficient to support the introduction and development of the program. The external reviewer found the faculty to be qualified to teach the proposed courses and has noted that “three full-time and two part-time faculty members collectively have 40 years of Pharmaceutical industry and/or government (FDA) experience”.

Financial Considerations

The York College M.S. in Pharmaceutical Science and Business program is intended to be self-supporting from the revenue generated by the higher graduate tuition.

Program Start Date

The M.S. program in Pharmaceutical Science will be offered in the 2016-2017 academic year, starting in the Fall of 2016.

Conclusion

Throughout the entire process of preparing the proposal, the Missions of the College as well as the program have been the main focus. The external reviewer, Gail Baura, Ph.D., Director of Engineering Science and Professor, Loyola University, Chicago and an Accreditation Commissioner of the Accreditation Board for Engineering and Technology has noted in her report “the program will train M.S. students to enter the pharmaceutical and biotechnology industries as well as provide growth opportunities for persons with an undergraduate degree who are already working in this sector. Considering York’s diverse student population, this program will increase the diversity of the pharma/biotech workforce”. Introduction of the Master’s degree will allow continued success of CUNY’s unique Pharmaceutical Science program at York College. Consistent with CUNY’s Decade of Science effort to highlight and support science programs at the University, the proposed program will introduce a new interdisciplinary science degree program in a crucial growing field, very important for the NY State’s and NY City’s economy. This program supported by the York-FDA Partnership as the Program Advisory Board is expected to become a magnet program for NYC metropolitan and regional students.
I. Purpose and Goals

York College of The City University of New York (CUNY) is proposing a Master’s program in Pharmaceutical Science and Business. This program will lead to a Master of Science (M.S.) degree to be initiated in the Fall of 2016. Students who complete the M.S. in Pharmaceutical Science and Business will have the knowledge and skills to work not only in the flourishing, New York and tri-state pharmaceutical, cosmetics, chemicals and related industries, but nationally and globally as well. Graduates of this program will be employed in areas such as drug discovery; pharmaceutical formulations; package development; chemistry and manufacturing process improvement; physicochemical analysis of drugs, pharmaceuticals and cosmetics; clinical research; pharmacology and metabolism of drugs; drug safety and surveillance; regulatory affairs; quality assurance; compliance; licensing; etc. In addition, graduates of the M.S. program will be able to pursue further studies leading to M.D., D.D.S., Pharm.D. as well as other professional or Ph.D. degrees.

This interdisciplinary, applied science program will be the first M.S. in Pharmaceutical Science and Business in CUNY, and one of few in the tri-state area that would train students specifically for employment and career advancement in the pharmaceutical and related industries. With this program CUNY and other students will have opportunities to enhance their professional careers in a field with the most educated workforce. According to a recent report, in the field of Pharmacy, Pharmaceutical Science, and Pharmaceutical Science Administration, 52% of the employees have a B.S. degree, while 48% have M.S. or Ph.D. degree [1]. The average earnings by the pharmaceutical industry employees are 10% higher than corresponding specialties in other industries [2].

The Master of Science (M.S.) degree will allow York College to increase its collaboration and program development with the Northeast Regional Laboratory of the U.S. Food and Drug Administration (NRL FDA). The close collaboration started when the NRL FDA relocated to the York campus on May 2, 2000. York students participate as scholars and interns at the FDA each semester. York College and the FDA jointly sponsor workshops on Food Safety and Pharmaceutical techniques through York’s Continuing Education Division. The FDA scientific staff teaches lectures and laboratory sections at York. York College faculty members serve as science advisers at the FDA. York College and the FDA are engaged in many other important collaborations and events. Recently, York College signed a Memorandum of Understanding with the U.S. FDA’s Office of Minority Health aiming to expand the partnership to the field of public health, consistent with the agency’s enhanced mission. The introduction of the proposed M.S. in Pharmaceutical Science and Business will further highlight the existing partnership and support the college’s growth in this crucial area in which CUNY has only a B.S. program (at York College), but no M.S. or other graduate degree programs.

Graduates of the M.S. in Pharmaceutical Science and Business will have the training, knowledge and skills to seek and enhance their employment opportunities in the local,
regional, national and global pharmaceutical and related industries. They will be able to make contributions in areas such as drug research and discovery, manufacturing, medicine formulations, clinical evaluation, quality control, quality assurance, validation, compliance and regulatory affairs. The proposed program will become a vital educational pathway for the diverse CUNY student body (with students from more than 140 countries) and an industry with an increasingly global impact. As such, it will allow York College and CUNY to attract students not only from the New York City metropolitan area, but also from other regions and countries. Professionals from other countries (Nigeria, Uganda) participated regularly in the York-FDA continuing education training workshops. Instituting this program in New York City (York College/CUNY) will provide United States and international undergraduate and graduate students with opportunities to participate and visit the annual international industry exhibitions that take place at the Jacob Javits Center. One of the most notable among these is the INTERPHEX (International Pharmaceutical Expo) which is a single source for complete biopharmaceutical and pharmaceutical manufacturing solutions for processing all dosage forms for life-enhancing drugs. The Parenteral Drug Association is the premier sponsor of the event. It is the leading trade event to create innovative solutions that improve manufacturing and supply chain performance for pharmaceutical, biologic, generic and service provider professionals.

The proposed M.S. program in Pharmaceutical Science and Business will also increase the diversity of the current pharmaceutical workforce, in which minorities are severely underrepresented. This program will provide educational pathways and career opportunities to a highly competitive global industry for CUNY and non CUNY NYC metropolitan region students. One of the main goals and objectives of the National Science Foundation and one of the major challenges of the scientific community is to increase the number of minorities in scientific and technical fields. Providing suitable graduate educational pathways, such as the proposed program, will not only increase the number of minority undergraduate students in the field of science and technology, but prepare them for the highly competitive pharmaceutical industry and the global pharmaceutical workforce. This program is also in support of the NY Startup and CUNY 2020 initiatives by introducing a degree and graduate educational pathways in support of the targeted high technology industries.

II. Need for the Program

The United States Bureau of Labor Statistics projects that approximately 30,000 new positions will be created for pharmaceutical scientists with M.S. degrees during the decade of 2008-2018. Pharmaceutical and medicine production is among the fastest growing manufacturing industries. Unlike many other industries, this industry sector is not highly sensitive to changes in economic conditions. Even during periods with high unemployment, work is relatively stable in this industry.

The recent and projected growth of the industry is driven not only by scientific and technological advances in traditional disciplines, such as biology, biochemistry,
chemistry, and physics, but also in the newly established disciplines like biotechnology, nanotechnology, and bioinformatics among others. The scientific and technological progress has resulted in the discovery and introduction of numerous new medicines and other therapeutic procedures, with many more at various stages of discovery and clinical trials. The new medications not only address treatment of diseases, they are also designed for preventive or routine healthcare. These go far beyond vaccines to “lifestyle drugs” that treat symptoms of non-life threatening conditions, from aging to genetic predisposition. More than three billion prescriptions are processed every year. The growing number of aging people, combined with the need of preventive medicines and vaccines as the population grows, and the popularity of lifestyle drugs and related products explain the anticipated growth of the industry.

There are approximately 300,000 people employed in pharmaceutical and medicine manufacturing nationwide [5]. Six out of ten of these employees hold B.A., B.S. or higher education and professional degrees (M.A., M.S., M.D., and Ph.D.) [2]. On average, their earnings are much higher (10-15%) than other manufacturing jobs [2]. The recent scientific and technological advances have introduced more sophisticated manufacturing, testing and analytical procedures that require highly skilled and trained workforce that must also be educated on current federal and state laws and regulations applicable to the field, as well as be aware of ethical issues pertaining to the applications of advances in research. In the United States, the pharmaceutical and medicine manufacturing industry is mainly concentrated in a few states of which California, New Jersey, New York, Pennsylvania and Massachusetts are the most important ones. Currently approximately 55,000 people are employed in pharmaceutical and medicine manufacturing in the New York State, 65,000 in New Jersey and almost twice as many in California [6]. Pharmaceutical and medicine manufacturing is the only industry in New York that has been growing consistently during the last 25 years, even during periods of economic stagnation and recession [7]. In the period 2000-2003, 2,000 jobs were added in the New York State pharmaceutical industry despite a national recession [6]. Projections estimate that in the next decade approximately 7,000 new jobs will be added to the industry workforce. In addition, the indirect and induced benefit for New York State is equivalent to another 55,000 employment positions bringing the total benefit to 110,000 jobs [6]. Based on EvaluatePharma’s coverage of the world’s leading 4,800 pharmaceutical and biotech companies, for the first time in the pharmaceutical industry’s history, the consensus forecast of worldwide prescription drug sales is set to exceed one trillion dollars, reaching $1,017 billion by 2020, equating to an average growth of 5.1% per year from 2013 to 2020 [8].

During 2008, the biopharmaceutical industry estimated that it paid an average salary of $96,563 to the 650,000 people it employs, and that its direct contribution to GDP was $114.6 billion – approximately three and a half times the average per sector for the rest of the U.S. economy [9]. In 2003, the total contribution of the industry to New York’s economy was estimated to be $18.1 billion with $3.3 billion in direct employee wages [6]. The 7,000 new industry positions predicted for the last decade would have created an additional 7,000 positions in other supportive industries, thus increasing the overall contribution to the State’s economy [6]. At the median, Pharmacy, Pharmaceutical
Sciences, and Administration majors earn between $80,000 and $120,000, and this group is ranked second among the top 10 majors with the highest median earnings\textsuperscript{[1]}. Research from the Federal Reserve Bank of Cleveland shows that the median pay for those with a bachelor’s plus a master’s, doctorate or professional degree, is approximately 30 percent higher than that for workers with just a bachelor's degree\textsuperscript{[10]}.

Approximately two thirds of New York State’s pharmaceutical industry is located within driving distance from the metropolitan New York City area (Nassau, Suffolk, Rockland, and Westchester in New York and Bergen counties in New Jersey). Many global pharmaceutical companies have their headquarters in Manhattan and manufacturing facilities within the metropolitan area. Additional employment opportunities for graduates of the proposed program exist in neighboring New Jersey, which is also within close proximity of the metropolitan New York City. Consistent with CUNY’s \textit{Decade of Science} effort to highlight and support science programs at the University, the proposed program will introduce a new interdisciplinary science degree program in a crucial growing field for the State’s and City’s economy. This proposal will also introduce the first standalone graduate science degree program at York College. This program supported by the York-FDA Partnership will become a magnet program for NYC metropolitan and regional students. This will provide them with competitive education and training for rewarding professional careers or towards graduate and professional education programs. Further, it will also provide curriculum support for graduate research in cooperation with the FDA facility located on campus.

According to MedTRACK, an on-line Research Tool for Biomedical Intelligence, 1,274,095 people work for the top 20 Pharmaceutical/Biotechnology companies ranked according to their number of employees. An astonishing number of 14,834 unique drugs are currently under development or awaiting regulatory approval\textsuperscript{[7]}. The United States is the world’s largest market for pharmaceuticals and is the world leader in biopharmaceutical research. U.S. firms conduct 80% of the world’s research and development in biotechnology and hold the intellectual property rights to a large number of new medicines. The markets for biologics, over-the-counter (OTC) medicines, and generics show the most potential for growth and have become increasingly competitive. Biologics accounts for a quarter of all new drugs in clinical trials or awaiting Food and Drug Administration approval. The OTC market growth is driven by an increase in the aging population as well as consumer trend\textsuperscript{[11]}. EvaluatePharma finds that worldwide pharmaceutical R&D totaled $137 billion in 2013 representing an increase of 2.1% on the previous year when R&D spending, in dollar terms, actually declined. Looking forward, R&D spending is forecast to grow at a rate of 2.4% per year, which contrasts with the compound annual growth rate of 3.4% between 2006 and 2013. Over the past ten years, the pharmaceutical industry invested over $1.2 trillion in R&D\textsuperscript{[8]}.

III. Students

The proposed M.S. program in Pharmaceutical Science and Business will become an engine for recruiting qualified students from many institutions and undergraduate programs. The well-known professional and career opportunities and the increasing need
for pharmaceutical and related products will attract qualified college graduates and professionals. Out of state and international students meeting York’s and CUNY’s admission criteria will also be accepted in the program.

Graduates of CUNY and non-CUNY colleges will be eligible for admission to the program. The design of the curriculum articulates effectively with Chemistry and Biology as well as CUNY York’s unique Biotechnology and Pharmaceutical Science degree programs. A B.S. degree program in Pharmaceutical Science at York College launched in 2008 by the Department of Chemistry currently has over 150 students. Similarly the unique B.S. in Biotechnology program at York College has close to 70 students as well. These unique B.S. programs are integrated and articulated with corresponding associate degree programs at Bronx Community College, Queensborough Community College and Kingsborough Community College. Dual Joint degree programs are also being developed and facilitated in their implementation by the restructuring of the general education program. Therefore the proposed graduate program becomes an opportunity for all qualified CUNY students. The proposed program will also enhance existing science programs at York College. These include the traditional B.A./B.S. in Chemistry, Biology, Physics and Geology and innovative programs such as Environmental Health Science, Biotechnology and Pharmaceutical Science. Enrollment in Biotechnology, Biology, Chemistry and Pharmaceutical Science at York College from Fall 2000 through Fall 2013 is shown in the Table 1.

**Table 1**: Enrollment in Biotechnology, Biology, Chemistry and Pharmaceutical Science at York College from Fall 2000 through Fall 2013.

<table>
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<th>Semester</th>
<th>BIOTECHNOLOGY</th>
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<td>Fall 2008</td>
<td>8</td>
<td>293</td>
<td>43</td>
<td>N/A</td>
</tr>
<tr>
<td>Fall 2009</td>
<td>10</td>
<td>380</td>
<td>52</td>
<td>11</td>
</tr>
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<td>Fall 2012</td>
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<tr>
<td>Fall 2013</td>
<td>71</td>
<td>440</td>
<td>35</td>
<td>161</td>
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<tr>
<td>TOTAL</td>
<td>351</td>
<td>4151</td>
<td>538</td>
<td>557</td>
</tr>
</tbody>
</table>
N/A = Not Applicable.
The “BIOLOGY (All)” category includes all of the Biology programs/majors: Biology BA, Biology BS, Biology, Biology Child ED, and Biology Education 7-12. The “CHEMISTRY (All)” category includes all of the Chemistry programs/majors: Chemistry BA, Chemistry BS, Chemistry, and Chemistry Education 7-12. Some of these subcategories are due to recoding and renaming over the years.
Prepared by the Office of Institutional Research and Assessment, York College: on 6 May 2014.

Students completing the B.S. degree in life sciences and closely related programs with a minimum GPA of 3.0 will be considered for admission to the Masters of Science degree in Pharmaceutical Science and Business. A program admissions committee will review admission applications every Fall and Spring semesters following CUNY’s established policies. Students who meet the admissions criteria from other York, CUNY and non-CUNY science programs will also be eligible to apply for admission to this M.S. program. The design and curriculum of the proposed M.S. program with emphasis on regulatory affairs and current industry practices will make the program attractive to current industry employees who seek to enhance their careers. The York-FDA Partnership will ensure that the program meets its objectives and is maintained abreast of development and regulatory changes in the field. Accessibility of the York campus by major highways, Long Island Rail Road and the New York City subway/bus system, afternoon-evening course scheduling and innovative on-line and hybrid course offerings (when possible) will increase enrollment and facilitate program participation. It is expected that international students interested in the field will also be admitted in the program (funded by their governments or their employers). The location of York’s campus between two major airports (John F. Kennedy and LaGuardia) and in the affordable diverse southeast Queens’ communities will also help the program’s growth.

Additionally, the proposed M.S. program in Pharmaceutical Science and Business is consistent with the NYS-CUNY 2020 challenge grant program aiming to support and promote regional economic growth. York College participated in the recent CUNY 2020 with three applications to expand its health science and environmental science programs, two in partnership with other colleges. York’s CUNY 2020 partnership with Queensborough Community College has been funded to promote health services and training for the Queens community. Also, York College is actively participating in the NY StartUp program, as one of five CUNY colleges and the only one in the borough of Queens. York College is seeking qualified partners following the plan by Governor Cuomo’s initiative to jump-start the state’s economy by pairing SUNY and CUNY colleges with newly formed and technology-oriented firms. The program’s goal is to generate new jobs by offering qualifying companies an opportunity to operate 100% State tax-free for ten years. The tax exemption includes that for new employees from their state income tax liability.

Diverse employment opportunities exist for students graduating from the proposed curriculum. These may be positions in Pharmaceutical and Biotechnology companies or
as consultants in the life sciences field, including Pharmaceutical, Biotechnology and Medical Devices. Opportunities also exist in professional societies, government and international agencies. Suitable positions include those in: business development, financial planning and analysis, revenue forecasting, pricing, cost and margin analysis, contract negotiations, budgeting, long range strategic planning, accounting, business systems consultation, project management, risk management, product development, clinical trials, commercialization, preparation and filing of Investigational New Drug (IND) / Investigational Device Exemption (IDEs) / Pre-Market notifications (510k) / Biological License Applications (BLA) / New Drug Applications (NDAs) and related documents, database management that includes electronic cataloging and storage capabilities of INDs / NDAs / IDEs / 510ks / PMAs packages, Post Marketing Surveillance for NDAs and PMAs, suitability assessments of data to support regulatory filings, auditors for clinical trials, preclinical trials, assay development and validation, product manufacturing that includes compliance with current Good Manufacturing Practices (cGMPs), current Good Clinical Practices (cGCPs) and current Good Laboratory Practices (cGLPs), etc.

A. Student Recruitment

The Office of Academic Affairs and the Departments of Chemistry, Biology, and Business and Economics, in collaboration with the Admissions Office at York will develop and establish outreach programs and recruitment events to promote the proposed program. Qualified graduates of the unique B.S. in Pharmaceutical Science and Biotechnology programs, as well as other traditional chemistry and biology programs will be actively recruited. Recent (Fall 2013) enrollment data indicate that there are close to 1000 students encompassing Pharmaceutical Science (161), Biotechnology (71), Biology (440), Chemistry (35), and Clinical Laboratory Science/ Medical Technology (257), who potentially can consider the proposed graduate program. In addition, the program will be appropriate for current industry employees wishing to enhance their careers and their employment opportunities. Also, the close coordination and articulation of the proposed program with undergraduate programs and dual joint degree programs and articulation provide educational pathways to CUNY community college STEM students. York admission officers and faculty will visit CUNY colleges to make presentations to student science clubs, or during transfer days, career and graduate school days and other events to recruit and provide information about the program and professional and career opportunities in the field. Also, program presentations and information will be disseminated during professional conferences and through human resources offices and outreach to regional industry employees.

