



# The University of Georgia

University Council  
Athens, Georgia 30602

March 16, 2011

## UNIVERSITY CURRICULUM COMMITTEE – 2010-2011

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Undergraduate Student Representative – Mr. Stephen Thompson

Graduate Student Representative – Ms. Lauren Moret

Dear Colleagues:

The attached proposal for a new major in Pharmaceutical Sciences (B.S.) will be an agenda item for the March 23, 2011, Full University Curriculum Committee meeting.

Sincerely,

David E. Shipley, Chair  
University Curriculum Committee

cc: Provost Jere W. Morehead  
Dr. Laura D. Jolly



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# The University of Georgia

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College of Pharmacy

March 8, 2011

Dr. Jere W. Morehead  
Senior Vice President for Academic Affairs and Provost  
Administration Building  
Campus

Dear Dr. Morehead:

I am pleased to forward you a proposal for a Bachelors of Science Degree Program in Pharmaceutical Sciences with my endorsement. The proposal was approved during the College of Pharmacy faculty meeting held on February 25, 2011 with a vote of 40-0.

Please do not hesitate to contact me should you or your staff have questions or need additional information. Thank you for your consideration.

Sincerely,

Svein Oie  
Dean

**Proposal for Baccalaureate Degree in Pharmaceutical Sciences**

**Institution: University of Georgia**

**Institutional Contact: Michael Adams**

**Date: March 7, 2011**

**School/Division: College of Pharmacy**

**Department: Pharmaceutical and Biomedical Sciences**

**Name of Proposed Program/Inscription: BS Program in Pharmaceutical Sciences**

**Degree: Bachelor of Science**

**Major: Pharmaceutical Sciences**

**CIP Code: PMCY**

**Anticipated Starting Date: Fall 2012**

## **Basic Information**

**Proposed Starting Date:** Semester following final approval.

### **Votes:**

- UGA Department of Pharmaceutical and Biomedical Sciences	12 yes, 3 no
- UGA College of Pharmacy Curriculum Committee	7 yes, 0 no
- UGA College of Pharmacy Faculty	40 yes, 0 no

### **1. Program Description and Objectives**

- a. Objectives of the program. The objective of this program is to prepare students with strong training in the pharmaceutical sciences built on a broad background in mathematics and the basic sciences. Our graduates will be able to integrate their knowledge with significant research experience to enhance career path development. We anticipate an annual class size of 20 students which can be accommodated by our facilities and also is consistent with other programs throughout the country, which are mostly in the range of 15-20 students per year (Purdue, Buffalo, Michigan, Massachusetts) although Ohio State has 110-120 students per year in their program.
- b. Needs the program will meet. The pharmaceutical sciences represent the collective basic sciences that underlie the field of pharmacy. They are rooted in the discovery and development of therapeutics. The pharmaceutical sciences seek to identify and understand chemical, biological, physical and other fundamental processes that are necessary to define and sustain a desired therapeutic effect. The pharmaceutical sciences clearly require training in biology, chemistry and physics. While students in these more basic disciplines move on to increased specialization, particular to these sciences, students in the pharmaceutical sciences will pursue studies that blend the fundamentals of the basic sciences with the increasing complexity of the interactions of therapeutic agents with living systems.

According to the 2009 report from the Selig Center entitled *shaping infinity*, the life sciences, including the pharmaceutical industry, are the 5<sup>th</sup> largest employer in the state and the fast growing segment of employment. This degree program directly addresses the needs of this growing industry. Graduates of the program will be highly sought after by the global pharmaceutical industry to support research, development and manufacturing operations. Graduates of the degree program will be among the strongest available candidates for entry to the best graduate and professional schools and for entry to the pharmaceutical industry. Recruitment of outstanding pharmacy students into graduate is vital to the future of pharmacy academe. This is not a new issue or concern, but it rapidly is becoming a serious problem for many colleges and schools of pharmacy as noted in many studies from the American Association of Colleges of Pharmacy. This is especially true for the basic pharmaceutical sciences. The proportion of pharmacy graduates from A CPE-accredited colleges and schools of pharmacy entering graduate education and training programs has diminished consistently over the past several years. If this trend continues, there will be a severe shortage of pharmacy trained faculty to serve as role models for students. Over time, graduates of this program are expected to assume significant leadership positions in the pharmaceutical industry and academia further enhancing the stature of the College of Pharmacy and the University of Georgia.