In a survey carried out on the proposed program with 62 students, approximately 70% indicated that they considered the location and the low cost of the program to be very attractive. Almost half of them (39%) were extremely likely to seek admission to the program.
B. Student Advisement

Students interested and admitted in the M.S. program will be advised by qualified faculty and graduate advisors assigned to the program. In addition to the faculty and other student advisors that students will meet during their undergraduate studies, department and program faculty advisors will be assigned to provide on-going year round advice to students about program requirements, careers and professional opportunities. Student seminars and other presentations will introduce students and faculty to current industry topics and highlight career opportunities. Student and faculty presentations at CUNY, local, regional, national and even international conferences will highlight the program activities and contributions. Feedback from students will help the faculty and the Department to adjust and improve course scheduling and expand student and faculty development activities. Professor Deb Chakravarti, Director of the York College-US Food and Drug Administration (YC-FDA) Partnership will be the main faculty advisor and advisement coordinator.

C. Enrollment Estimates

The projected enrollment for this M.S. degree program in Pharmaceutical Science and Business is expected to be at least 5 full time and 20 part time graduate students who will be admitted to the program during the first academic year. During the following years, a comparable number of students will also be admitted. A detailed enrollment projection for the M.S. program during the first five years is shown in Table 2. Full time students in the program will have an average of 12 credit hours per semester and part timers will have an average of 6 credit hours per semester. With this course load, full time students should be able to complete the degree requirements in approximately one and half / less than two academic years. Enrollment in courses offered during winter and summer sessions will accelerate their graduation as well.

Table 2: Five-year enrollment projections for the M.S. in Pharmaceutical Science and Business.

<table>
<thead>
<tr>
<th>Academic Year</th>
<th>Full Time</th>
<th>Part Time</th>
<th>Total Number</th>
<th>FTEs/Academic Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-2017</td>
<td>5</td>
<td>20</td>
<td>25</td>
<td>30</td>
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<tr>
<td>2017-2018</td>
<td>9</td>
<td>35</td>
<td>44</td>
<td>53</td>
</tr>
<tr>
<td>2018-2019</td>
<td>9</td>
<td>35</td>
<td>44</td>
<td>53</td>
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<td>2019-2020</td>
<td>9</td>
<td>35</td>
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</tr>
<tr>
<td>2020-2021</td>
<td>9</td>
<td>35</td>
<td>44</td>
<td>53</td>
</tr>
</tbody>
</table>

The York College-FDA Continuing Education Professional Development Workshops of years were always oversubscribed. More than 30 industry employees participated in each of them. In the one held in May 2006, there were 33 participants from major
pharmaceutical manufacturers, such as, Astra Zeneca, Monsanto and Eli Lilly as well as participants came from countries such as Uganda and Nigeria.

This new Master’s program will be marketed and advertised through the College’s and CUNY’s website, distribution and mailing of flyers, and posters describing the program to undergraduate academic institutions, giving talks about the program at New York City area colleges, etc. The outcomes will be tracked and success of the program will be measured from the enrollment numbers, the rate of graduation and placement of students. With the goal of providing the highest quality education to our students, the essential learning outcomes of the proposed program has an important task as part of its mission to prepare students for responsible positions in pharmaceutical and biotechnology industry in research and development, regulatory affairs and management.

D. Admission Requirements

Admission to the M.S. in Pharmaceutical Science and Business will be the responsibility of the program Graduate Admissions Faculty Committee. Applications for admission to the program will be consistent with the general CUNY graduate program application policy. Eligible students will submit applications directly to the York College Admissions office or through CUNY Admissions Office for review by the York College Graduate Admissions Faculty Committee for the program. Eligible applicants will have degrees in Pharmaceutical Science, Biotechnology, Biology, Chemistry, Clinical Laboratory Science/Medical Technology or other closely related disciplines. Qualified applicants for the M.S. program must have by the time of their application a minimum GPA of 3.0 and strong support by their professors or their employer (two letters of recommendation). Their application to the program will also include a statement describing their career objectives (not more than 1,500 words). To fulfill graduate course prerequisites, undergraduate science students (Chemistry, Biology, Physics or others) who apply to the M.S. program in Pharmaceutical Science and Business may have to meet additional course requirements depending on their background, such as undergraduate level Biochemistry or Pharmaceutical Science courses. The program Graduate Admissions Faculty Committee will determine such requirements on an individual case by case basis. Students will be advised and offered guidance of appropriate course offerings within York or other colleges to fulfill the graduate course prerequisites. GRE score is not a requirement for admission, but good GRE scores will be preferred.

Students not meeting the formal admissions criteria may appeal to the Graduate Admissions Faculty Committee to be conditionally admitted as non-matriculated. Nevertheless these students must have a B.A. or B.S. science degree from an accredited college or university and very strong support of their professors or employers (at least three letters of recommendation).

Student anticipation and demand projects a healthy program enrollment. Many of York College’s B.S. (Major: Pharmaceutical Science) graduates have been requesting a Masters in Pharmaceutical Science Program. In addition, a flexible, cost effective and
high quality Master’s Degree program offered in the Borough of Queens is expected to be very attractive as well as greatly beneficial to the large number of personnel employed in the Pharmaceutical industry in the tri-state area.

IV. Proposed Curriculum

The Pharmaceutical industry operates in a very complex manner. Drugs and other pharmaceuticals, such as vaccines, are discovered and developed through application of innovative science and technology. Following clinical trials, development of properly controlled manufacturing and quality assurance and quality control processes as well as approvals by regulatory authorities, these are distributed through a complex supply chain that is highly regulated by a complicated array of ever evolving regulations. This huge industry is constantly growing and globalizing due to continually increasing worldwide demands for drugs and pharmaceuticals. A number of Professional Science Master’s (PSM) as well as MBA programs have emerged in the past decade with curriculum embracing business management together with the technical knowledge required to compete and excel in this scientific field. Persons with adequate knowledge of the pharmaceutical business along with technical backgrounds tend to succeed and are highly sought after by the industry. Because of the complexity of the pharmaceutical industry, there is a great need for scientists who know the technology to acquire management skills.

The establishment of a Master of Pharmaceutical Science and Business Program at York College of The City University of New York that combines Pharmaceutical Science with Business Administration skills required for competitive and successful employment is being proposed. This is a joint effort involving the School of Arts and Sciences and the School of Business and Information Systems of York College. The program will draw heavily on the expertise and experience of faculty in Pharmaceutical Science, Biotechnology and Business Administration. York College is unique among CUNY colleges in offering a B.S. degree with major in Pharmaceutical Science. The first batch of 3 students with a Pharmaceutical Science B.S. graduated in 2012 followed by 8 more in 2013. This is about a year or two earlier than that expected based on initiation of student recruitment. At least 4 of these students are currently pursuing graduate studies at other institutions. The proposed Master’s curriculum supplements core business topics with specific scientific and technical knowledge along with the emerging regulatory, legal and financial challenges of the pharmaceutical sector. This would allow students to be employed in a wide variety of positions in Pharmaceutical, Biotechnology, Biomedical as well as other parts of the rapidly changing industry. Larger pharmaceutical companies are able to recruit personnel with an array of interests, from R&D and drug delivery management to corporate finance, business strategy development, project management and marketing. Experience across the board is highly sought after in a startup or a smaller Pharmaceutical/Biotechnology company as well.

The needs for this specific Master’s program were identified by following emerging trends in introduction of similar programs at a number of major universities. This is highlighted in a recent article entitled “MBA Programs in Pharmaceuticals: Beyond the
Lab - How MBA programs can help students tap into a wide range of roles in both big and small Pharma firms. The article also provides a list of related programs at major institutions around the world. In addition, the success of the first professional science master's degree in this area, Master of Bioscience (MBS) offered by the Keck Graduate Institute of Applied Life Sciences of The Claremont University Consortium, that combines business and science using a team-based applied curriculum is well documented. Also, enquiries received from interested students were considered in identifying the need for the program.

Students should develop high levels of knowledge, competence and analytical skillsets required in the pharmaceutical industry.

- Students should develop strong problem solving, creative thinking, management and leadership skills, together with high ethical standards and be able to generate maximum benefits for the society.
- Students should acquire an understanding of the current methods of drug discovery, development and manufacturing, FDA approval and marketing processes.
- Students should participate in appropriate professional and scientific organizations.

Program Description

The goal of the proposed Master of Pharmaceutical Science and Business Program at York College will be to prepare students for responsible positions in pharmaceutical and biotechnology industry management. Opportunities for students successfully completing the program include careers with Biotechnology and Pharmaceutical companies, professional societies, government and international agencies. In this proposed two-year graduate program, students will complete a total of 36 credits toward the degree, of which 24 will be from the common Core Courses and 12 from the optional Elective Courses. Full time students will take a minimum of 12 credits per semester.

As part of this program, three to four courses in regulatory science and business administration will be developed as online (WEB) courses. This would allow the courses to be offered during the Summer and the Winter sessions for students who would like to have a semester off due to personal or job related issues. Whenever possible, classes will be scheduled in the evening or on a single or two day(s) per week or over the weekend for the benefit of individuals working in the pharmaceutical and biotech industry in the New York metropolitan area.

Students are expected to choose elective courses based on their career goals, such as: Pharmaceutical Research and Development for individuals who would like to pursue or enhance a career in the area of drug discovery, biotherapeutics, pharmaceutics, product formulation, manufacturing process development, design of clinical trials, etc. Regulation of Pharmaceuticals for individuals who would like to pursue or enhance a career in the area of US or international regulatory affairs, writing and submission of regulatory applications, compliance, quality assurance, process validation, product labeling, quality control and design of clinical trials related to the regulation of pharmaceuticals, etc.
Pharmaceutical Management for individuals who would like to pursue or enhance a career in pharmaceutical product management, project management, supply chain management, marketing, etc.

Master of Pharmaceutical Science and Management Program Core Courses (24 credits)

1. Pharmaceutical Discovery and Development (3 cr.)
2. Pharmaceutical Discovery and Development Techniques (3 cr.)
[The laboratory courses may be substituted with other elective courses for students with a minimum of 1 year laboratory experience in industry.]
3. Advanced Pharmacology (3 cr.)
4. Advanced Biostatistics (3 cr.)
5. Foundations of Regulatory Affairs (3 cr.)
6. Pharmaceutical Ethics and Intellectual Property Management (3 cr.)
7. Pharmaceutical Industry and Business (3 cr.)
8. Pharmaceutical Science and Business Capstone Project (3 cr.) [This course is in lieu of a Master’s Thesis and Comprehensive Exam.]

Master of Pharmaceutical Science and Management Program Elective Courses (12 credits)

Elective courses are 3 credits each; total requirement is 4 courses (12 credits) to be chosen from the following:

1. Biotherapeutics
2. Advanced Pharmaceutics
3. Special Topics in Pharmaceutical Discovery and Development
4. Pharmaceutical Quality Assurance, Process Validation and Controls
5. Design of Clinical Trials
6. Advanced Toxicology
7. International Regulatory Affairs
8. Pharmaceutical Product Labeling
9. Writing and Submission of Regulatory Applications
10. Pharmaceutical Supply Chain Management
11. Pharmaceutical Marketing
12. Pharmaceutical Product Management
13. Pharmaceutical Project Management

V. Faculty

The proposed M.S. program will be housed in the Department of Chemistry at York College with faculty participation from the Departments of Biology, and Business and Economics. Currently there are eleven (11) full time faculty members appointed in the Department of Chemistry. The research interests and scholarship of the Chemistry and Biology faculty are mainly interdisciplinary with biomedical applications. In addition, the Department of Chemistry appoints approximately twenty adjunct faculty members every term to meet its instructional obligations. The departments of Biology, and Business and Economics have similar numbers of full time and adjunct faculty. Several
scientists from the U.S. FDA located on the York campus have also been serving as adjunct faculty for the Department and the College and as mentors for York FDA student interns.

Dr. Deb Chakravarti the current YC-FDA Partnership Director, has been designated the Director of the proposed M.S. program. Dr. Chakravarti joined the Chemistry faculty at York College after gaining extensive industry experience at Wyeth Vaccines (now Pfizer) as well as faculty experience as a research scientist and faculty at the Keck Graduate Institute of Applied Life Sciences. As the Arnold and Mabel Beckman Professor at the Keck Graduate Institute of Applied Life Sciences in Claremont, California, he helped establish the first curriculum devoted to creating a best-in-class professional science master’s program [13]. With his experience, Dr. Chakravarti will spearhead the program development and coordinate its initial implementation. He will be assisted by Drs. Daniele Musumeci, Adam Profit and Kang Bok Lee.

Dr. Musumeci recently joined the college after years of experience as a research scientist at the University of Wisconsin, New York University, and Wyeth Pharmaceuticals, specializing in solid-state pharmaceutical chemistry. Dr. Profit, who worked at Merck’s assay development and high throughput screening division, is a 10-year faculty veteran specializing in the synthesis of peptides and peptidomimetic compounds. Dr. Lee’s areas of expertise include operations research, management science and supply chain management. At Rutgers Business School, he worked for a project on Pharmaceutical supply chain management with the US Department of Homeland Security.

Dr. Chakravarti will be teaching Foundations of Regulatory Affairs; Biotherapeutics; Pharmaceutical Quality Assurance, Process Validation and Controls; and Writing and Submission of Regulatory Applications. Dr. Musumeci will teach Pharmaceutical Discovery and Development; Pharmaceutical Discovery and Development Techniques; and Advanced Pharmaceuticals. Dr. Profit will handle Advanced Pharmacology as well as Advanced Toxicology. Dr. Emmanuel Chang will teach Pharmaceutical Ethics and Intellectual Property Management. Implementation of the Advanced Biostatistics course will be assigned to Dr. Laura Beaton of the Department of Biology, who has taught the undergraduate biostatistics course for years. Dr. Dilcia Granville of the U.S. FDA will teach International Regulatory Affairs and Pharmaceutical Product Labeling as an adjunct faculty. Dr. Bulbul Chakravarti, who has both academic and industry experience (Wyeth Vaccines, now Pfizer) and has taught in the undergraduate Pharmaceutical Science program at York College, will teach Special Topics in Pharmaceutical Discovery and Development. Design of Clinical Trials will be taught by an adjunct faculty with appropriate expertise. Dr. Kang Bok Lee from the Business and Economics Department will be in-charge of Pharmaceutical Industry and Business; Pharmaceutical Supply Chain Management; Pharmaceutical Marketing; Pharmaceutical Product Management; and Pharmaceutical Project Management.

Coordination of the Pharmaceutical Science and Business Capstone Project will be the responsibility of Dr. Chakravarti and will draw upon the expertise of a number of
faculty members. In addition to the course instructors stated above, Drs. Ruel Desamero, Lawrence Johnson, Stephen Fearnley, Jong Lee, Yolanda Small and Catherine Foster of the Department of Chemistry, and Drs. Louis Levinger and Ivica Arsov of the Department of Biology with similar expertise will contribute. Potential research/internship sites will be the laboratories of science faculty, collaborating FDA scientists and other companies. Dr. Olajide Oladipo, Department Chair of Business and Economics, will help coordinate the business and management courses. Dr. Ruel Desamero, Chair of the Department of Chemistry will handle the overall coordination of the MS program.

VI. Program Advisory Board

The Advisory Council of the York College-FDA Partnership will also serve as the advisory board of the proposed program. Current members of the York-FDA Advisory Council include the York President (or her designee), the York Provost and Senior Vice President of Academic Affairs (or his designee), the York Vice President of Administration and Finance (or his representative), the York Dean of Arts and Sciences, Dr. Ivica Arsov (Biology, FDA Faculty Science Advisor), Dr. Deb Chakravarti (Chemistry, York-FDA Partnership Director), Dr. Ruel Desamero (Chair of the Department of Chemistry), Mr. Charles Becoat (Deputy Regional Director, Northeast Regional Office, FDA), Mr. Michael Palmieri (Director, NRL, FDA), Mr. Kent Hermann (Deputy Director, NRL, FDA), Mr. Ronald Pace (District Director, New York District, FDA), Dr. Dilcia Granville (Public Affairs Specialist, FDA), Mr. Carlisle Towery (President, Greater Jamaica Development Corporation), Dr. Ansil Dyal (Interpharm), Dr. Michael Verlander (President, PolyPeptide Laboratories), Dr. John Eldridge (Chief Scientific Officer – Vaccines, Profectus Biosciences and former Vice President of Research at Wyeth Vaccines/Pfizer) and Mr. Steve Roberts, Jr. (Retired Assistant Vice President, TD Bank).

The Advisory Board has been created to marshal community and industry support for the YC-FDA Partnership and to spearhead the development of related programs and activities. The YC-FDA continuing education training workshop for employees of the pharmaceutical industry is one of the activities that have been supported. Employees from organizations such as Astra Zeneca, Merck, Pfizer, Johnson & Johnson, Sun Pharmaceuticals, Monsanto, Wyeth Pharmaceuticals and many others participated over the years in the training workshops. The development of the proposed program is one of the main objectives of the Advisory Board that will support further development and strengthening of the YC-FDA Partnership. The members of the Board are committed to help the faculty and the program director to set up additional internships, scholarship opportunities, and job placement. Government and industry members of the Board will be instrumental on advising the program on new developments, techniques and policy changes that need to be incorporated to maintain the program current and relevant.
VII. Cost Assessment

A. Faculty

The proposed M.S. program will be housed in the Department of Chemistry at York College. Currently there are eleven full time faculty members appointed in the department. The research interests and scholarship of the Chemistry and Biology faculty are mainly interdisciplinary, with biomedical applications. In addition, the Department appoints approximately twenty adjunct faculty members every term to meet its instructional obligations. With the appointment of the new faculty members, adjunct faculty needs will be reduced. Several scientists from the Northeast Regional Laboratory of the FDA have also been serving as adjunct faculty for the Department and the College and as mentors for York FDA student interns. As the program is implemented, in order to maintain and sustain the fulltime instruction levels, additional fulltime faculty lines will be needed. Appropriate faculty searches will be authorized (at least two in years two and three of the program) with the needed expertise.

B. Support Staff

The Departments of Biology, Chemistry, and Business and Economics employ 6 college laboratory technicians, three office administrative assistants and several part time administrative assistants. They will provide support as needed for the implementation of the proposed program and courses. A part time office assistant provides clerical support for the York-FDA Partnership, which includes student internship placements and support in the organization of the York-FDA training workshops. One of the part time administrative positions (York-FDA) will be converted to a full time position to meet the additional administrative needs of the program as it grows, attracts students and the internship administration needs increase.

C. Facilities and Equipment

The proposed program will be housed in the Department of Chemistry in the School of Arts and Sciences, which will have the administrative responsibility. It will use the current Department facilities (office space, laboratories, conference rooms, etc.). In addition to the faculty offices, conference room, and reception areas, the Department of Chemistry operates instructional and research laboratories. Each full time faculty member has his/her own research laboratory. The undergraduate laboratories are dedicated to the instruction of specific chemistry courses. For example, there are the general chemistry laboratories, the organic chemistry laboratories, and the analytical and physical chemistry laboratories. Other departments (Biology, and Earth and Physical Sciences) operate dedicated laboratories for their courses as well. In addition, the Department of Chemistry has its own computer laboratory with appropriate instructional programs.

Supporting the instructional and research laboratories are several instrument rooms. They house state-of-the-art instruments that have been recently added to the
Department’s inventory. These instruments include the Varian 500 MHz NMR spectrometer; Nexus 470, 670, and 6700 Thermo Nicolet FTIR spectrometers (the Nexus 670 and 6700 are equipped with the more sensitive liquid nitrogen cooled MCT detector); Luminescence LS50B (Perkin Elmer) and Fluorolog (Jobin Yvon Horiba Spex) spectrofluorimeter; Jasco V-570 and V-650 UV/vis/NIR spectrometers; and an NRS-3100 dispersive confocal micro Raman Spectrometer from Jasco Inc. Separation instruments like HPLC (Waters) and GC-MS (Agilent Technologies) are also available for both purification and identification purposes including protein purification, ultra and microcentrifuges (Sorvall), freeze dryer (Labconco), and electrophoretic set-ups (BioRad). In addition, the department has acquired a couple of high end mass spectrometers, MALDI-TOF and LC-MS. These instruments are commonly used in research and development and quality assurance and quality control and other analytical and manufacturing facilities.

D. Library

Library services at York College include a Library faculty who teach Information Literacy courses on basic library usage, bibliographic tools for information management, and database specific demonstrations such as the intricacies of Medline and Evidence Based Medicine for the allied health fields. The library faculty maintains open hours for all students and faculty to consult with the Library’s Reference Desks almost any time during the Library’s operational hours. In addition, for lengthy research consultation, appointments may be made with individual librarians. Librarians also fulfill a liaison role with various departments giving librarians a degree of specialization. This role incorporates communication responsibilities with collection development request processing and other concerns as they arise within the context of the academic department/library team in assuring student success. Librarians also fulfill roles defined by functional responsibilities. The public service functions include having any circulating book in the entire set of CUNY Libraries searched for and delivered to York College Library Circulation Desk (CLICS) usually within 3 working days. Also any article not at York or book not in CUNY can be obtained through interlibrary loan, usually within ten working days.

The Library is open about eighty hours a week for access by students and faculty with added hours during times of high usage, such as the finals week. Over 120 computers are available for use by students. These computers are loaded with presentation, word processing, statistical, spreadsheet, Mathematica, and personal research and bibliographic management tools. They also have the chemical structure searching software for SciFinder Scholar (Chemical Abstracts).

Besides SciFinder Scholar, the library has over twenty Science and Medical related databases including those accessible for searching from anywhere with internet connectivity through VPN student accounts: American Chemical Society journals and publications, Annual Reviews, CINAHL with Headings (EBSCO), The Cochrane Library, General Science Collection (EBSCO), General Science Full Text (Wilson) and General Science Abstracts, Health Source Nursing/Academic Edition (EBSCO), Medline,
The Library’s electronic book collection includes numerous specialized dictionaries, encyclopedias and a growing set of monographs. Over one hundred science and medical titles have been added recently to the over 160,000 volumes book collection. Included in this collection are volumes directly related to the proposed program such as: The United States Pharmacopeia; Good Manufacturing Practices for Pharmaceuticals; Goodman and Gilman’s The Pharmacological Basis of Therapeutics; An Introduction to Medicinal Chemistry; Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients; Therapeutics and Human Physiology: How Drugs Work; A Small Dose of Toxicology: The Health Effects of Common Chemicals; Illegal Drugs: A Complete Guide to their History, Chemistry, Use and Abuse; The Rise of Viagra: How the Little Blue Pill Changed Sex in America; Revenge of the Microbes: How Bacterial Resistance is Undermining the Antibiotic Miracle; Dangerous Doses: How Counterfeiters are Contaminating America's Drug Supply; The Vaccine Controversy: The History, Use, and Safety of Vaccinations; Molecular Medicine: An Introductory Text; The New Medicines: How Drugs are Created, Approved, Marketed, and Sold; etc.

Library subscription to the American Chemical Society and ScienceDirect online publications provides access to many relevant research journals and other publications. In addition, the periodical collection includes bound paper, microfilm and a vast electronic set of journals and other forms of periodicals. According to the serials management system, which allows library users to look up individual titles for access, approximately 300 electronic periodicals with varying degrees of relevancy to pharmaceutical sciences, such as the American Journal of Pharmacogenomics, Molecular Diagnosis & Therapy, are available. There are thousands more electronic journals that allow access to the research of various sciences.

Professor D. Cleary is the science librarian of the College with responsibilities: a) to maintain, to improve and to update the science journal and book collection; b) to provide training for faculty and students in using the library facilities, journals, books and search engines; and c) to be the liaison with the science departments and programs in order to provide the necessary library support.

York Library has been undergoing renovation in terms of physical space and upgrading and enrichment in terms of its holdings to support the new programs that are being designed and implemented. A College wide Library Committee with department representatives ensures that its holdings are current and serve the college programs.

E. Marketing

The program will be formally launched at a ceremony to be held at York College for which interested current students and alumni, personnel from the FDA and area pharmaceutical industry, as well as the local press will be invited. A concerted marketing
effort will be initiated to inform potential students about the program. An attractive tri-fold handout describing the program, similar to the one for our undergraduate Pharmaceutical Science Program, will be prepared and distributed. Electronic versions of the brochure will be sent through Email Blasts and printed copies will be mailed to area pharmaceutical industries and undergraduate college faculty in appropriate disciplines. This will be augmented with the use of the print and radio media, advertising in professional publications, as well as through the York College Alumni Association and Open House events organized by the York College Admissions Office. Current undergraduate students will be routinely informed through the Chemistry Pharmaceutical Science Club of York College.

F. Budget

For the cost and revenue projections for the proposed program, which is anticipated based on the expected enrollment, please see the following Appendices: F (New Resources), G (Projected Revenue Related to the Proposed Program), H (Supporting Materials: Expenditures) and I (Supporting Materials: Revenue). Appointment of two faculty members will help meet increased instructional demands of the new program. In addition, the departments of Chemistry as well as Business and Economics will require adjunct faculty members to meet some of the instructional needs.

Other program costs include library acquisitions and laboratory supplies. Library acquisitions will be books and subscriptions to journals and publications that are not part of the current collection. York College currently has adequate laboratory space and classroom space to accommodate the program’s instructional needs.

Revenues are calculated based on the breakdown of full and part time students described in Table 2 (Section III: Students; Subsection C: Enrollment Estimates) and Appendix I (Supporting Materials: Revenue).

VIII. Program Evaluation

All York College programs, including the proposed M. S. in Pharmaceutical Science and Business, must meet the standards of New York State’s Education Department registration and Middle States Association accreditation. In addition, the Department of Chemistry, the Office of Academic Affairs and the Office of Institutional Research and assessment will be monitoring the program during the first five years of its implementation to assess its impact and outcomes.

Program Annual Report: The Department of Chemistry in collaboration with the Office of Academic Affairs appointed Dr. Deb Chakravarti to be the program Director. The program Director will conduct an annual review that will report on enrollment, student and faculty activities, achievements, internships, placement of graduates, instructors’ teaching effectiveness, and student and faculty scholarly and other professional activities. The program will also be evaluated and assessed during the cycle
of the 5-year Academic Program Review that each academic department and its programs undergo.

**Student Grades and Retention:** The program director in collaboration with the Office of Academic Affairs, The Office of the Registrar and the Office of Institutional Research will monitor the student grades and performance (GPAs and portfolios). Analysis of student performance and retention will provide insights for program improvement and to increase student support and to improve recruitment and retention.

**Student Activities:** Students enrolled in the proposed program will have the opportunity to participate in many enrichment and research activities. These include: a) campus presentations and seminars by students and faculty, b) CUNY-wide presentations and conferences, c) regional and national conferences and seminars, such as the INTERPHEX conference, American Chemical Society conferences, etc. Students will not just attend these events; they will also be active participants and presenters.

**Student Internships:** The Department of Chemistry and the other STEM departments are active participants and hosts of a number of funded programs that support student internships. Opportunities for research are also integrated in the proposed curriculum. Graduate students will have the opportunity to intern with FDA scientists and participate in faculty research projects. These opportunities will provide them with hands-on experience in the field. Presentations from their work will also be encouraged.

**Job Placement of Graduates:** The placement of Pharmaceutical Science graduates in appropriate jobs will be an important measure of the program’s success. Graduates will be invited to the annual Open House event and to other Department presentations and recruitment events to share their experiences with students and faculty and provide networking opportunities for other students. When they graduate, they will become part of the program’s alumni file that will track their subsequent career. They will also be the recipients of newsletters and other informational materials about the department, with the college keeping them abreast of developments and opportunities to support their alma mater. Employment opportunities for graduates of this program exist within the tri-state pharmaceutical, chemical and related industries.

**Graduate School Placement:** Graduates of the M.S. Program in Pharmaceutical Science and Business will be qualified to seek admission to graduate and professional schools. Proper advisement by faculty will provide students with information on graduate and professional school opportunities and careers. The proposed program prepares students to seek admission to graduate science programs (Pharmaceutical Science, Chemistry and Biochemistry), or professional schools (Medical, Dental, Veterinary, etc.). Admission to programs of graduate and professional studies is also an important indicator of the proposed program’s success. This program will follow the tradition of the current York science programs. Among the successes of the current programs are the four Salk Scholars, one in every year (2004, 2005, 2006, and 2007). Other students have also been admitted to prestigious graduate programs. Also, three of
our pharmaceutical science graduates are currently pursuing Doctor of Pharmacy (Pharm.D.) degree.

**Faculty Evaluation:** Following established college procedures, all instructors will be evaluated by means of formal classroom observations and student evaluations of teaching effectiveness. Fulltime and adjunct faculty members will be evaluated annually by the Chair of the Department of Chemistry. Faculty members will be evaluated in terms of teaching effectiveness, instructional and grading practices, scholarly and professional activities, and other contributions to the program, the Department, the College and the University.
IX. References

1 What’s it Worth?: The Economic Value of College Majors. Anthony P. Carnevale, Jeff Strohl and Michelle Melton. Center on Education and the Workforce. Georgetown University. Released: May 24, 2011 available online at: https://georgetown.app.box.com/s/5bgczqc0nefsx68bj4u4; accessed 3 February 2014.


4 MS in Pharmaceutical Sciences at Campbell University, NC available at: http://www.campbell.edu/cphs/academic-programs/ms-pharmaceutical-science/; accessed 6 February 2014.


12 MBA Programs in Pharmaceuticals: Beyond the Lab - How MBA programs can help students tap into a wide range of roles in both big and small pharma firms. FIND-MBA:
APPENDICES
Appendix – A

Course Descriptions and Syllabi for Required Courses
Course Description: The drug discovery and development processes; identification and validation of target molecules; identification and optimization of active substances; preclinical and clinical development; formulation; drug delivery systems, with emphasis on solid dosage forms. **3 hrs. 3 crs.**

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program.

Learning Objectives: By the end of this course, students should be able to:

1. Describe and justify the role and importance of the various disciplines involved in the different phases of drug discovery and development.
2. Evaluate the balance between medical benefit, medical risk, economic reward and economic risk in the decision making process.
3. Demonstrate the basic scientific principles involved in drug delivery such as dissolution, chemical stability, physical stability, content uniformity, absorption and elimination.
4. Illustrate the basic scientific principles involved in the design of solid dosage forms.


Grading Policy: Final grade will be determined as follows:

- Quizzes: 15%
- Exams (2 one-hour exams): 50%
- Final Exam (1 two-hour exam): 35%

Course Outline:

- **Week 1:** Introduction to the Pharmaceutical Industry
- **Week 2:** The Drug Discovery Process
- **Week 3:** The Drug Development Process
- **Week 4:** Principles of Drug Absorption and Pharmacokinetics
Week 5: Factors Affecting Oral Drug Absorption and Drug Availability
Week 6: Effect of Route of Administration and Distribution on Drug Action
Week 7: Chemical Kinetics and Drug Stability; Exam
Week 8: Crystalline and Amorphous Solids, Salts, Solvates, and Co-crystals
Week 9: Crystallization, Glass transition, Structural Analysis of Solid-State Pharmaceuticals
Week 10: Excipient Design and Characterization
Week 11: Preformulation
Week 12: Solid Dosage Forms: Powders and Granulates
Week 13: Solid Dosage Forms: Tablets
Week 14: Solid Dosage Forms: Hard- and Soft-Shell Capsules; Exam
Final Exam

College Policies:

INC Grades:
The following overview is condensed from York's Grading Policies website:
http://york.cuny.edu/academics/policies/grading-policies
A student who, because of extenuating circumstances, has not taken the final examination and/or completed the work for the course and has a passing average may be assigned an INC grade. The student, in consultation with the instructor, has up to 10 weeks in the subsequent semester to complete the work and have the grade resolved even if not registered in the subsequent semester. Grade changes resolving INC grades must be received by the Office of the Registrar by the last day of the 10th week of classes of the subsequent semester (See Academic Calendar for exact due date). Grades received after the deadline will not be processed unless the student has obtained approval from the Committee on Academic Standards.

The grade of INC is not considered in computing the academic index. However, if a grade change is not received by the Office of the Registrar within the above specified limits, the grade of INC is changed to FIN. This grade is considered an F grade when computing the academic index. When compiling the Dean's List INC grades are calculated as F.

Policy on Academic Integrity:
York College Policy and Procedures on Academic Integrity can be found at:
http://www.york.cuny.edu/academics/academic-affairs/academic-integrity-officer/york-college-policy-and-procedures-on-academic-integrity

Policy on Accommodations for Disabled Students:
Information about the services provided to students at York College can be found at the Office of Services for Students with Disabilities, located in room AC-1G02, and on-line at:
http://york.cuny.edu/student-development/ossd
Instructor's Bibliography:


Course Description: The basic process of production and characterization of biologics; validation of analytical methods; characterization of solid state drugs; manufacturing of tablets; generation of manufacturing documents. **1 hr. lecture, 4 hrs. laboratory; 3 crs.**

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program.

Learning Objectives: By the end of this course, students should be able to:
1. Demonstrate the basics of bioprocessing for production biologics and their characterization.
2. Illustrate the basic scientific principles involved in the design of solid dosage forms.
3. Apply concepts learned in the lecture to the practical problems presented by lab experiments.
4. Operate modern instrumentation to produce pharmaceutical dosage forms and conduct various kinds of chemical analysis.
5. Compose manufacturing documents.


Grading Policy: Final grade will be determined as follows:
- Pre-lab Assignments/Quizzes: 15%
- Lab Data Sheets: 45%
- Formal Lab Reports: 15%
- Final Exam (1 two-hour exam): 25%

Course Outline:
- **Week 1**: The Purpose of This Course and its Organization
- **Week 2**: Batch Production of Recombinant Protein or Monoclonal Antibody
- **Week 3**: Purification of Recombinant Protein or Monoclonal Antibody
Week 4: Analytical Characterization of Recombinant Protein or Monoclonal Antibody
Week 5: Analytical Characterization of Recombinant Protein or Monoclonal Antibody (continued); 1st Lab Report Due
Week 6: Analytical HPLC Method Validation
Week 7: Preformulation of Solid State Forms: Re-crystallization From Solution
Week 8: Characterization of Crystals: Polymorphism, IR, RAMAN, DSC, TGA, X-Ray
Week 9: Amorphous: Glass Transition Measurement, Stabilization Against Crystallization by Polymer Additives; 2nd Lab Report Due
Week 10: Manufacturing of Tablets: Granulation: Dry Blend, Wet Mass, Drying
Week 11: Manufacturing of Tablets: Compression: Mill, Blend, Lubrication, Compression
Week 12: Manufacturing of Tablets: Coating
Week 14: Manufacturing of Tablets: Dissolution; 3rd Lab Report Due
Final Exam

College Policies:

INC Grades:
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http://www.york.cuny.edu/academics/academic-affairs/academic-integrity-officer/york-college-policy-and-procedures-on-academic-integrity

Policy on Accommodations for Disabled Students:
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YOU MUST READ THE LAB HANDOUTS AHEAD OF TIME. If you come to class without reading the lab handouts, you are wasting your time, your partners’ time, and the instructors’ time. If you are not prepared, you will not be allowed to participate in lab, and your grade for all the assignments associated with this lab will be zero. No make-up labs for this reason will be given.

**Instructor’s Bibliography:**
*Modern Pharmaceutics Volume 1*, 5th edition by Florence and Siepmann, Abridged textbook
*Pharmaceutical Powder Compaction Technology*, Alderborn and Nyström, Dekker, c1996
MS Pharmaceutical Science and Business
ADVANCED PHARMA COLOG Y

Course Number: PHS 503         Section:                 Semester:
Professor:                          Office:                   
Phone:  
Email:  
Office Hours:
Class in Session:

Course Description: The basic principles of pharmacology; general principles of drug action; pharmacokinetics; pharmacodynamics; neuropharmacology; cardiovascular pharmacology; endocrine pharmacology; pharmacology of chemotherapeutic agents.  
3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program.