- c. Brief explanation of how the program is to be delivered. The four-year curriculum for the Bachelors of Science (BS) in the Pharmaceutical Sciences begins with a strong foundation of coursework in mathematics and the basic sciences (chemistry, biology and physics). The program then progresses to advanced coursework in the pharmaceutical sciences including aspects of drug design, mechanism of action, drug targeting and delivery, pharmacology, toxicology, drug development, manufacturing, quality assurance and regulatory compliance. The advanced portions of the curriculum will be accompanied by laboratories to allow students to gain relevant experience with the many techniques that are relevant to the pharmaceutical sciences. Finally, there will be a two semester undergraduate research requirement for students in the program further enhancing the laboratory, literature evaluation and presentation skills of the students.
- d. Prioritization within the institute's strategic plan. This program is highly aligned with the strategic plans of the University and the College. The 2020 strategic plan of the University of Georgia calls for Building on Excellence in Undergraduate Education. One of the benchmarks for this goal in the strategic plan is to increase the percentage of undergraduate students involved in research. Our expectation is that undergraduate research will be a significant component of this degree program. Another major part of the strategic plan called for investing in emerging areas of research excellence at UGA. A key part of this portion of the plan involves working with industry in Georgia to create regional areas of strength. This program supports the recent emphasis UGA has placed in the development of therapeutic agents as a result of founding of the Center for Drug Discovery in 2006. In addition to supporting the goals of UGA, the first goal of the 2020 strategic plan of the College of Pharmacy calls for the expansion of program offerings to meet the healthcare workforce needs of the State of Georgia. Other programs send approximately half of their graduates to industry and half to graduate or professional schools. Therefore, this program is well suited to address the needs for industry for workers at all educational levels and also will be produce graduates appropriate for academic faculty positions.

**2. *Description of the program's fit with the institutional mission and nationally accepted trends in the discipline.***

Over the past several years the University System of Georgia Board of Regents and the University of Georgia (UGA) have made significant financial and programmatic commitments to enhancing biomedical programs and research at UGA. These enhancements include the formation of the Medical College of Georgia (MCG) – UGA Medical Partnership, the formation of the School of Public Health, construction of the new Complex Carbohydrate Research Center, Pharmacy South and the Paul D. Coverdell Center for Biomedical and Health Sciences as well as enhancements to a wide variety of other facilities. As a central player in biomedical education at UGA, the College of Pharmacy has as its mission to advance the health of the citizens of Georgia, the Nation and the Global Community. Central to its mission is the College's focus on providing nationally recognized quality educational programs including Pharm.D. education, postgraduate training, undergraduate and graduate programs in the pharmaceutical sciences.

Therefore, the Department of Pharmaceutical Sciences and the College of Pharmacy propose the creation of a bachelor's of science program in the Pharmaceutical Sciences. Creation of this program is a major part of the 2020 strategic plan of the UGA College of Pharmacy. Undergraduate programs in the pharmaceutical sciences in the United States began at the State University of New York at Buffalo (now the University of Buffalo) in the late 1960s. Since this time, 18 additional programs have appeared at a number of universities primarily concentrated in the northeast and midwestern regions of the United States (e.g. University of Michigan, Ohio State University, Purdue University, University of Massachusetts). Not surprisingly, these correspond to the locations of the majority of the U.S. pharmaceutical industry. With the more recent trend of life sciences research, including pharmaceutical research and manufacturing, moving to other regions of the country several BS programs in the pharmaceutical sciences have been started outside the initial cluster including Campbell University in North Carolina, the University of Missouri and in the Fall of 2010 the University of California at Irvine. The strong growth in life sciences, pharmaceutical R&D, manufacturing and biotechnology companies in Georgia (now ranked 9<sup>th</sup> in the United States in the number of companies) demonstrates a growing need for a program to support these industries in this region. Supporting letters to this effect can be found in Appendix 1.