Learning Objectives: By the end of this course, students should be able to:

1. Demonstrate the principles of drug action, including basic pharmacokinetics, dose-response relationships, and receptor binding.
2. Describe the therapeutic uses and routes of administration of the major classes of drugs.
3. Demonstrate the mechanism of action of each of the major classes of drugs at the molecular, cellular, organ and organ system levels.
4. Use their knowledge of drug mechanisms of action to predict therapeutic and adverse effects.
5. Recognize the side effects associated with major classes of drugs.


Grading Policy: Final grade will be determined as follows:

Quizzes 25%
Exams (3 one-hour exams) 40%
Final Exam (1 two-hour exam) 35%

Course Outline:
Week 1: General Principles of Pharmacology
Week 2: Drug Receptors, Pharmacokinetic, and Pharmacodynamics
Week 3: Introduction to the Autonomic Pharmacology
Week 4: Cholinceptor–Activating, Cholinceptor-Blocking and Cholinesterase-Inhibiting Drugs
**Week 5:** Adrenoreceptors Agonists, Antagonists, and Sympathomimetic Drugs; Exam

**Week 6:** Cardiovascular-Renal Drugs

**Week 7:** Histamine, Serotonin, and Ergot Alkaloids

**Week 8:** Drugs with Important Actions on Smooth Muscle

**Week 9:** Introduction to the Pharmacology of the Central Nervous System

**Week 10:** Drugs that Act in the Central Nervous System; Exam

**Week 11:** Anti-inflammatory Drugs

**Week 12:** Hypothalamic and Pituitary Hormones

**Week 13:** Endocrine Drugs

**Week 14:** Chemotherapeutic Drugs; Exam

**Final Exam**

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**College Policies:**

**INC Grades:**
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Instructor's Bibliography:
MS Pharmaceutical Science and Business
ADVANCED BIOSTATISTICS

Course Number: PHS 504                Section:                 Semester:
Professor:                        Office:
Phone:                            Email:
Office Hours:
Class in Session:

Course Description: Biostatistical methods with emphasis on those generally used in the design of clinical trials for development of pharmaceuticals for human use. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program.

Learning Objectives: By the end of this course, students should be able to:
1. Demonstrate the fundamentals of biostatistics.
2. Illustrate the methodology necessary to summarize data and make informed decisions about observed outcomes.
3. Apply the most appropriate experimental design and methods for data evaluation to obtain reliable results.
4. Perform basic statistical analysis for clinical trial applications.


Grading Policy: Final grade will be determined as follows:
Quizzes 15%
Exams (2 one-hour exams) 50%
Final Exam (1 two-hour exam) 35%

Course Outline:
Week 1: General Overview
Week 2: Descriptive Statistics
Week 3: Probability
Week 4: Discrete Probability Distributions
Week 5: Continuous Probability Distributions
Week 6: Estimation
Week 7: Hypothesis Testing: One-Sample Inference
Week 8: Hypothesis Testing: Two-Sample Inference; Exam
Week 9: Nonparametric Methods
Week 10: Hypothesis Testing: Categorical Data
Week 11: Regression and Correlation Methods
Week 12: Multisample Inference
Week 13: Design and Analysis Techniques for Epidemiologic Studies
Week 14: Hypothesis Testing: Person-Time Data; Exam
Final Exam

College Policies:

INC Grades:
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Instructor's Bibliography:
MS Pharmaceutical Science and Business
FOUNDATIONS OF REGULATORY AFFAIRS

Course Number: PHS 505                Section:                Semester:
Professor:                                       Office:
Phone:                                             Email:
Office Hours:                                   Class in Session:

**Course Description:** US Federal laws, regulations, procedures and guidelines that control drugs and biologics during their development, production and distribution stages; the functions of the US Food and Drug Administration (FDA) and their impact on the approval process. **3 hrs. 3 crs.**

**Prerequisites:** Formal admission to the MS Pharmaceutical Science and Business Program.

**Learning Objectives:** By the end of this course, students should be able to:

1. Demonstrate the importance of laws and regulations with respect to development, production and distribution of drugs and biologics.
2. Illustrate the basic functions and organization of the FDA.
3. Recognize the basic steps of the application filing process to the FDA.
4. Describe the basic steps of the approval process of the FDA.


Also documents available in US FDA’s Electronic Reading Room: [http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/default.htm](http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/default.htm)

**Grading Policy:** Final grade will be determined as follows:

- Exam (1 one-hour exam)  40%
- Final (1 two-hour exam)  40%
- Final Report  10%
- Oral Presentation  5%
- Classroom Participation  5%

**Course Outline:**

- **Week 1:** Milestones in U.S. Biologics and Food and Drug Laws
- **Week 2:** Introduction to the Drug/Biologics laws; New Drug/Biologic Approval Process
- **Week 3:** Pre-Clinical Trials
**Week 4:** The Investigational New Drug Application (IND)

**Week 5:** CDER/CBER and the IND Review Process

**Week 6:** The Clinical Development of New Drugs

**Week 7:** The Clinical Development of New Biologics; Exam

**Week 8:** Application to market a new or abbreviated new drug or biologic for human use (NDA, ANDA, BLA)

**Week 9:** The NDA/ANDA/BLA Review Process

**Week 10:** The Supplemental applications and post-approval changes to marketed drugs/biologics

**Week 11:** Post-Marketing Surveillance

**Week 12:** Accelerated Drug Approval/Accessibility Programs

**Week 13:** FDA's Prescription Drug User Fee Program

**Week 14:** Case Studies and Presentations

Final Exam; Final Report Due

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**College Policies:**

**INC Grades:**

The following overview is condensed from York's Grading Policies website: [http://york.cuny.edu/academics/policies/grading-policies](http://york.cuny.edu/academics/policies/grading-policies)

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**Policy on Academic Integrity:**

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Instructor’s Bibliography:
How Drugs are Developed and Approved:
http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/default.htm
Investigational New Drug (IND) Application:
Clinical Trials and Human Subject Protection:
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm
New Drug Application (NDA):
Drug Master Files: Guidelines:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm122886.htm
Modernization Act:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065012.htm
IND Application Form:
IND Forms and Instructions:
Pre-IND Consultation Program:
Good Review Practices:
Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PUDFA Products:
Guidance for Industry: Premarketing Risk Assessment:
Research List of Guidance Documents:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm310704.htm#INDs
MS Pharmaceutical Science and Business

PHARMACEUTICAL ETHICS AND INTELLECTUAL PROPERTY MANAGEMENT

Course Number: PHS 506                Semester:
Professor:                              Office:
Phone:                                  Email:
Office Hours:
Class in Session:

**Course Description:** Ethical and economic issues related to pharmaceutical research and clinical trials; policy considerations; scientific misconduct; control of intellectual property. 3 hrs. 3 crs.

**Prerequisites:** Formal admission to the MS Pharmaceutical Science and Business Program.

**Learning Objectives:** By the end of this course, students should be able to:

1. Recognize the ethical principles faced by the scientific community.
2. Recognize the limitations government regulation places on animal and human subject research.
3. Illustrate the basic concepts of Good Clinical Practice.
4. Differentiate patent, trademark, and copyright regulations.
5. Demonstrate how intellectual property rights are protected.
6. Illustrate the application of laws and regulations to real-life cases.


*The Nuremberg Code and the World Medical Association Declaration of Helsinki*: available online – Appendix 6 - [http://www.hhs.gov/ohrp/archive/irb/irb_appendices.htm](http://www.hhs.gov/ohrp/archive/irb/irb_appendices.htm)

Grading Policy: Final grade will be determined as follows:

Exam (1 one-hour exam)  30%
Final (1 two-hour exam)  30%
Final Report  25%
Oral Presentation  10%
Classroom Participation  5%

Course Outline:

Week 1: Drug Research: Ethical Demands and Economic Constraints
Week 2: The Ethical Challenges of Using Animals in Pre-Clinical Research
Week 3: Emerging International Standards for Clinical Testing: Current Good Clinical Practice
Week 4: The Rights of Patients to Participate in Clinical Trials – Backgrounds and Procedures for Human Subject Research
Week 5: Racial and Ethnic Inclusiveness in Clinical Trials
Week 6: Third World Perspectives on Global Pharmaceutical Access
Week 7: Direct-to Consumer Advertising of Prescription Drugs; Exam
Week 8: Public Health Service Policies on Research Misconduct
Week 9: Patent, Trademark, and Copyright
Week 10: Protection of Intellectual Property Rights, International Treaties and Agreements
Week 11: Intellectual Property Rights, Access to Life-Enhancing Drugs, and Corporate Moral Responsibilities
Week 12: Case studies: Major Drug Recalls: The Long Path to Recall of Vioxx
Week 13: Development of Priority Vaccines for Disease-Endemic Countries: Risks and Benefits
Week 14: Case studies: The Recall of the Rotavirus Vaccine RotaShield: Ethical Concerns with Acceptable Risk; and the Influenza Vaccine Shortage of 2004

Final Exam; Final Report Due

College Policies:

INC Grades:
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A student who, because of extenuating circumstances, has not taken the final examination and/or completed the work for the course and has a passing average may be assigned an INC grade. The student, in consultation with the instructor, has up to 10 weeks in the subsequent semester to complete the work and have the grade resolved even if not registered in the subsequent semester. Grade changes resolving INC grades
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**Policy on Academic Integrity:**
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[http://www.york.cuny.edu/academics/academic-affairs/academic-integrity-officer/york-college-policy-and-procedures-on-academic-integrity](http://www.york.cuny.edu/academics/academic-affairs/academic-integrity-officer/york-college-policy-and-procedures-on-academic-integrity)

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[http://york.cuny.edu/student-development/ossd](http://york.cuny.edu/student-development/ossd)

**Instructor’s Bibliography:**
MS Pharmaceutical Science and Business
PHARMACEUTICAL INDUSTRY AND BUSINESS

Course Number: PHS 507  Section:  Semester:
Professor:  Office:
Phone:  Email:
Office Hours:  Class in Session:

Course Description: This course introduces to pharmaceuticals and its scope and provides an overall look at the pharmaceutical industry, market structure, and past and current trends. It discusses historical background and pharmaceutical industry characteristics in United States. It also identifies business issues, challenges, and opportunities in the future. **3 hrs. 3 crs.**

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program.

Learning Objectives: By the end of this course, students should be able to:
1. Demonstrate the basic structure of the pharmaceutical industry.
2. Illustrate the basics of the business forces in the pharmaceutical industry.
3. Recognize the impact of important trends and issues on pharmaceutical companies.
4. Identify a business issue, challenge, or opportunity facing the industry and understand the importance of information technology solutions.


Grading Policy: Final grade will be determined as follows:
- Quizzes: 15%
- Exams (2 one-hour exams): 50%
- Final Exam (1 one-hour exam): 35%

Course Outline:
- **Week 1:** Course Overview: Introduction, outline and learning objectives. Grading policy
- **Week 2:** Industry Overview
- **Week 3:** Historical events and Recent Trends, Issues & Strategies
- **Week 4:** Industry Regulation
Week 5: Drug Development: Pharmaceutics
Week 6: Pharmaceutical Manufacturing, Logistics, & Supply Chain
Week 7: Pharmaceutical Marketing; Exam
Week 8: Pharmaceutical Sales
Week 9: Pharmaceutical project management
Week 10: Information Technology
Week 11: Industry Strategies
Week 12: Pharmaceutical Research and Development
Week 13: Global pharmaceutical business
Week 14: Future Trends; Exam
Final Exam

College Policies:

INC Grades:
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Policy on Accommodations for Disabled Students:
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Instructor’s Bibliography:

Course Description: Research or internship in pharmaceutical sciences. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program.

Learning Objectives: By the end of this course, students should be able to:
1. Gain educational and professional experience.
2. Get career advice and guidance.
3. Demonstrate key skills such as project management, collection, analysis and interpretation of data, oral and written presentation of their results.

Text: No text book required.

Grading Policy: Final grade will be determined as follows:
- Final Report 50%
- Oral Presentation 40%
- Research/Internship performance 10%

Course Outline
The Capstone Project can either be Thesis Based or Internship Based. In each case, at the beginning of the semester, students will be assigned an academic mentor for the project.

Thesis Based: In consultation with their mentor, the students will choose an appropriate advanced topic relevant to pharmaceutical research, drug or biologic discovery, development, manufacturing, regulatory sciences, clinical studies, or pharmaceutical business. The research can be carried out either as an individually guided independent study conducted in a non-laboratory setting (Non-Laboratory Research Projects) or independent laboratory research conducted in a laboratory setting (Laboratory Research Projects).

Internship Based: In consultation with their mentor, students will need to find an industry internship in a pharmaceutical related company and intern there for approx.
120 hrs during the semester. The internship will provide students with in-depth training, an opportunity to obtain a mentored experience that is challenging and stimulating, the ability to acquire technical skills and work with professionals in their field, and an opportunity to gain invaluable experience helping students with their future career or educational paths.

The basic guidelines for any type of Capstone Project are:

- At the beginning of the project, students will submit a one page document (standard typed double-spaced page) containing the title and a summary of the proposed research or goals, its aims and scope, and the deliverables for approval of the Faculty Advisor.
- Students will submit a formal academic paper based on their research/internship between 25 and 35 double-spaced pages.
- Students will present their work, to an academic committee for evaluation as well as to other students.
- A schedule of meetings between the mentor and the students will be established to monitor the research progress. The mentoring process will involve both formal monitoring of the student research progress and an informal process of advisement and facilitation for the development of the students.

**Milestones:**
- **Week 1:** Academic Mentors are assigned
- **Week 3:** Abstract/Proposal Due
- **Week 13:** Written Report Due
- **Week 14:** Oral Presentation

**College Policies:**

**INC Grades:**
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MS Pharmaceutical Science and Business

BIOThERAPEUTICS

Course Number: PHS 509               Section:                  Semester:
Professor:                                  Office:
Phone:                                      Email:
Office Hours:  
Class in Session:

Course Description: Development, production, validation, regulation and case studies of biotherapeutic pharmaceutical products. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; PHS 501: Pharmaceutical Discovery and Development.

Learning Objectives: By the end of this course, students should be able to:
1. Demonstrate the basic principles of the development, production and regulation of biotherapeutics.
2. Recognize the importance of biotherapeutics in the pharmaceutical industry.
3. Illustrate the marketing and proprietary issues related to generic biotherapeutics.


Grading Policy: Final grade will be determined as follows:
   Exam (1 one-hour exam)  40%
   Final (1 two-hour exam)  40%
   Final Report            20%

Course Outline:
Week 1: Introduction to Biotechnology
Week 2: Biotherapeutics: Biologics and Vaccines
Week 3: Natural and Recombinant Biotherapeutic Proteins and Polypeptides
Week 4: Purification of Proteins and Polypeptides, and formulation
Week 5: Characterization of Proteins and Polypeptides
Week 6: ICH Topic Q6B – Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products

Week 7: Hormones and Growth Factors; Exam

Week 8: Blood Clotting Factors and Thrombolytic Agents

Week 9: Therapeutic Antibodies

Week 10: Vaccines: From Concept to Clinic

Week 11: Vaccines: From Concept to Clinic (Continued)

Week 12: Biosimilars / Follow-on-Biologics

Week 13: Bioresearch Monitoring Program for Biologics

Week 14: Biologics and Regulation of Combination Products

Final Exam; Final Report Due

College Policies:

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Instructor’s Bibliography:


Course Description: Basic scientific principles in the design of drug delivery systems, with emphasis on liquid dosage forms, nanomedicine, and controlled drug delivery systems. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; PHS 501: Pharmaceutical Drug and Development.

Learning Objectives: By the end of this course, students should be able to:
1. Illustrate the scientific principles involved in the design of solution, emulsion, suspensions, semisolid dosage forms and dermatological delivery systems.
2. Demonstrate the scientific principles of preparation and administration of sterile solutions, including key factors to maintain sterility, solution isotonicity and isoosmolality.
3. Explain the scientific principles of sustained, controlled, target-specific, dermatological and mucosal drug delivery.
4. Develop a general understanding of nanomedicines and veterinary products.


Grading Policy: Final grade will be determined as follows:
- Quizzes 15%
- Exams (3 one-hour exams) 50%
- Final Exam (1 two-hour exam) 35%

Course Outline:
- Week 1: The purpose of this course and its organization
- Week 2: Solution Dosage Form
- Week 3: Sterile Solutions
- Week 4: Emulsion Dosage Form
- Week 5: Parenteral Products; Exam
- Week 6: Dermatologic Drug Delivery System
- Week 7: Controlled Release Systems Overview
- Week 8: Pharmaceutical Polymers
Week 9: Controlled Drug Delivery
Week 10: Target-oriented Drug Delivery; Exam
Week 11: Mucosal Drug Delivery: Oral, Ocular, Nasal
Week 12: Nanomedicine
Week 13: Pediatric and Geriatric Pharmaceutics and Formulation
Week 14: Veterinary Products; Exam
Final Exam

College Policies:

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http://york.cuny.edu/student-development/ossd
Instructor’s Bibliography:  
MS Pharmaceutical Science and Business

SPECIAL TOPICS IN PHARMACEUTICAL DISCOVERY AND DEVELOPMENT

Course Number: PHS 511               Section:                  Semester:
Professor:                                      Office:
Phone:                                          Email:
Office Hours:
Class in Session:

Course Description: State-of-the-art special topics in the areas of pharmaceutical discovery and development. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; PHS 501: Pharmaceutical Discovery and Development.

Learning Objectives: By the end of this course, students should be able to:
1. Identify critical issues in drug discovery and development.
2. Recognize special issues with vaccine preventable diseases.
3. Describe future prospects for the pharmaceutical industry.


Grading Policy: Final grade will be determined as follows:
Exam (1 one-hour exam) 35%
Final (1 two-hour exam) 35%
Final Report 20%
Oral Presentation 10%

Course Outline:
Week 1: Orphan Drugs
Week 2: Open Source Drug Discovery in Practice: A Case Study
Week 3: Stagnation of Antibiotic Discovery
Week 4: Trends in Cancer Research
Week 5: Stem Cell Therapy: Hope for the Future
Week 6: Pharmacogenetics and Pharmacogenomics, and the Rise of Personalized Medicine
Week 7: Role of Genomics, Proteomics and Metabolomics in Drug and Vaccine Target Discovery
Week 8: Diagnostics and Biomarker Development; Exam
Week 9: Drug Discovery and Development Business Opportunities in India
Week 10: Global Burden of Disease
Week 11: Vaccine Safety: Real and Perceived Issues
Week 12: Glyco-Conjugate Vaccines
Week 13: Introduction of New Vaccines in the Healthcare System
Week 14: Student Presentation of Case Studies
Final Exam; Final Report Due

College Policies:

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Instructor’s Bibliography:
Developing Products for Rare Diseases & Conditions, available on US Food and Drug Administration’s website: http://www.fda.gov/forindustry/DevelopingProductsforrareDiseasesConditions/default.htm
Bad Bugs, No Drugs: As Antibiotic Discovery Stagnates ... A Public Health Crisis Brews, Infectious Disease Society of America (2004).


MS Pharmaceutical Science and Business
PHARMACEUTICAL QUALITY ASSURANCE, PROCESS VALIDATION AND CONTROLS

Course Number: PHS 512                 Section:                  Semester:
Professor:                        Office:
Phone:                           Email:
Office Hours:
Class in Session:

Course Description: The basic principles of quality control and validation of pharmaceutical manufacturing processes; basic elements of pharmaceutical production, including packaging, equipment, personnel and Good Manufacturing Practices (GMPs).
3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; PHS 505: Foundations of Regulatory Affairs.

Learning Objectives: By the end of this course, students should be able to:
1. Recognize the scientific and regulatory basis for the need of quality assurance, process validation and controls.
2. Gather the necessary documents to design and develop a rigorous validation program.
3. Demonstrate the fundamentals of current Good Manufacturing Practices.
4. Explain specific problems that have been observed in the pharmaceutical industry through review and citations by the FDA through enforcement actions, such as, inspectional observations and warning letters.


Grading Policy: Final grade will be determined as follows:
Exam (1 one-hour)            30%
Final (1 two-hour exam)    35%
Final Report                25%
Quizzes                     10%
Course Outline:
Week 1: Why Validation?
Week 2: Organizing for Validation: FDA Guidelines and Industry Technical Reports
Week 3: Validation of Environmental Control Systems
Week 4: Application and Evaluation of Cleaning Solutions used on Equipment
Week 5: Monitoring for Non-Viable Particles and Viable Microorganisms in Production Areas
Week 6: Quality Control Testing on Finished Products using Validated USP Methods
Week 7: Validation of Aseptic Processing: Sterile Media Simulation Studies; Exam
Week 8: Validation of Purified Water Systems
Week 9: Validation of Process Chromatography
Week 10: Cell Culture Process Validation
Week 12: Clinical Trial Supplies and current Good Manufacturing Practices
Week 13: The Inspection Procedure for Compliance in the United States; Rationale for Inspection
Week 14: Worldwide Good Manufacturing Practices
Final Exam; Final Report Due

College Policies:

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Instructor’s Bibliography:
Course Description: Design and development of clinical trials of pharmaceutical products; applications of specific biostatistical methods. **3 hrs. 3 crs.**

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; PHS 504: Advanced Biostatistics.

Learning Objectives: By the end of this course, students should be able to:
1. Illustrate clinical trial design elements, such as, objectives, eligibility criteria, treatment regimen, adverse events assessment, dose modification, efficacy response assessment, informed consent, etc.
2. Demonstrate the basic principles of phase 1, 2, 3 and 4 of clinical trials.
3. Recognize the appropriate settings in which to use a particular biostatistical test method.
4. Perform clinical trial analysis and data reporting.


Grading Policy: Final grade will be determined as follows:
- Quizzes 15%
- Exams (2 one-hour exams) 50%
- Final Exam (1 two-hour exam) 35%

Course Outline:
- **Week 1:** Introduction and History of Clinical Trials
- **Week 2:** Phase 1 and Phase 2 Study Design
- **Week 3:** Phase 3 Study Design
- **Week 4:** Phase 4 and Post-Marketing Surveillance Study Design
- **Week 5:** Clinical Trial Elements including Objectives, Eligibility Criteria, Treatment Regimen
**Week 6:** Adverse Event Assessment and Reporting, Dose Modification, Efficacy Response Assessment

**Week 7:** Informed Consent, Data Monitoring Committees; Exam

**Week 8:** Operational Issues including Clinical Site Selection, Investigational Review Boards

**Week 9:** Data monitoring, Clinical Data Management, Case Report Forms

**Week 10:** Clinical Trial Study Reports and Analyses

**Week 11:** Basic Biostatistics related to Superiority, Non-Inferiority and Equivalence Study Designs

**Week 12:** Clinical Development and Problem Solving

**Week 13:** Clinical Development Strategy in a Competitive Landscape

**Week 14:** Case Studies and Review of Course Materials; Exam

Final Exam

**College Policies:**

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Instructor’s Bibliography:


Course Description: The mechanisms by which toxicants enter the body and the biotransformation processes that result in disease-producing entities; cellular mechanisms of toxicity and the major target organs affected by toxins; some applications of toxicology, such as clinical toxicology and regulatory toxicology. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; PHS 503: Advanced Pharmacology.

Learning Objectives: By the end of this course, students should be able to:
1. Recognize the principles and approaches used to investigate the metabolism of toxicants in laboratory mammals and in humans and of the metabolic activation of chemicals to toxic metabolites.
2. Demonstrate the fundamental process of cancer, cell proliferation, chemical-induced DNA damage and DNA repair mechanisms.
3. Illustrate the target organ toxicity involving the following organ systems: liver, kidney, blood, cardiovascular, immune, skin, gastrointestinal, pulmonary, reproductive, endocrine, and central and peripheral nervous systems.
4. Describe methods involved in evaluation of the toxic effects of chemicals on selected organ systems.


Grading Policy: Final grade will be determined as follows:
- Quizzes 15%
- Exams (3 one-hour exams) 50%
- Final Exam (1 two-hour exam) 35%

Course Outline:
Week 1: General Principles of Toxicology
Week 2: Absorption, Distribution, Excretion of toxicants, Biotrasformations of Xenobiotics.
Week 3: Non-Organ Directed Toxicity
Week 4: Toxic Response of the Immune System
Week 5: Toxic Response of the Liver; Exam
Week 6: Toxic Response of the Kidney
Week 7: Toxic Response of the Respiratory System
Week 8: Toxic Response of the Nervous System
Week 9: Toxic Response of the Heart and the Blood
Week 10: Toxic Response of the Skins; Exam
Week 11: Toxic Response of the Reproductive System
Week 12: Toxic Agents: pesticides, metals, solvents, radioactive materials
Week 13: Environmental Toxicology
Week 14: Clinical Toxicology, Regulatory Toxicology, Food Toxicology; Exam
Final Exam

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Instructor’s Bibliography:

MS Pharmaceutical Science and Business
INTERNATIONAL REGULATORY AFFAIRS

Course Number: PHS 515          Section:          Semester:
Professor:          Office:
Phone:          Email:
Office Hours:
Class in Session:

Course Description: Study of the relations between international regulatory authorities and analysis of the regulatory processes for pharmaceuticals in the European Union, Japan, Canada, South America, China and India. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; PHS 505: Foundations of Regulatory Affairs.

Learning Objectives: By the end of this course, students should be able to:

1. Recognize the significance of the International Conference on Harmonization (ICH) for the registration of pharmaceuticals for human use.
2. Differentiate and compare the regulatory processes of different countries.
3. Recognize global problems in the pharmaceutical business and the common strategies used by the Food and Drug Administration (FDA) and other agencies to overcome them.


Grading Policy: Final grade will be determined as follows:
- Exam (1 one-hour exam) 35%
- Final (1 two-hour exam) 35%
- Final Report 20%
- Oral Presentation 5%
- Participation 5%

Course Outline:
- Week 1: Overview of FDA and Regulatory Process in the US
- Week 2: Pathway to Global Product Safety and Quality
- Week 3: Pathway to Global Product Safety and Quality (Continued)
- Week 4: International Conference on Harmonisation
- Week 5: Core Elements of Regulatory System
- Week 6: Critical Issues in Developing Countries
- Week 7: European Union; Exam
- Week 8: European Medicines Agency
- Week 9: Ministry of Health, Labour and Welfare - Japan
- Week 10: Health Canada
- Week 11: Global Engagement
- Week 12: Global Engagement (Continued)
- Week 13: The Problem of Counterfeit Medications
- Week 14: Case Studies and Presentations

Final Exam; Final Report Due

College Policies:

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**Instructor's Bibliography:**
Documents available in US FDA’s Electronic Reading Room: [http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/default.htm](http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/default.htm)
Course Description: The regulations and laws on the requirements for drug labeling in the United States and other countries. Labeling issues generated by post-marketing surveillance activities and alterations in federal regulation or guidance will be discussed. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; PHS 505: Foundations of Regulatory Affairs.

Learning Objectives: By the end of this course, students should be able to:
1. Explain the purpose of a drug label.
2. Identify the main criteria that should be on a label.
3. Describe the regulatory approval process of drug labels.
4. Recognize the importance of labeling in terms of International Conference of Harmonization.

Also documents available in US FDA’s Electronic Reading Room: (http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/default.htm)

Grading Policy: Final grade will be determined as follows:
- Exam (1 one-hour exam) 40%
- Final Exam (1 two-hour exam) 40%
- Final Report 20%

Course Outline:

Week 4: US Code of Federal Regulations (CFR) Title 21 Part 201: Labeling, Subpart B - Labeling Requirements for Prescription Drugs and/or Insulin and Case Studies

Week 5: US Code of Federal Regulations (CFR) Title 21 Part 201: Labeling, Subpart B - Labeling Requirements for Prescription Drugs and/or Insulin and Case Studies (Continued)

Week 6: US Code of Federal Regulations (CFR) Title 21 Part 201: Labeling, Subpart B - Labeling Requirements for Prescription Drugs and/or Insulin and Case Studies (Continued)

Week 7: US Code of Federal Regulations (CFR) Title 21 Part 201: Labeling, Subpart C - Labeling Requirements for Over-the-Counter Drugs and Case Studies; Exam

Week 8: US Code of Federal Regulations (CFR) Title 21 Part 201: Labeling, Subpart C - Labeling Requirements for Over-the-Counter Drugs and Case Studies (Continued)


Week 14: Improved FDA Prescription Drug Labeling – Online Exercises

Final Exam; Final Report Due

College Policies:

INC Grades:
The following overview is condensed from York's Grading Policies website: http://york.cuny.edu/academics/policies/grading-policies

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received after the deadline will not be processed unless the student has obtained approval from the Committee on Academic Standards.

The grade of INC is not considered in computing the academic index. However, if a grade change is not received by the Office of the Registrar within the above specified limits, the grade of INC is changed to FIN. This grade is considered an F grade when computing the academic index. When compiling the Dean's List INC grades are calculated as F.

**Policy on Academic Integrity:**
York College Policy and Procedures on Academic Integrity can be found at:
http://www.york.cuny.edu/academics/academic-affairs/academic-integrity-officer/york-college-policy-and-procedures-on-academic-integrity

**Policy on Accommodations for Disabled Students:**
Information about the services provided to students at York College can be found at the Office of Services for Students with Disabilities, located in room AC-1G02, and on-line at:
http://york.cuny.edu/student-development/ossd

**Instructor’s Bibliography:**
Standardizing Medication Labels: Confusing Patients Less - Workshop Summary, Institute of Medicine (2008). Electronic copy available at:

The Safe Use Initiative and Health Literacy - Workshop Summary, Institute of Medicine (2010). Electronic copy available at:


An Introduction to the Improved FDA Prescription Drug Labeling - Additional Information, available at:
http://www.fda.gov/Training/ForHealthProfessionals/ucm090721.htm (Online Training and Continuing Education Course available)
MS Pharmaceutical Science and Business

WRITING AND SUBMISSION OF REGULATORY APPLICATIONS

Course Number: PHS 517  Section:  Semester:
Professor:  Office:
Phone:  Email:
Office Hours:
Class in Session:

Course Description: Basic principles in the development and preparation of the common technical documents required for the submission of regulatory applications. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; PHS 505: Foundations of Regulatory Affairs.

Learning Objectives: By the end of this course, students should be able to:
1. Explain the purpose of the Common Technical Document.
2. Demonstrate the general requirements and procedures for drug approvals.
3. Recognize the laws and regulations that are required for drug approvals.
4. Navigate the FDA website.


Grading Policy: Final grade will be determined as follows:
- Exam (1 one-hour exam) 40%
- Final Exam (1 two-hour exam) 40%
- Group Project 20%

Course Outline:
- Week 1: History of FDA Related Laws and Regulations
- Week 2: ICH and the Common Technical Document
Week 13: Differences and Similarities between NDA, BLA, SNDAs and ANDAs
Week 14: Case studies
Final Exam; Group Project Due

College Policies:

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Instructor’s Bibliography:
Documents available in US FDA’s Electronic Reading Room:
(http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/default.htm)
Course Description: Pharmaceutical industry consists of a variety of suppliers, manufacturers, service providers and government. In order to achieve operational excellence and increase customer satisfaction, Supply Chain Management (SCM) integrates all activities in the process from procurement of materials to delivery to customers. This course examines knowledge and strategies of SCM and its application to the pharmaceutical industry. It explores the unique issues in recent pharmaceutical industry such as regulation, security and government role. **3 hrs. 3 crs.**

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program.

Learning Objectives: By the end of this course, students should be able to:

1. Recognize supply chain strategies and its application to pharmaceutical organizations for a competitive advantage.
2. Demonstrate key issues and developments in managing supplier, customer management and supply chain partner relationships.
3. Describe the role of manufacturing capabilities for supply chain objectives.
4. Illustrate the relationship between customer satisfaction and inventory management.
5. Identify the importance of the lean supply chains with the appropriate levels of risk.


Grading Policy: Final grade will be determined as follows:

- Quizzes: 15%
- Exams (2 one-hour exams): 50%
- Final Exam (1 one-hour exam): 35%
Course Outline:

Week 1: Introduction to Supply Chain Management Principles and Strategies
Week 2: Supply Chain Processes
Week 3: Supply Chain Forecasting
Week 4: Manufacturing
Week 5: Inventory and Warehouse Management
Week 6: Procurement and Sourcing Management
Week 7: Transportation and Distribution Management; Exam
Week 8: Supply Chain Information Technology
Week 9: Supply Chain Metrics and Performance Management
Week 10: Lean Enterprise and Supply Chain
Week 11: Supply Chain Coordination and Relationships
Week 12: Risk Management
Week 13: Legal and Ethical Implications
Week 14: Future Trends and Directions; Exam
Final Exam

College Policies:

INC Grades:
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Instructor’s Bibliography:

MS Pharmaceutical Science and Business
PHARMACEUTICAL MARKETING

Course Number: PHS 519  Section:  Semester:
Professor:  Office:
Phone:  Email:
Office Hours:  Class in Session:

Course Description: This course provides an understanding of current pharmaceutical marketing environment and the role of the marketing department in the organization. It will present an overview of general marketing principles including marketing mix (4P-price, product, promotion, and place) and then apply them to all aspects of marketing pharmaceuticals. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program.

Learning Objectives: By the end of this course, students should be able to:
1. Apply basic marketing principles to the process of bringing pharmaceutical products to the market.
2. Illustrate the economics of the pharmaceutical industry.
3. Demonstrate the regulatory framework of the industry and the “typical” organizational structure of a large pharmaceutical company.
4. Recognize the significant ethical issues facing the industry.


Grading Policy: Final grade will be determined as follows:
- Quizzes 15 %
- Exams (2 one-hour exams) 50 %
- Final Exam (1 one-hour exam) 35%

Course Outline:
- Week 1: Course introduction and overview
- Week 2: Pharmaceutical Marketing & the Industry Environment
- Week 3: Marketing Principles & Process (4P)
- Week 4: 4P: Product - Products in the Pharmaceutical Industry
- Week 5: 4P: Price - Pharmaceuticals & Pricing
Week 6: 4P: Place - The Pharmaceutical Industry Supply Chain
Week 7: 4P: Promotion - Promotional Marketing Activities & Practices; Exam
Week 8: 4P: Promotion - Regulation, Social media
Week 9: Application of the Marketing Mix in the Pharmaceutical Industry
Week 10: Marketing to physicians
Week 11: Marketing to patients
Week 12: Market research
Week 13: Ethical considerations in the marketing of pharmaceutical products
Week 14: Future Trends and Directions; Exam
Final Exam

College Policies:

INC Grades:
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http://york.cuny.edu/student-development/ossd
Instructor’s Bibliography:

MS Pharmaceutical Science and Business
PHARMACEUTICAL PRODUCT MANAGEMENT

Course Number: PHS 520       Section:       Semester:
Professor:                  Office:
Phone:                      Email:
Office Hours:               
Class in Session:

Course Description: This course focuses on Product Lifecycle Management (PLM) in pharmaceutical industry. PLM is a business transformation approach to manage products across the enterprise and it includes drug development, competitive analysis, and coordination with the sales force. 3 hrs. 3 crs.

Prerequisites: Formal admission to the MS Pharmaceutical Science and Business Program; 519: Pharmaceutical Marketing.

Learning Objectives: By the end of this course, students should be able to:
1. Identify Product Life Management as the primary strategic framework for analysis.
2. Demonstrate new product development process and brand management.
3. Recognize the importance of marketing research as input to product decision.

Text: Tony Ellery and Neal Hansen, Pharmaceutical Lifecycle Management: Making the Most of Each and Every Brand, Wiley

Grading Policy: Final grade will be determined as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quizzes</td>
<td>15%</td>
</tr>
<tr>
<td>Exams (2 one-hour exams)</td>
<td>50%</td>
</tr>
<tr>
<td>Final Exam (1 one-hour exam)</td>
<td>35%</td>
</tr>
</tbody>
</table>

Course Outline:
Week 1: Introduction to Pharmaceutical Product Management
Week 2: Marketing strategy
Week 3: Product Lifecycle Management
Week 4: PLM Physical Flow
Week 5: PLM Digital Flow
Week 6: PLM Impact on Supply Chains
Week 7: PLM system; Exam
Week 8: Pharmaceutical product development
Week 9: Portfolio Management  
Week 10: Pharmaceutical brand management  
Week 11: Pharmaceutical market segmentation  
Week 12: Situational analysis  
Week 13: Environmental Life Cycle Assessment  
Week 14: Future Trends and Directions; Exam  
Final Exam

College Policies:

INC Grades:
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Instructor’s Bibliography:
John Stark, Product Lifecycle Management 21st Century Paradigm for Product Realisation, Springer

Pharmaceutical Executive, The Successful Product Manager's Handbook Spiral-bound
Course Number: PHS 521  Section:  Semester:
Professor:  Office:
Phone:  Email:
Office Hours:  
Class in Session:

Course Description:  Project management is the process and activity of planning, organizing, and controlling resources and procedures to produce a specific output. This course examines knowledge, skills and techniques for project management and applies them to pharmaceutical project management with the unique features, such as regulatory, compliance and quality related needs. 3 hrs. 3 crs.