**3. *Description of how the program demonstrates demand and a justification of need in the discipline and geographic area and is not unnecessary program duplication.***

As stated above, there are no undergraduate programs in the Pharmaceutical Sciences in the State of Georgia. In addition, there are very few such programs even in the southeastern United States. Officially there is a program at the University of Mississippi however; this program offers the BS Degree in Pharmaceutical Sciences after year 4 to students in the six year professional Pharm.D. program. Therefore, this program is not contributing toward the necessary trained workforce for the biosciences in this region. The program at Campbell University has been very successful and helps to provide a pool of talent for companies in the Research Triangle Park. According to the 2009 report from the Selig Center report entitled *shaping infinity*, the life sciences, including the pharmaceutical industry, are the 5<sup>th</sup> largest employer in the state of Georgia (greater than 17,000 jobs) and the fast growing segment of employment (more than 10% per year). In several recent cases major pharmaceutical companies (Merck and Novartis) choose not to locate major facilities in Georgia and one of their primary reasons was the lack of a trained workforce. This degree program overcomes this deficit and directly addresses the needs of this growing industry. It also fits in well with the other graduate and professional degree offerings of the College of Pharmacy and creates complete portfolio of degree programs to support the pharmaceutical industry from the discovery and development of new therapeutic agents through to the delivery of these agents to patients. The College of Pharmacy will create a program of scientific excellence that will be recognized at both the regional and national levels.

**4. *Brief description of institutional resources that will be used specifically for the program (e.g., personnel, library, equipment, laboratories, supplies and expenses, capital expenditures at program start-up) and when the program undergoes its first comprehensive program review.***

There are several programmatic needs for this program in terms of faculty, staff, space and operational resources. Each of these needs is addressed individually below with a categorized budget at the end of this section.

**Space:** The program will be housed within existing space in the College of Pharmacy. The laboratories previously used for teaching compounding pharmacy in the professional Pharm.D. Program has become available with the opening of Pharmacy South. Space for teaching laboratories exists on the 2<sup>nd</sup> floor of the RC Wilson Pharmacy Building. This room (Room 232) is 2562 sq ft however; this space will need to be renovated for use by the proposed program. The Dean of Pharmacy has committed funds to fully renovate this space and convert it into two separate laboratories (see attached letter). The first lab will be dedicated to pharmaceutical manufacturing and will include a current Good Manufacturing Practices (cGMP) training facility. This laboratory will allow students to gain direct experience with the handling of bulk pharmaceutical materials and also in the preparation of small scale batches of pharmaceutical dosage forms. This laboratory will be associated with the Drug Development Courses in the fourth year of the Pharmaceutical Sciences program and should be viewed as a unique feature of this program. Currently only one other program in the nation has such a teaching/training facility (Purdue University) as part of a pharmaceutical sciences program, although a few other schools have training facilities that they use for industrial training programs (e.g., University of Tennessee). In addition to the unique training for our students that such a facility would provide, there would also be synergies created for our Masters of Science program in Regulatory Affairs where these students could use the facility for projects creating opportunities for integration with the BS students. In the future, such a facility could also be used for offering training courses to industry during the summer potentially creating an additional revenue stream to further enhance the educational programs in the College of Pharmacy and to allow for continual updating of the facility. The second laboratory would be dedicated to techniques related to basic biological testing and quality assurance / quality control testing of pharmaceutical products. This laboratory would be able to support the third year Pharmaceutical Technology Laboratory (PMCY 3200L) as well as the two fourth year Drug Development Laboratories. In the didactic courses Pharmaceutical Sciences I (PMCY 3100), Pharmaceutical Analysis (PMCY 3500), Modern Pharmacology (PMCY 3800) students will gain a theoretical understanding of many of the major techniques used in drug development. The laboratory course PMCY 3200L then provides an opportunity for students to gain direct hands-on experience with the most significant techniques in the pharmaceutical sciences. The following year the Drug Development Courses (PMCY 4500 and 4510) integrate the knowledge gained in the third year courses dedicated to dosage form design and characterization (PMCY 3100), pharmacology (PMCY 3800) and pharmaceutical analysis (PMCY 3500). In addition, the Drug Development courses have a laboratory component that will also provide more applied training for the students. The laboratory will allow students to assess therapeutic drug targets, evaluate biological data, create

drug formulations, and characterize both bulk drug materials and finished products. One of the greatest strengths of this will be when students are able to use the cGMP training facility to make products and then take them to the QA/QC laboratory and evaluate their own materials. Exposure to the regulatory issues involved in formulating, manufacturing and characterizing pharmaceuticals from the didactic portion of the class will be able to be efficiently integrated with the laboratory to create a student with both substantial understanding of the pharmaceutical sciences, but more uniquely, one that has significant practical experiences. Office space for faculty, staff and graduate teaching assistants is available following the opening of Pharmacy South building. Therefore, no funds are needed for additional office space.