Prerequisites:  Formal admission to the MS Pharmaceutical Science and Business Program; 519: Pharmaceutical Marketing.

Learning Objectives:  By the end of this course, students should be able to:
1. Demonstrate project management strategy design, development, and deployment.
2. Identify key performance metrics for project success.
3. Create Project Management Office (PMO) architecture in your organization.
4. Apply project management knowledge to pharmaceutical project.


Grading Policy:  Final grade will be determined as follows:
Quizzes  15 %  
Exams (2 one-hour exams)  50 %  
Final Exam (1 one-hour exam)  35%

Course Outline:
Week 1: Course Introduction
Week 2: Foundations of Project Management
Week 3: Initiating Projects
Week 4: Planning Projects
Week 5: Executing Projects
Week 6: Controlling Project
Week 7: Closing the Project; Exam
Week 8: Professional Communications
Week 9: Organizational Leadership and Decision Making
Week 10: Negotiating and Conflict Resolution
Week 11: Advanced Scheduling and Control
Week 12: Clinical Trial Project Management
Week 13: Risk Management in Projects and Programs
Week 14: Future Trends and Directions; Exam
Final Exam

College Policies:

INC Grades:
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Instructor's Bibliography:
Project Management Body of Knowledge, 5th Edition. Published by Project Management
Institute (PMI)


Verzuh, Eric. The Fast Forward MBA in Project Management. Published by John Wiley and Sons, Inc. 332 pages.
Appendix – B

Table 1b: Graduate Program Schedule
Table 1b: Graduate Program Schedule – FULL TIME STUDENTS

- Indicate academic calendar type: _X_Semester _Quarter _Trimester _Other (describe)
- Label each term in sequence, consistent with the institution’s academic calendar (e.g., Fall 1, Spring 1, Fall 2)
- Use the table to show how a typical student may progress through the program; copy/expand the table as needed.

<table>
<thead>
<tr>
<th>Term: Fall 1</th>
<th>Term: Spring 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Course Number &amp; Title</td>
<td>Credits</td>
</tr>
<tr>
<td>PHS 501: Pharmaceutical Discovery and Development (Core Course)</td>
<td>3</td>
</tr>
<tr>
<td>PHS 502: Pharmaceutical Discovery and Development Techniques (Core Course)</td>
<td>3</td>
</tr>
<tr>
<td>PHS 503: Advanced Pharmacology (Core Course)</td>
<td>3</td>
</tr>
<tr>
<td>PHS 504: Advanced Biostatistics (Core Course)</td>
<td>3</td>
</tr>
</tbody>
</table>

Term credit total: 12  
Term credit total: 12

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<tr>
<th>Term: Fall 2</th>
<th>Term: Spring 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Course Number &amp; Title</td>
<td>Credits</td>
</tr>
<tr>
<td>Elective 1</td>
<td>3</td>
</tr>
<tr>
<td>Elective 2</td>
<td>3</td>
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<tr>
<td>Elective 3</td>
<td>3</td>
</tr>
<tr>
<td>Elective 4</td>
<td>3</td>
</tr>
</tbody>
</table>

Term credit total: 12  
Term credit total:

Program Totals:  
Credits: 36

Identify any comprehensive, culminating element(s) (e.g., thesis or examination), including course number if applicable:

New: indicate if new course  
Prerequisite(s): list prerequisite(s) for the noted courses
Table 1b: Graduate Program Schedule – PART TIME STUDENTS

- Indicate **academic calendar** type: __X__Semester ____Quarter ____Trimester ____Other (describe)
- Label each term in sequence, consistent with the institution’s academic calendar (e.g., Fall 1, Spring 1, Fall 2)
- Use the table to show **how a typical student may progress through the program**; copy/expand the table as needed.

<table>
<thead>
<tr>
<th>Term: Fall 1</th>
<th>Course Number &amp; Title</th>
<th>Credits</th>
<th>New</th>
<th>Prerequisite(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PHS 501: Pharmaceutical Discovery and Development (Core Course)</td>
<td>3</td>
<td>✓</td>
<td>Formal admission to the MS Pharmaceutical Science and Business Program.</td>
</tr>
<tr>
<td></td>
<td>PHS 502: Pharmaceutical Discovery and Development Techniques (Core Course)</td>
<td>3</td>
<td>✓</td>
<td>Formal admission to the MS Pharmaceutical Science and Business Program.</td>
</tr>
<tr>
<td>Term credit total:</td>
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<thead>
<tr>
<th>Term: Spring 1</th>
<th>Course Number &amp; Title</th>
<th>Credits</th>
<th>New</th>
<th>Prerequisite(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PHS 503: Advanced Pharmacology (Core Course)</td>
<td>3</td>
<td>✓</td>
<td>Formal admission to the MS Pharmaceutical Science and Business Program.</td>
</tr>
<tr>
<td></td>
<td>PHS 504: Advanced Biostatistics (Core Course)</td>
<td>3</td>
<td>✓</td>
<td>Formal admission to the MS Pharmaceutical Science and Business Program.</td>
</tr>
<tr>
<td>Term credit total:</td>
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<tr>
<th>Term: Fall 2</th>
<th>Course Number &amp; Title</th>
<th>Credits</th>
<th>New</th>
<th>Prerequisite(s)</th>
</tr>
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<tr>
<td></td>
<td>PHS 505: Foundations of Regulatory Affairs (Core Course)</td>
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<td>✓</td>
<td>Formal admission to the MS Pharmaceutical Science and Business Program.</td>
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<tr>
<td></td>
<td>PHS 506: Pharmaceutical Ethics and Intellectual Property Management (Core Course)</td>
<td>3</td>
<td>✓</td>
<td>Formal admission to the MS Pharmaceutical Science and Business Program.</td>
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<th>Credits</th>
<th>New</th>
<th>Prerequisite(s)</th>
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<tr>
<td></td>
<td>PHS 507: Pharmaceutical Industry and Business (Core Course)</td>
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<td>Formal admission to the MS Pharmaceutical Science and Business Program.</td>
</tr>
<tr>
<td></td>
<td>PHS 508: Pharmaceutical Science and Business Capstone Project (Core Course)</td>
<td>3</td>
<td>✓</td>
<td>Formal admission to the MS Pharmaceutical Science and Business Program.</td>
</tr>
<tr>
<td>Term credit total:</td>
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<td></td>
<td></td>
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<tr>
<th>Term: Fall 3</th>
<th>Course Number &amp; Title</th>
<th>Credits</th>
<th>New</th>
<th>Prerequisite(s)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Elective 1</td>
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</tr>
<tr>
<td></td>
<td>Elective 2</td>
<td>3</td>
<td>✓</td>
<td>As applicable</td>
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<tr>
<td>Term credit total:</td>
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<table>
<thead>
<tr>
<th>Term: Spring 3</th>
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<th>New</th>
<th>Prerequisite(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Elective 3</td>
<td>3</td>
<td>✓</td>
<td>As applicable</td>
</tr>
<tr>
<td></td>
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<td>As applicable</td>
</tr>
<tr>
<td>Term credit total:</td>
<td></td>
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<td></td>
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</tbody>
</table>

**Program Totals:**  **Credits: 36**

Identify any comprehensive, culminating element(s) (e.g., thesis or examination), including course number if applicable:

**New:** indicate if new course  **Prerequisite(s):** list prerequisite(s) for the noted courses
Appendix – C

Table 2: Full-Time Faculty
Table 2: Full-Time Faculty

Faculty teaching at the graduate level must have an earned doctorate/terminal degree or demonstrate special competence in the field. Provide information on faculty members who are full-time at the institution and who will be teaching each course in the major field or graduate program. The application addendum for professional licensure, teacher certification, or educational leadership certification programs may provide additional directions for those types of proposals.

<table>
<thead>
<tr>
<th>Faculty Member Name and Title (include and identify Program Director)</th>
<th>Program Courses to be Taught</th>
<th>Percent Time to Program</th>
<th>Highest and Other Applicable Earned Degrees &amp; Disciplines (include College/University)</th>
<th>Additional Qualifications: list related certifications/licenses; occupational experience; scholarly contributions, etc.</th>
</tr>
</thead>
</table>
| Deb N. Chakravarti Program Director Professor, Department of Chemistry; Director, Pharmaceutical Sciences Program (Undergraduate); Director, York College – US Food and Drug Administration Partnership. | PHS 505: Foundations of Regulatory Affairs  
PHS 508: Pharmaceutical Science and Business Capstone Project  
PHS 509: Biotherapeutics  
PHS 512: Pharmaceutical Quality Assurance, Process Validation and Controls  
PHS 517: Writing and Submission of Regulatory Applications | 70 | D. Phil. (Protein Chemistry/Immunology, University of Oxford, UK)  
Ph.D. (Biochemistry, University of Calcutta, India)  
M.Sc. (Biochemistry, University of Calcutta, India)  
B.Sc. (Chemistry, University of Calcutta, India) | • Initiated teaching new B.S. Pharmaceutical Science major at York College, CUNY.  
• Research training: University of Oxford (mentor Rodney Porter, Nobel Laureate) and The Scripps Research Institute, CA.  
• Vaccine research: University of Alabama at Birmingham and Wyeth/Pfizer.  
• Beckman Professor, Keck Graduate Institute: helped launching professional science master’s curriculum.  
• Publications: 57 papers and book chapters; Patents: 2. |
| Laura L. Beaton Associate Professor, Department of Biology | PHS 504: Advanced Biostatistics | 15 | Ph.D. (Biological Sciences, McMaster University, Canada)  
H.B.Sc. (Biology, McMaster University, Canada) | • Faculty, Doctoral Program in Biology, The Graduate School and University Center, CUNY. |
| Emmanuel J. Chang Associate Professor, Department of Chemistry | PHS 506: Pharmaceutical Ethics and Intellectual Property Management | 15 | Ph.D. (Biological Sciences, The Rockefeller University, NY)  
B.A. (Chemistry, Princeton University, NJ) | • Postdoctoral research: The Rockefeller University, NY.  
• Faculty, Doctoral Program in Biochemistry, The Graduate School and University Center, CUNY. |
| Kang Bok Lee Assistant Professor, Department of Business and Economics | PHS 507: Pharmaceutical Industry and Business  
PHS 518: Pharmaceutical Supply Chain | 70 | Ph.D. (Operations Research, Pohang University of Science and Technology, Korea) | • Research Associate Professor, Department of Supply Chain Management, Rutgers |
Faculty teaching at the graduate level must have an earned doctorate/terminal degree or demonstrate special competence in the field. Provide information on faculty members who are **full-time at the institution** and who will be teaching each course in the major field or graduate program. The application addendum for professional licensure, teacher certification, or educational leadership certification programs may provide additional directions for those types of proposals.

<table>
<thead>
<tr>
<th>Faculty Member Name and Title (include and identify Program Director)</th>
<th>Program Courses to be Taught</th>
<th>Percent Time to Program</th>
<th>Highest and Other Applicable Earned Degrees &amp; Disciplines (include College/University)</th>
<th>Additional Qualifications: list related certifications/ licenses; occupational experience; scholarly contributions, etc.</th>
</tr>
</thead>
</table>
| Management  
PHS 519: Pharmaceutical Marketing  
PHS 520: Pharmaceutical Product Management  
PHS 521: Pharmaceutical Project Management |  | M.S. (Operations Research, Pohang University of Science and Technology, Korea)  
B.S. (Industrial Engineering, Pohang University of Science and Technology, Korea) | Business School, Rutgers University, NJ (2010-2013).  
• Publications: 28 research papers. |
| Daniele Musumeci  
Assistant Professor, Department of Chemistry  
PHS 501: Pharmaceutical Discovery and Development  
PHS 502: Pharmaceutical Discovery and Development Techniques  
PHS 510: Advanced Pharmaceutics |  | Ph.D. (Chemistry, University of Sheffield, UK)  
B.S./M.S. (Pharmaceutical Sciences, Universita’ di Catania, Italy) | • Postdoctoral research: New York University, NY and University of Wisconsin, Madison, WI.  
• Regulatory Affairs Officer, Wyeth, Catania, Italy.  
• Publication: 9 research papers. |
| Adam A. Profit, Associate Professor, Department of Chemistry  
PHS 503: Advanced Pharmacology  
PHS 514: Advanced Toxicology |  | Ph.D. (Bioorganic Chemistry, Stony Brook University, NY)  
B.S. (Chemistry, Herbert H. Lehman College, CUNY) | • Postdoctoral research: Albert Einstein College of Medicine, NY.  
Appendix – D

Table 3: Part-Time Faculty
Table 3: Part-Time Faculty

Faculty teaching at the graduate level must have an earned doctorate/terminal degree or demonstrate special competence in the field. Provide information on part-time faculty members who will be teaching each course in the major field or graduate program. The application addendum for professional licensure, teacher certification, or educational leadership certification programs may provide additional directions for those types of proposals.

<table>
<thead>
<tr>
<th>Faculty Member Name and Title</th>
<th>Program Courses to be Taught</th>
<th>Highest and Other Applicable Earned Degrees &amp; Disciplines (include College/University)</th>
<th>Additional Qualifications: list related certifications/licenses; occupational experience; scholarly contributions, etc.</th>
</tr>
</thead>
</table>
| Bulbul Chakravarti Adjunct Faculty | PHS 511: Special Topics in Pharmaceutical Discovery and Development | Ph.D. (Biochemistry, University of Calcutta, India)  
M.Sc. (Biochemistry, University of Calcutta, India)  
B.Sc. (Chemistry, University of Calcutta, India) |  
• Teaching experience: Pharmacology, Chemistry, Biology and Parasitic Diseases: York College (CUNY), Bronx Community College (CUNY), Keck Graduate Institute, College at Brockport (SUNY), Rochester Institute of Technology, and University of Alabama at Birmingham.  
• Published 45 research papers in peer reviewed journals and 9 book chapters.  
• PI of NIH RO1, P60 and PSC CUNY grants.  
• Pharmaceutical industry experience: Research Scientist at Wyeth Vaccines (Pfizer). |
| Dilcia M. Granville Adjunct Faculty | PHS 515: International Regulatory Affairs  
PHS 516: Pharmaceutical Product Labeling | Ph.D. (Social Work, Adelphi University, NY)  
M.S.W. (Social Work, Adelphi University, NY)  
B.S. (Health Management, Queens College, CUNY)  
A.A. (Mental Health, LaGuardia Community College, CUNY) |  
• Senior Public Affairs Specialist and Consumer Safety Officer, US Food and Drug Administration, Jamaica, NY (1990 to present). |
| TBA | PHS 513: Design of Clinical Trials | | |
Appendix – E

Table 4: Faculty to be Hired
Table 4: Faculty to be Hired

If faculty must be hired, specify the number and title of new positions to be established and minimum qualifications.

<table>
<thead>
<tr>
<th>Title/Rank of Position</th>
<th>No. of New Positions</th>
<th>Minimum Qualifications (including degree and discipline area)</th>
<th>F/T or P/T</th>
<th>Percent Time to Program</th>
<th>Expected Course Assignments</th>
<th>Expected Hiring Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistant/Associate Professor</td>
<td>1</td>
<td>Ph.D.</td>
<td>F/T</td>
<td>50%</td>
<td>Pharmaceutical Science</td>
<td>Year 2: 2017-2018</td>
</tr>
<tr>
<td>Assistant/Associate Professor</td>
<td>1</td>
<td>Ph.D.</td>
<td>F/T</td>
<td>50%</td>
<td>Pharmaceutical Science</td>
<td>Year 3: 2018-2019</td>
</tr>
<tr>
<td>Part-Time/Adjunct</td>
<td>0.75</td>
<td>Ph.D.</td>
<td>P/T</td>
<td>100%</td>
<td>Pharmaceutical Science</td>
<td>Year 1: 2016-2017</td>
</tr>
</tbody>
</table>
Appendix – F

Table 5: New Resources
### Table 5: New Resources

<table>
<thead>
<tr>
<th>Expenditures</th>
<th>Year 1 Academic Year(^\d) 2016-2017</th>
<th>Year 2 Academic Year(^\d) 2017-2018</th>
<th>Year 3 Academic Year(^\d) 2018-2019</th>
<th>Year 4 Academic Year(^\d) 2019-2020</th>
<th>Year 5 Academic Year(^\d) 2020-2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Time Faculty</td>
<td>$15,000.00</td>
<td>$80,000.00</td>
<td>$163,200.00</td>
<td>$166,464.00</td>
<td>$169,793.00</td>
</tr>
<tr>
<td>Part Time Faculty</td>
<td>$15,300.00</td>
<td>$15,606.00</td>
<td>$15,918.00</td>
<td>$15,918.00</td>
<td>$16,236.00</td>
</tr>
<tr>
<td>Full Time Staff</td>
<td>$15,000.00</td>
<td>$15,300.00</td>
<td>$15,606.00</td>
<td>$15,918.00</td>
<td>$16,236.00</td>
</tr>
<tr>
<td>Part Time Staff</td>
<td>$15,000.00</td>
<td>$15,300.00</td>
<td>$15,606.00</td>
<td>$15,918.00</td>
<td>$16,236.00</td>
</tr>
<tr>
<td>Library (Includes Staffing)</td>
<td>$2,500.00</td>
<td>$3,000.00</td>
<td>$3,000.00</td>
<td>$3,000.00</td>
<td>$3,000.00</td>
</tr>
<tr>
<td>Equipment</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Laboratories</td>
<td>$2,500.00</td>
<td>$2,500.00</td>
<td>$2,500.00</td>
<td>$2,500.00</td>
<td>$2,500.00</td>
</tr>
<tr>
<td>Supplies &amp; Expenses (Other than Personal Services)</td>
<td>$2,500.00</td>
<td>$2,500.00</td>
<td>$2,500.00</td>
<td>$2,500.00</td>
<td>$2,500.00</td>
</tr>
<tr>
<td>Capital Expenditures</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Other</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Total all</td>
<td>$22,500.00</td>
<td>$103,300.00</td>
<td>$186,806.00</td>
<td>$190,382.00</td>
<td>$194,029.00</td>
</tr>
</tbody>
</table>