Personnel: With the creation of 9 new courses will come the need to have new faculty lines, with appropriate expertise, to provide these courses without impacting the existing professional pharmacy (Pharm.D.) program. The Department of Pharmaceutical and Biomedical Sciences received two faculty lines as cluster hires from the 2<sup>nd</sup> Presidents Faculty Hiring Initiative. In addition to these two faculty lines, the College of Pharmacy will redirect two additional FTE's to this effort. Over time the support for these two additional faculty lines will be recovered through credit hour reimbursement from the program. The two cluster hires will be made during Spring 2011 and the additional hires will be made during the 2011-2012 academic year allowing the program to begin offering classes in the Fall of 2012. These faculty lines are expected to be tenure track appointments that would also be expected to develop extramurally funded research programs. These faculties primary teaching responsibilities would be to support the BS Program; however their presence would have benefits to graduate education in the College of Pharmacy. They would immediately provide additional major advisor opportunities for graduate students. Also after establishing the new courses in the BS Program, they would develop graduate level course offerings. The new faculty will each be provided a 120 sq. ft. office in Pharmacy South and will be provided approximately 1000 sq. ft. of laboratory space from the new space available in Pharmacy South. Therefore, no additional funds are needed to provide office or laboratory space for the faculty.

The program will also require a Student Affairs Professional to confer with students and prospective students about the program. This position will also provide student services and aid the program coordinator with procedures, policies, assessment and conflict mediation. Existing departmental staff is expected to be sufficient to handle the additional faculty without the need to create any other staff positions. A 120 sq. ft. office will be made available in Pharmacy South for the new staff member and therefore no additional funds are needed for office space for this position. Funding for this position will be redirected by the Dean of Pharmacy but will eventually be covered through credit hour reimbursement.

In addition to faculty and staff needs, the program will also require teaching assistants to help with the three laboratory courses. With 20 students per year the laboratory courses are proposed to be done in two sections of 10 students each to minimize the need to purchasing greater amounts of major equipment and also to maximize student's ability to have individual time with various techniques. Dividing students in this manner would create six laboratory sections, two in the third



year and four in the fourth year. There will be significant preparation time associated with these laboratories and also office hours and grading. In addition to the instructor, who would be present for all of the laboratory sections, one teaching assistant would also be needed. The teaching assistant requirements of the program can be met from the existing pool of graduate students in the Department of Pharmaceutical and Biomedical Sciences and therefore no additional funds are required for teaching assistants.

**Library:** No additional library resources needed as the students will have access to the main UGA library, the Science Library. In addition, students in the program have access to the Kroger Student Learning Center in the Pharmacy Building where a librarian maintains office hours to assist students with the use of library services including many of the databases that would be helpful with classes.

**Equipment:** There will be three laboratory courses associated with the program. Some of the major equipment needed for these laboratories is already in the shared equipment facilities in pharmacy such as LC-MS, NMR, UV-Vis Spectrophotometer. However, in addition to these there will be needs for items to characterize pharmaceuticals such as Karl-Fischer titration apparatus, dissolution apparatus, gas chromatograph, high-performance liquid chromatograph, differential scanning calorimeter, particle sizer and surface area determination apparatus. The pharmaceutical technology laboratory will use much of the same equipment needed for the drug development laboratory, however, the pharmacology portions of the lab will require items such as PCR equipment, gel electrophoresis equipment, cell culture equipment and a microscope. Funds for the equipment are available from College of Pharmacy resources; however, the Development Office of the College of Pharmacy will also work to secure the donation of some of the equipment needed for these laboratories.

**Budget**

Category	Items Requested	Year 1 (2010-11)	Year 2 (2011-12)	Year 3 (2012-13)
Space	Lab. Renovations	\$ 200,000	\$ 200,000	
	Office Space	\$ 0	\$ 0	
Personnel	Faculty	2 FTE (Cluster Hires)	2 FTE (Redirected Funds)	
	Staff		1 FTE (Redirected Funds)	
Library		No Additional Funds Requested	No Additional Funds Requested	No Additional Funds Requested
Equipment	Lab. Equipment		\$ 200,000	\$ 100,000
	Computer Lab.		\$ 6,000	\$ 1,000
Program Operations	Staff Computer		\$ 1,000	
	Office Supplies		\$ 7,500	\$ 7,500
	Laboratory Supplies		\$ 10,000	\$ 20,000

	Maintenance		\$ 5,000	\$ 10,000
Total		\$ 200,000	\$ 429,500	\$ 138,500

With an annual enrollment of 20 students the program will create 640 student credit hours per year (32 PMCY credits x 20 students). However, several of the courses will likely be popular with other majors (pharmacology, medicinal chemistry and membranes and organ systems, in particular) and therefore we believe generating at least 1000 student credit hours per year is very realistic within a few years of starting the program. With a reimbursement rate of \$ 175.00 per credit hour that means that the program will generate approximately \$175,000 per year, which is sufficient to cover the personnel and administrative costs associated with the program. If the enrollment in the program continues to rise then additional faculty can be added as credit hour production allows.

**5. Curriculum: List the entire course of study required and recommended to complete the degree program. Provide a sample program of study that would be followed by a representative student.**

The curriculum for the BS in Pharmaceutical Sciences was created after evaluating all other programs in the United States. A composite curriculum of these programs was created as the beginning template. We next evaluated specialized offerings of other programs and the needs of industry to have workers with training in cGMP manufacturing and also regulatory affairs. The courses recommended for the BS degree in Pharmaceutical Sciences comply with all aspects of the University of Georgia and the University System Board of Regents policies for coursework requirements for Bachelor's degrees. The first two years coursework is distributed over the categories shown below.

Area 1 – Foundation Courses (10 Credit Hours)	ENGL 1101 – 3 credits ENGL 1102 – 3 credits MATH 2250 – 4 credits
Area 2 – Science Courses (8 Credit Hours)	BIOL 1107/1107L – 4 credits CHEM 1211/1211L – 4 credits
Area 3 – Quantitative Reasoning (4 Credit Hours)	PHYS 1211/1211L – 4 credits
Area 4 – World Languages, Culture, Humanities and the Arts (12 Credit Hours)	SPCM 1100 – 3 credits Remaining courses unspecified but must satisfy UGA requirements for inclusion in the area.
Area 5 – Social Sciences (9 Credit Hours)	Course unspecified but must satisfy UGA requirements for inclusion in the area.
Area 6 – Courses related to Major (13 Credit Hours)	CHEM 1212/1212L – 4 credits BIOL 1117L – 1 credit CHEM 2211/2211L – 4 credits CHEM 2212/2212L – 4 credits
Area 7 – Graduation Requirements (2 credit Hours)	1 credit hour of physical education 1 credit hour FYOS 1001 Students must satisfy the US/GA History, Federal and Georgia Constitution, Cultural Diversity, and the Environmental Literacy requirements.
Total Credit Hours for Areas 1-7	58

The courses in the final two years of the program are shown in the table below. These courses contain additional foundation courses in statistics, calculus, biochemistry and physical chemistry before moving into the more specialized courses in the degree program. Topical outlines of the newly proposed pharmaceutical sciences courses are found in Appendix 2.

Major Courses (50 Credit Hours including 42 upper division credit hours)	STAT 2000 – 4 credits MATH 2260 – 4 credits BCMB 3100 – 4 credits CHEM 3110 – 3 credits ENGL 3590 – 3 credits PMCY 3010 – 4 credits PMCY 3100 – 3 credits PMCY 3200L – 1 credit PMCY 3500 – 3 credits PMCY 3800 – 3 credits PMCY 4100 – 3 credits PMCY 4200 – 3 credits PMCY 4500/4500L – 4 credits PMCY 4510/4510L – 4 credits PMCY 4900 – 2 credits PMCY 4910 – 2 credits
Major Electives (9 Credit Hours, 6 Hours are required as upper division courses)	BIOL 1108/1108L – 4 credit hours PHYS 1212/1212L – 4 credit hours GENE 3200 – 3 credits BCMB 3600 – 3 credits CBIO 3400 – 3 credits CHEM 4615 – 3 credits STAT 4210 – 3 credits STAT 4220 – 3 credits STAT 4230 – 3 credits
General Electives (3 Credit Hours)	Undefined
Total Credit Hours Years 3-4	62
Total Program Hours	120

An example of a typical program of study is shown below.