**Notes:**

1. Specify the inflation rate used for projections.
2. Specify the academic year.
3. Include fringe benefits.
4. New resources means resources engendered specifically by the proposed program. The new resources from the previous year should be carried over to the following year, new resources with adjustments for inflation, if a continuing cost.
5. Specify what is included in "other" category, (e.g., student financial aid).
Appendix – G

Projected Revenue Related to the Proposed Program
# Projected Revenue Related to the Proposed Program

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tuition Revenue[3]</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>01. From Existing Sources[4]</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td><strong>03. Total</strong></td>
<td><strong>$156,200</strong></td>
<td><strong>$271,509</strong></td>
<td><strong>$276,939</strong></td>
<td><strong>$282,478</strong></td>
<td><strong>$288,128</strong></td>
</tr>
<tr>
<td><strong>Other Revenue[7]</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>07. From Existing Sources§</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>08. From New Sources**</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td><strong>09. Total</strong></td>
<td><strong>$0</strong></td>
<td><strong>$0</strong></td>
<td><strong>$0</strong></td>
<td><strong>$0</strong></td>
<td><strong>$0</strong></td>
</tr>
<tr>
<td><strong>Grand Total[8]</strong></td>
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</tr>
<tr>
<td>10. From Existing Sources§</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>11. From New Sources**</td>
<td>$156,200</td>
<td>$271,509</td>
<td>$276,939</td>
<td>$282,478</td>
<td>$288,128</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$156,200</strong></td>
<td><strong>$271,509</strong></td>
<td><strong>$276,939</strong></td>
<td><strong>$282,478</strong></td>
<td><strong>$288,128</strong></td>
</tr>
</tbody>
</table>

---

[1] Specify the inflation rate used for projections.
[2] Specify the academic year.
[3] Please explain how tuition revenue was calculated. **Current CUNY Tuition and Fees Rate**
[4] Existing sources means revenue generated by continuing students. Please remember to account for attrition and graduation rates
[5] New sources means revenue engendered by new students. The revenue from new sources from one year should be carried over to the next year as revenues from continuing sources with adjustments for inflation.
[6] Public institutions should include here regular State appropriations applied to the program.
[7] Specify what is included in “other” category.
[8] Enter total of Tuition, State and Other Revenue, from Existing or New Sources.
Appendix – H

Supporting Materials: Expenditures
## DIRECT OPERATING EXPENSES

Include additional expenses incurred by other programs when satisfying needs of new program. Faculty need should be commensurate with "net section needs" based on enrollment (see "Enroll & Seat Need Projections" tab)

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Full Time Faculty Overload (include Summer)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Full Time Faculty Base Salary (list separately)</td>
<td>$80,000.00</td>
<td>$163,200.00</td>
<td>$166,464.00</td>
<td>$169,793.00</td>
<td></td>
</tr>
<tr>
<td>New Full Time Faculty Overload (include Summer)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Faculty Re-assigned Time (list separately)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full Time Employee Fringe Benefits (41.6%)</td>
<td>0</td>
<td>33280</td>
<td>67891.2</td>
<td>69249.024</td>
<td>70633.888</td>
</tr>
<tr>
<td><strong>Total</strong> (Links to Full-Time Faculty on Program Exp Worksheet)</td>
<td>$ -</td>
<td>$113,280.00</td>
<td>$231,091.20</td>
<td>$235,713.02</td>
<td>$240,426.89</td>
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<tr>
<td>Part Time Faculty Actual Salaries</td>
<td>$15,000.00</td>
<td>$15,300.00</td>
<td>$15,606.00</td>
<td>$15,918.00</td>
<td>$16,236.00</td>
</tr>
<tr>
<td>Part Time Faculty Actual Fringe Benefits (24.3%)</td>
<td>3645</td>
<td>3717.9</td>
<td>3792.258</td>
<td>3868.074</td>
<td>3945.348</td>
</tr>
<tr>
<td><strong>Total</strong> (Links to Part-Time Faculty Program Exp Worksheet)</td>
<td>$18,645.00</td>
<td>$19,017.90</td>
<td>$19,398.26</td>
<td>$19,786.07</td>
<td>$20,181.35</td>
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<tr>
<td>Full Time Staff Base Salary (list separately)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full Time Staff Fringe Benefits (41.6%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong> (Links to Full-Time Staff on Program Exp Worksheet)</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
</tbody>
</table>

## PART-TIME STAFF

(do not include library staff in this section)

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part Time Staff Base Salary (list separately)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Faculty Replacement Costs (replacement of full-time faculty - e.g. on release time - with part-time faculty)</td>
<td></td>
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<td>--------------------------------------------------</td>
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<td>Graduate Assistants</td>
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<td>Student Hourly</td>
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<tr>
<td>Part Time Employee Fringe Benefits (24.3%)</td>
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<tr>
<td><strong>Total</strong> (Links to Part-Time Staff on Program Exp Worksheet)</td>
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<tr>
<td>$</td>
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</tbody>
</table>

| LIBRARY |
|------------------|------------------|------------------|------------------|------------------|
| Library Resources | 2500  | 3000  | 3000  | 3000  | 3000  |
| Library Staff Full Time (List Separately)        |
| Full Time Staff Fringe Benefits (41.6%)            |
| 0                  | 0                  | 0                  | 0                  | 0                  |
| Library Staff Part Time (List Separately)         |
| Part Time Employee Fringe Benefits (24.3%)         |
| 0                  | 0                  | 0                  | 0                  | 0                  |
| **TOTAL** (Links to Library on Program Exp Worksheet) |
| $2,500.00        | $3,000.00         | $3,000.00         | $3,000.00         | $3,000.00         |

| EQUIPMENT |
|------------------|------------------|------------------|------------------|------------------|
| Computer Hardware |                  |                  |                  |                  |
| Office Furniture  |                  |                  |                  |                  |
| Other (Specify)   |                  |                  |                  |                  |
| **Total** (Links to Equipment on Program Exp Worksheet) |
| $                     | $                     | $                     | $                     | $                     |

<p>| LABORATORIES |
|------------------|------------------|------------------|------------------|------------------|
| Laboratory Equipment | 2500  | 2500  | 2500  | 2500  | 2500  |
| Other (list separately) |
| <strong>TOTAL</strong> (Links to Laboratories on Program Exp Worksheet) |
| $                     | $                     | $                     | $                     | $                     |</p>
<table>
<thead>
<tr>
<th>SUPPLIES AND EXPENSES (OTPS)</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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</thead>
<tbody>
<tr>
<td>Consultants and Honoraria</td>
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<tr>
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<tr>
<td>Instructional Supplies</td>
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<td>Faculty Development</td>
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<tr>
<td>Travel and Conferences</td>
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<tr>
<td>Membership Fees</td>
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<td>Advertising and Promotion</td>
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<td>Accreditation</td>
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<td>Computer Software</td>
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<td>Computer License Fees</td>
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<td>Computer Repair and Maintenance</td>
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<tr>
<td>Equipment Repair and Maintenance</td>
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<tr>
<td><strong>New Total Supplies and OTPS Expenses</strong> (Links to Supplies on Program Exp Worksheet)</td>
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<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
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<tr>
<td><strong>CAPITAL EXPENDITURES</strong></td>
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<tr>
<td>Facility Renovations</td>
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<tr>
<td>Classroom Equipment</td>
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</tr>
<tr>
<td>Other (list separately)</td>
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<tr>
<td><strong>TOTAL</strong> (Links to Capital Expenditures on Program Exp Worksheet)</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
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<tr>
<td><strong>Other</strong> (list separately)</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td><strong>TOTAL</strong> (Links to Other on Program Exp Worksheet)</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
<td>$ -</td>
</tr>
</tbody>
</table>
Appendix – I

Supporting Materials: Revenue
The Five-Year Revenue Projections for Program
SENIOR COLLEGE (UNDERGRADUATE) WORKSHEET
Year 1 = Fall 2016

<table>
<thead>
<tr>
<th>EXISTING FULL-TIME STUDENTS</th>
<th>Year One</th>
<th>Year Two</th>
<th>Year Three</th>
<th>Year Four</th>
<th>Year Five</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuition &amp; Fees:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># of EXISTING FULL-TIME, In-State Students (linked from &quot;Enroll &amp; Seat Need Projections&quot;)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tuition Income (calculates 2% increase per year after Fall 2015)</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Total Tuition</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Student Fees (enter ANNUAL program fees other than standard CUNY fees)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Fees</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total In-State Tuition &amp; Fees</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
</tbody>
</table>

| Tuition & Fees:              |          |          |            |           |           |
| # of EXISTING FULL-TIME, Out-of-State Students (linked from "Enroll & Seat Need Projections") | 0       | 0       | 0          | 0         | 0         |
| Annual Avg # of Credits per FT student (24-30) |          |          |            |           |           |
| Tuition Income (Specify Rate per credit. Calculates 2% annual increase after Fall 2015) | $0 | $0 | $0 | $0 | $0 |
| Total Tuition                | $0       | $0       | $0          | $0         | $0         |
| Student Fees (enter ANNUAL program fees other than standard CUNY fees) |          |          |            |           |           |
| Total Fees                   | 0        | 0        | 0           | 0          | 0          |
| Total Out-of-State Tuition & Fees | $0       | $0       | $0          | $0         | $0         |
| TOTAL EXISTING FULL-TIME TUITION REVENUE | $0 | $0 | $0 | $0 | $0 |
| EXISTING PART-TIME STUDENTS | Year One | Year Two | Year Three | Year Four | Year Five |
| Tuition & Fees: | |
| # of EXISTING PART-TIME, In-State Students (linked from "Enroll & Seat Need Projections") | 0 | 0 | 0 | 0 | 0 |
| Total Enrolled Credits (Enter Avg # credits per student per year-Fall+ Spring+Summer -- i.e. 6 Fall, 6 Spring, 3 Summer=15) | |
| Tuition Income (Specify Rate per credit. Calculates 2% increase per year after Fall 2015) | $0 | $0 | $0 | $0 | $0 |
| Total Tuition | $0 | $0 | $0 | $0 | $0 |
| Student Fees (enter ANNUAL program fees other than standard CUNY fees) | |
| Total Fees | 0 | 0 | 0 | 0 | 0 |
| **Total In-State Tuition & Fees** | $0 | $0 | $0 | $0 | $0 |

<p>| Tuition &amp; Fees: | |
| # of EXISTING PART-TIME Out of State Students (linked from &quot;Enrollment and Seat Need Projections&quot;) | 0 | 0 | 0 | 0 | 0 |
| Total Enrolled Credits (Enter Avg # credits per student per year-Fall+ Spring+Summer -- i.e. 6 Fall, 6 Spring, 3 Summer=15) | |
| Tuition Income (Specify Rate per credit. Calculates 2% increase per year after Fall 2015) | $0 | $0 | $0 | $0 | $0 |
| Total Tuition | $0 | $0 | $0 | $0 | $0 |
| Student Fees (enter ANNUAL program fees other than standard CUNY fees) | |
| Total Fees | 0 | 0 | 0 | 0 | 0 |
| <strong>Total Out-of-State Tuition &amp; Fees</strong> | $0 | $0 | $0 | $0 | $0 |</p>
<table>
<thead>
<tr>
<th>NEW FULL-TIME STUDENTS</th>
<th>Year One</th>
<th>Year Two</th>
<th>Year Three</th>
<th>Year Four</th>
<th>Year Five</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuition &amp; Fees:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># of NEW FULL-TIME, In-State Students (linked from &quot;Enroll &amp; Seat Need Projections&quot;)</td>
<td>4</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Tuition Income (Calculates 2% increase per year after Fall 2015)</td>
<td>$9,650</td>
<td>$9,843</td>
<td>$10,040</td>
<td>$10,241</td>
<td>$10,445</td>
</tr>
<tr>
<td>Total Tuition</td>
<td>$38,600</td>
<td>$68,901</td>
<td>$70,279</td>
<td>$71,685</td>
<td>$73,118</td>
</tr>
<tr>
<td>Student Fees (enter ANNUAL program fees other than standard CUNY fees)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total Fees</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total In-State Tuition &amp; Fees</td>
<td>$38,600</td>
<td>$68,901</td>
<td>$70,279</td>
<td>$71,685</td>
<td>$73,118</td>
</tr>
</tbody>
</table>

<p>| Tuition &amp; Fees:        |          |          |            |           |           |
| # of NEW FULL-TIME, Out-of-State Students (linked from &quot;Enroll &amp; Seat Need Projections&quot;) | 1 | 2 | 2 | 2 | 2 |
| Annual Avg # of Credits per FT student (24-30) |          |          |            |           |           |
| Tuition Income (Specify Rate per credit. Calculates 2% increase per year after Fall 2015) | $17,880 | $18,238 | $18,603 | $18,975 | $19,354 |
| Total Tuition         | $0       | $0       | $0         | $0        | $0        |
| Student Fees (enter ANNUAL program fees other than standard CUNY fees) | 0 | 0 | 0 | 0 | 0 |
| Total Fees            |          |          |            |           |           |
| Total Out-of-State Tuition &amp; Fees | $0 | $0 | $0 | $0 | $0 |</p>
<table>
<thead>
<tr>
<th>Year</th>
<th>Year</th>
<th>Year</th>
<th>Year</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>Two</td>
<td>Three</td>
<td>Four</td>
<td>Five</td>
</tr>
<tr>
<td># of NEW PART-TIME, In-State Students (linked from &quot;Enroll &amp; Seat Need Projections&quot;)</td>
<td>15</td>
<td>28</td>
<td>28</td>
<td>28</td>
</tr>
<tr>
<td>Total Enrolled Credits (Enter Avg # credits per student per year-Fall+ Spring+Summer -- i.e. 6 Fall, 6 Spring, 3 Summer=15)</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Tuition Income (Specify Rate per credit. Calculates 2% increase per year after Fall 2015)</td>
<td>$405</td>
<td>$413</td>
<td>$421</td>
<td>$430</td>
</tr>
<tr>
<td>Total Tuition</td>
<td>$72,900</td>
<td>$138,768</td>
<td>$141,543</td>
<td>$144,374</td>
</tr>
<tr>
<td>Student Fees (enter ANNUAL program fees other than standard CUNY fees)</td>
<td>Total Fees</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total In-State Tuition &amp; Fees</td>
<td>$72,900</td>
<td>$138,768</td>
<td>$141,543</td>
<td>$144,374</td>
</tr>
</tbody>
</table>

Tuition & Fees:

# of NEW PART-TIME, Out-of-State Students | 5   | 7   | 7   | 7   | 7   |
Total Enrolled Credits (Enter Avg # credits per student per year-Fall+ Spring+Summer -- i.e. 6 Fall, 6 Spring, 3 Summer=15) | 12   | 12   | 12   | 12   | 12   |
Tuition Income (Specify Rate per credit) calculates 2% increase per year | $745 | $760 | $775 | $791 | $807 |
Total Tuition | $44,700 | $63,840 | $65,117 | $66,419 | $67,748 |
Student Fees (enter ANNUAL program fees other than standard CUNY fees) | Total Fees | 0 | 0 | 0 | 0 |
Total Out-of-State Tuition & Fees | $44,700 | $63,840 | $65,117 | $66,419 | $67,748 |
<table>
<thead>
<tr>
<th>TOTAL NEW PART-TIME REVENUE</th>
<th>$117,600</th>
<th>$202,608</th>
<th>$206,660</th>
<th>$210,793</th>
<th>$215,009</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL NEW REVENUE (LINKS TO REVENUE SPREADSHEET ROW 7)</td>
<td>$156,200</td>
<td>$271,509</td>
<td>$276,939</td>
<td>$282,478</td>
<td>$288,128</td>
</tr>
<tr>
<td>OTHER REVENUE</td>
<td>Year One</td>
<td>Year Two</td>
<td>Year Three</td>
<td>Year Four</td>
<td>Year Five</td>
</tr>
<tr>
<td>Other Revenue From Existing Sources (specify and explain)</td>
<td>LINKS TO REVENUE SPREADSHEET ROW 13</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Revenue New (specify and explain) (LINKS TO REVENUE SPREADSHEET ROW 15)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix – J

Sample Job Opportunities
Sample Job Opportunities for Students with a M.S. degree in Pharmaceutical Science and Business

Sample Job Description #1

Sr. Regulatory Associate, CMC
Pharmaceutical Job
United Recruiters
Location: Cary, North Carolina

Job Description
Our client is a successful specialty pharmaceutical company focused on commercializing products for the hospital and adjacent specialty markets. They are currently seeking to fill a Senior Regulatory Affairs position. The focus of this position is to provide regulatory expertise with a concentration on Chemistry, Manufacturing and Controls (CMC) related issues including regulatory assessment on Change Controls, preparing CMC related FDA submissions and support of development and life-cycle management projects. This will require interfacing directly with various regulatory agencies, as required, to facilitate the review and approval of regulatory supplements and applications.

If you possess the skills and experience listed below and are interested in joining a world class company we would like to hear from you!

Key Responsibilities:

CMC Supplements
• Prepare CMC related supplements to New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs) and Biologics License Agreements (BLAs)
• Interface with Contract Manufacturing Organizations (CMOs) to obtain the necessary documentation for a CMC related submission
• Write concise and scientifically accurate sections/updates for Modules 2 and 3

Change Control Management
• Provide regulatory assessment on internal and external Change Controls with a focus on CMC related changes
• Attend Change Control meetings as Regulatory representative

Annual Reporting
• Draft CMC sections within Annual Reports for NDAs, ANDAs and BLAs
• Interface with CMOs and internal Quality representatives to obtain information required for CMC sections within Annual Reports

Support of Government Agency Requirements
• Ensure compliance to government agencies
• Assist with FDA inspections, as needed
• File agency correspondence in order to maintain complete regulatory files for each product
• Remain current with regulatory requirements and guidance documents

Life Cycle Management and Product Development
• Represent Regulatory Affairs on cross-functional product development/life-cycle management and manufacturing support teams
• Assist Regulatory Affairs Department to formulate submission strategies

We are very interested in talking to candidates with the following qualifications:
• BS/BA in Chemistry, Pharmacy, or Biologic Science; Graduate degree preferred
• Regulatory experience in the Pharmaceutical industry; 3-7 years
• Experience working with various government agencies including but not limited to the Federal Drug Administration (FDA) and OIG. Experience with Health Canada preferred
• Proficiency in reading, interpreting, and evaluating regulatory guidance documents and initiating changes in systems to ensure regulatory compliance
• Proficiency in Common Technical Document and global guidelines on content
• Comprehensive understanding of US federal regulations and processes related to the development of drugs and filing of an application
• Proficient in MS Office (Word, Excel, Project), Adobe and ISI Toolbox

Benefits
• Competitive Salary & Benefits Package

Candidates must be legally authorized to work in the United States.
We rely on you to provide us with information that is precisely related to our posting.

[Source: http://pharmaceutical.jobs.net/j/sr-regulatory-associate-cmc_JHR1N46B055WYPXZHXR.aspx; Accessed: 3 March 2015]

Sample Job Description #2

Pharmaceutical Label Writer
Telerx
Pharmaceutical, Legal, Marketing
351 N. Sumneytown Pike
North Wales, Pennsylvania 19454

Pharmaceutical Label Writer Job Description
Under the direction of the Therapeutic Area Leader, Worldwide Product Labeling, is responsible for the drafting of labels for new products for presentation to the Label Evaluation and Development Team (LEAD) and the Label Approval Strategy Team (LAST) and for revision and updating of product labeling for marketed products worldwide. Collects and reviews information pertinent to the safety and efficacy of marketed products. Prepares and circulates revised labeling for approval throughout the Company. Presents proposed labeling revisions to LEAD and LAST. Reviews periodic reports and Adverse Drug Reaction Reports and prepares labeling summaries for these reports. Prepares annotated files of labeling for the Company.

Pharmaceutical Label Writer Job Requirements
Required:
• Bachelor degree in a scientific/medically related discipline
• At least 4 years in the pharmaceutical industry or related field with knowledge of drug development.
• Excellent communication and organization skills and proficiency in MS WORD required.
• Ability to adapt to evolving regulations/priorities and maintain compliance and accuracy under tight timelines
Preferred:
• Master’s Degree
• Writing experience desirable
• Experience in product labeling/regulatory affairs or related discipline with demonstrated scientific/medical writing skills.

[Source: http://pharmaceutical.jobs.net/j/pharmaceutical-pharmaceutical-label-writer_JHL2PJ6L85YR1N7ZPX8.aspx; Accessed: 3 March 2015]

Sample Job Description #3

Medical Scientist with Drug Development Process Experience
Alpha Consulting Corp
Pharmaceutical
Gaithersburg, Maryland

Project Description: The Medical Scientist will be a renowned expert in own field and may specialize in more than one area. This individual will work independently with guidance in only the most complex situations and serve as a close partner to the physician on the team. S/he may coordinate the activity of a research team and will hold full accountability for projects, often with Global impact. This position will have key relationships internally with clinical project teams, marketing and business development, and brand or therapy area team leaders, and externally with regulatory bodies and external service providers.

Job Requirements:
Representative accountabilities will include, but not necessarily be limited to, the following:
• Integrate the research and commercial aspects of drug development to ensure successful, value creating product development, either by overseeing a team of clinical research professionals, or by supporting such a team as an expert in one or more areas of clinical research
• Ensure there is adequate input into the drug development process from experts in each of the various areas of drug development, or provide input into one or more of these areas as a technical expert
• Develop and design studies to determine the scientific or commercial viability of a particular drug or portfolio of drugs and interpret the results of these studies, either as the head of a team, or by providing expert input. Participate in protocol writing and strategy
• Ensure that all aspects of work being carried out by self or team is done with a focus on the commercial viability of the drug under development
• Coordinate actions between research and development, manufacturing and marketing teams to ensure the success of product development at each stage of the product life cycle
• Have responsibility for determining the commercial and scientific viability of drugs, and making decisions about whether to continue their development and how much resources to invest in them, or contribute to this decision making process as a valued expert
• Communicate information to multiple teams in various areas of the drug development process, ensuring all involved parties are aware of important developments in other areas of the product life cycle
• Manage cross functional projects to ensure the successful passage of drugs through all phases of the drug development process, or contribute to one or more elements of such a project as a technical expert
• May perform management of clinical research professionals, setting goals and objectives and overseeing their professional development
• Ensure own work, and work of team, is compliant with Safety, Health and Environment standards and all other relevant internal and external regulations
• Review and interpret medical data and clinical trial data and come up with conclusions
• Review patient consent forms and provide opinion on whether or not matches the data
• Engage in literature search and author background section of the disease from the literature search
• Provide initial screening for study proposals to ensure information's accurate; provide first review of the ISS proposals
• Have responsibility for delivery of pieces of the trials
• May lead submissions from a process standpoint

Requirements - Experience / Qualifications:
• Master's degree in a scientific field is required; considerable relevant experience in the pharmaceutical industry is preferred, however academic experience will be considered provided the candidate has current immune-therapy / oncology clinical trials experience
• Phase II/III industry-sponsored clinical trials experience is required; late stage (e.g., Phase IIb/IV) would be a plus
• Experience managing and interpreting the results of clinical trials as well as exposure to writing protocols to some degree
• Ability to work collaboratively in a cross functional setting
• Well-developed communication skills
• Experience leading and managing a team and project management experience is desirable.

manufacturing facilities, equipment and supporting systems. Supervises assigned department staff and consultants.

**Essential Functions:**
- organization's policies, procedures, and state, federal and local laws
- Manages, directs, coordinates and prioritizes the daily activities of the Pharmaceutical Technology Department and assigned staff
- Directs the coordination of product transfer activities; oversees and approves manufacturing rationalization process and projects in conjunction with Research and Development, Manufacturing, Quality Assurance and Regulatory Affairs to maximize the utilization of manufacturing
- Designs manufacturing processes for new products and leads the evaluation of new technology for manufacturing
- Coordinates validation activities for new products; prepares and reviews validation protocols and reports to ensure compliance with procedures and systems with regulations and quality standards
- Reviews documentation for the performance of validation such as Master Batch Records, Standard Operating Procedures (SOPs) laboratory results, product development information and cleaning validation
- Analyzes Stability Testing history of products in order to respond to any problems that may develop
- Supports the safety program activities to ensure that manufacturing and handling of drug substances does not pose a health threat to personnel
- Designs experimentation required to do scale-up, troubleshooting investigation and process control that lead into a controlled manufacturing process
- Prepares and implements SOPs for the Pharmaceutical Technology Department; provides consultation to Manufacturing, Quality Assurance, Research and Development, Engineering, and Packaging on correct manufacturing instructions, equipment set-up, development of SOPs to assure that products comply with applicable standards
- Coordinates cleaning validation, protocols, etc.
- Oversees, participates and approves the interviewing, hiring, and training of departmental employees; conducts performance evaluations for direct reports; and assists direct report managers with performance evaluation process for their units
- Ensures project deadlines and performance standards are established and met.
- Ensures compliance with all Company policies and procedures including safety rules and regulations
- Conducts investigations
- Performs related duties as assigned

**Minimum Qualifications:**
- Master Degree in Pharmacy, Life Science, Engineering or related field from an accredited college or university
- 8-10 years pharmaceutical technology experience with a variety of solid dosage forms, and
- Five (5) years management level experience or an equivalent combination of education and experience.

Sample Job Description #5

Supply Chain Manager
Synectics Inc.
Lees Summit, MO 64081

About the Job:
Since 1984, Synectics has been committed to aligning talented professionals with jobs they find challenging and fulfilling. Let us leverage our recruiting experience and our long-standing relationships with our clients to help you in your job search.

Job Summary:
This position is responsible for managing supply chain and SOP activities and customer service excellence for the US market and/or US source locations for vaccines and pharmaceuticals. The role acts as a liaison between manufacturing and markets to insure timely and accurate communication related to issues around supply, demand, or logistics.

Skills/Experience:
Proven understanding of supply chain processes
• Knowledge of planning systems including Manugistics/JDA and SAP preferred
• Strong written and oral communication skills
• Ability to work independently and in teams
• Ability to manage multiple projects simultaneously and prioritize work, goals and tasks in accordance with division and corporate objectives
• Ability to analyze data and synthesize to make data driven decision
• 5+ years of relevant experience in supply chain management, logistics or manufacturing

Education:
• Undergraduate degree in business, finance, logistics, or supply chain field of study
• Relevant advanced degree or training/certificate in supply chain or logistics preferred

Appendix – N

Evaluation Report Form for Program Proposals
Appendix N - Evaluation Report Form for Program Proposals

<table>
<thead>
<tr>
<th>Institution:</th>
<th>York College of The City University of New York</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluator(s):</td>
<td>Gail Baura, Ph.D., Professor and Director of Engineering Science, Loyola University, Chicago</td>
</tr>
<tr>
<td>Program title:</td>
<td>Masters Degree Program in Pharmaceutical Science and Business</td>
</tr>
<tr>
<td>Degree title:</td>
<td>Master of Science (M.S.)</td>
</tr>
<tr>
<td>Date of evaluation:</td>
<td>2/23/2015</td>
</tr>
</tbody>
</table>

I. Program

1. Assess program purpose, structure, and requirements as well as formal mechanisms for program administration and monitoring.

As the evaluator, it is evident to me that the proposed Master of Science in Pharmaceutical Science and Business aims to provide advanced training for students who want to work in the pharmaceutical and biotechnology industries in a systematic and pedagogically sound manner. Employees already working in industry will be able to pursue the master of science program to enhance their professional opportunities. York College is already offering a bachelor of science in Pharmaceutical Science and a bachelor of science in Biotechnology. These programs create a pipeline that can prepare undergraduate students for the master’s level program. I am aware of the currently thriving partnership with the Northeast Regional Laboratory of the FDA and the existing training opportunities it is providing. This is an added advantage for the master’s program as there is no need to forge new partnerships initially.

The master’s program will be administered by the Department of Chemistry.

In speaking with the Director of the York College-FDA Partnership, it is clear to me that the members of their Advisory Board are supportive and have contributed their expertise to the design of the master’s program. I have no doubt that the board members will continue to be instrumental in the implementation, development and success of the master’s program.

2. Comment on the special focus of this program, if any, as it relates to the discipline.

The master’s program is uniquely designed to focus on areas of great need and demand in the pharmaceutical industry and in the health community at large. The courses in the master’s program and provisions for internships as well as mentorships will ensure that students gain a solid foundation through the core courses taken and will be able to use specialized elective courses to enhance their specific professional interests and needs. Courses in pharmaceutical discovery and development, regulation of pharmaceuticals, and pharmaceutical management are
included in the master’s program. These courses and the other experiences provided in the master’s program will prepare students for specialized industry positions and allow them to tailor the program to meet their individual learning objectives and goals. One example is the pharmaceutical regulatory sequence with its elective courses. This will prepare students to work as regulatory affairs specialists. In reading through the program and the course proposals, the thoughtfulness of the design and attention to needs that must be met is well defined. The design of the program incorporates instruction on current manufacturing best practices, regulatory science and management as applied by practitioners.

3. Comment on the plans and expectations for continuing program development and self-assessment.

The team that created the proposal understands the way a new master’s program needs to be developed. The proposal outlines modest enrollment projections for the first five years of the program consistent with similar master’s programs. It also carefully outlines faculty needs to begin, establish and grow the master’s program utilizing the resources already in place at the undergraduate level and indicating what is needed as the master’s program commences. The strength of faculty already appointed in the department of Chemistry and the proposed schedule of new appointments of faculty members with complementary expertise will assure that the master’s program gets off to a strong start and that in the long-term, the master’s program will grow and mature as per the standards of the field. Existing and future partnerships will also support the growth of the master’s program and safeguard that it is up-to-date with industry regulations and practices.

The Department of Chemistry, Office of Academic Affairs, and Office of Institutional Research will monitor program educational objectives and student learning outcomes. Working with those on campus, the Advisory Board and external partnerships, they will be able to analyze results and adapt the curriculum as needed. It is understood that the master’s program will need to meet all accreditation standards set by the Middle States Association of Higher Education. Assessment of the master’s program and the monitoring of institutional effectiveness in the delivery of the master’s program will be part of this ongoing process. There are solid working relationships in place and I am confident that these will continue.

4. Assess available support from related programs.

The Departments of Biology, Chemistry, Business and Economics, and the Office of Academic Affairs will provide administrative and instructional support. Technical and administrative personnel currently on staff including six college laboratory technicians, three full-time office administrative assistants, and several part-time administrative assistants will participate in the setting up of classes, labs, record keeping, administration of related paperwork and other components separate from instructional activities in the master’s program as needed. Faculty currently appointed in the named departments with related expertise will be assigned to teach the courses, mentor students and organize program events. New faculty, full time and adjunct, will be appointed to enhance expertise as needed. The projection is two new hires in the second and third year. I anticipate based on their stated commitment that the York College-FDA Partnership
will continue to be instrumental in supporting both the undergraduate and master’s programs. Advice for curriculum design, program enhancement and creating new internships opportunities will help to maintain the program’s relevancy in the constantly changing pharmaceutical industry environment. As the master’s program grows, additional administrative and instructional support will be provided as needed.

5. (Only for programs requiring master plan amendment.) What is the evidence of need and demand for the program locally, in the State, and in the field at large? What is the extent of occupational demand for graduates? What is the evidence that demand will continue?

N/A

II. Faculty

1. Evaluate the faculty, individually and collectively, in regard to training, experience, research and publication, professional service, and recognition in the field.

In reading their CV’s and speaking with faculty at the college, it is essential to note that York College already has the necessary staff in place to offer master’s level coursework including several who have joint appointments at the CUNY Graduate Center. Their expertise and enthusiasm bode well for the initiation, growth and development of the master’s program. Currently, there are six full-time and three part-time faculty members who can provide instructional support. The Director of the Pharmaceutical Science program, Professor Deb Chakravarti (Chemistry), was a founding Curriculum Committee member of the Keck Graduate Institute, which implemented a similar program as a Masters in BioScience. Professors Daniele Musumeci and Adam Profit (Chemistry) have pharmaceutical industry post-doctoral and employment experience. Both have research programs that directly relate to pharmaceutical science. Professor Kang-Bok Lee (Business and Economics) has been studying pharmaceutical supply chain management. Other faculty members in the Biology and Chemistry departments have related research interests and experience. Collectively the full time and adjunct faculty members have more than 40 years of industry or government experience. Additionally, adjunct faculty with industry expertise, especially with FDA expertise, is already being recruited and are willing to participate in the program operations (instructional, curriculum design, research, and other events). Assigned full time faculty are active researchers supported by external and internal grant awards including NIH, NSF, and DOE; have been invited speakers to important conferences and they have a mounting slate of publications in the related fields.

2. Assess the faculty in terms of size and qualifications. What are plans for future staffing?

To reiterate what is stated above, the master’s program will be launched with the existing full-time and adjunct faculty members. They are qualified to meet the needs of the program in the first year and beyond. During the second and third years with the introduction of the next level of courses and specialty electives, two full time faculty and needed adjunct faculty will be recruited and appointed with specific pharmaceutical and FDA experience, knowledge of regulations and other expertise to support students in the master’s program and to maintain the learning objectives of the curriculum.
3. Evaluate credentials and involvement of adjunct and support faculty.

Two adjunct faculty members will be needed to teach pharmaceutical science courses in Chemistry and in Business and Economics. All adjunct faculty at York go through a rigorous hiring process where qualifications are substantiated and evidence for effective teaching or field supervision is required. The adjunct faculty in the master’s program will be subject to this scrutiny so that the program curriculum is appropriately delivered and students are able to receive the training needed from qualified instructors.

III. Resources

1. Comment on the adequacy of physical resources and facilities, e.g., library, computer, and laboratory facilities; practical and internship sites; and support services for the program, including use of resources outside the institution.

The master’s program can get underway with existing resources knowing that the plans to assign more resources as it grows are in place. The state of the art classrooms, conference rooms, research and instructional labs that will be used by students and faculty adds to the strength of the program. The proximity to the Northeast Regional Laboratory of the FDA, within walking distance, provides additional opportunities for instructional spaces, demonstrations of current regulatory practices and internship sites. All students working at the FDA through the internship partnership already in place will gain the knowledge and experience of working in a setting that is functioning as per industry standards. The college library is well equipped with related scientific journals and publications available in a variety of formats for access on or off campus. The York library is part of the CUNY library system with vast additional resources. The CUNY library system subscribes to all major scientific and technical journals with a large collection of publications available online or on campus. Students of the university have access to all CUNY and public libraries throughout New York City and there is an inter-library loan system in place to gain access to any educational library system that is a part of this network. Additionally, similar library resources are available at the FDA laboratory. IT and related support services are in place.

2. (Only for programs requiring master plan amendment.) What is the institution’s commitment to the program as demonstrated by the operating budget, faculty salaries, and the number of faculty lines relative to student numbers and workload.

N/A

IV. Summary Comments and Additional Observations

1. Summarize the major strengths and weaknesses of the program as proposed with particular attention to feasibility of implementation and appropriateness of objectives for the degree offered. Include any further observations important to the evaluation of this program proposal and provide any recommendations for the proposed program.

The York team has put together a solid master’s program addressing current and future needs in
the regulatory and pharmaceutical industries. The proposed master’s program is a natural progression from the two growing undergraduate bachelor of science programs in Pharmaceutical Science and Biotechnology. Interest for a master’s level program is strong among current majors in those programs and recent graduates. Students have articulated their desire to remain at York to work with their mentors at York and in the FDA and to enjoy the facilities on campus that support their educational and research endeavors. The curriculum incorporates not only current industry best practices, but also those pedagogical best practices suggested by its regional accrediting agency. The curriculum has been developed in accordance with national standards of excellence specific to pharmaceutical sciences as well as to the skills and abilities expected from students earning a post-baccalaureate degree. This is the case for delivery in all types of instructional modes. There are qualified faculty members in place with the needed experience and expertise to launch the program and the college has a plan in place to hire additional faculty members as needed. Instructional, facilities, IT, research and library resources meet the standards of a master’s level program. The proximity and partnership of the college with the Northeast Regional Laboratory of the FDA along with newly established internships and personnel collaborations will enhance the master’s program and will be instrumental in maintaining its growth, staying in the vanguard and becoming a model of innovation. The Pharmaceutical Science and Business master of science program will train students for various positions in the pharmaceutical and biotechnology industries while looking ahead to what will be needed for future graduates as the industry itself changes in response to changing regulations and technologies. York is poised to support the master’s program by providing the faculty and other programmatic resources that will be needed to sustain and build toward the future.