<b>First Year Fall</b>  ENGL 1101 – English Comp I – 3 credits CHEM 1211 – Fresh Chem. I – 3 credits CHEM 1211L – Fresh Chem. Lab I – 1 credit BIOL 1107 – Princ. Biol. I – 3 credits BIOL 1107L – Princ. Biol. Lab I – 1 credit Area D or E Elective – 3 credits	<b>First Year Spring</b>  ENGL 1102 – English Comp II – 3 credits CHEM 1212 – Fresh Chem. II – 3 credits CHEM1212L – Fresh Chem. Lab II – 1 credit PHYS1211 – Intro. Phys. Sci. & Eng. – 4 credits SPCM 1100 – Intro. Pub. Speak – 3 credits
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FYOS 1001 – Freshman Odyssey – 1 credit  Semester Total – 15	Semester Total – 14
Second Year Fall  CHEM 2211 – Mod. Org. Chem I – 3 credits CHEM 2211L – Mod. Org. Chem Lab I – 1 credit Physical Education Elective – 1 credit MATH 2250 – Calc. I Sci. Eng. – 4 credits Area D or E Elective – 3 credits Area D or E Elective – 3 credits  Semester Total – 15	Second Year Spring  CHEM 2212 – Mod. Org. Chem II – 3 credits CHEM 2212L – Mod. Org. Chem Lab II – 1 credit BIOL 1117 – Intro Cell Biol. Lab. – 1 credit Area D or E Elective – 3 credits Area D or E Elective – 3 credits Area D or E Elective – 3 credits  Semester Total – 14
Third Year Fall  BCMB 3100 – Intro BCMB – 4 credits CHEM 3100 – Fund. Phys. Chem. – 3 credits PMCY 3010 – Membrane & Organ Sys. – 4 credits MATH 2260 – Calc. II Sci. Eng. – 4 credits  Semester Total – 15	Third Year Spring  PMCY 3100 – Pharm. Sci. I – 3 credits PMCY 3200L – Pharm. Technology – 1 credit PMCY 3500 – Pharm. Analysis – 3 credits PMCY 3800 – Intro. Pharmacology – 3 credits STAT 2000 – Intro. Stat. – 4 credits Major Elective – 3 credits  Semester Total – 17
Fourth Year Fall  PMCY 4500 – Drug Development I – 4 credits PMCY 4100 – Pharm. Sci. II – 3 credits PMCY 4900 – Pharm. Sci. Res. I – 2 credits ENGL 3590 – Tech. & Prof. Comm. – 3 credits Major Elective – 3 credits  Semester Total – 15	Fourth Year Spring  PMCY 4510 Drug Development II – 4 credits PMCY 4200 – Med. Chem. – 3 credits PMCY 4910 – Pharm. Sci. Res. II – 2 credits Major Elective – 3 credits General Elective – 3 credits  Semester Total – 15 hours

**Minor in the Pharmaceutical Sciences:** In addition to providing a major in the pharmaceutical sciences we propose to also offer a minor. The minor will require 12 credit hours of coursework. Courses that could be considered for fulfilling the requirements for a minor in the pharmaceutical sciences would be BCMB 3100 and any of the courses with the PMCY prefix.

6. ***Admissions criteria. Please include required minima scores on appropriate standardized tests and grade point average requirements.***

The program anticipates admitting 20 students per year, however there will not be any cap on enrollment for this major. With the classroom and laboratory facilities in place we can easily increase class size up to 50 students per year. However, increases beyond this level would require additional laboratory facilities. Admission to the Pharmaceutical Sciences will occur after two years and require the completion of areas A-E and the area F courses required for major. A cumulative GPA of 2.5 will be needed for successful admission. In addition, all CHEM, BIOL, MATH, ENGL and PHYS courses will be satisfied with grades of "C" (2.0) or better.

**7. *Availability of assistantships (if applicable).***

Since this is an undergraduate degree there are no assistantships. However, we will work with the College of Pharmacy Development Office to seek funds for merit and need based scholarships for students within the program.

**8. *Student learning outcomes and other associated outcomes of the proposed program.***

The learning outcomes of the program can broadly be distributed into five categories. The categories and their outcomes measurements are provided below.

1. A broad knowledge of the pharmaceutical and related sciences and be able to integrate and apply this knowledge to identify and solve problems.
  - a. Demonstrate a basic understanding of chemistry, biology, physics, statistics and mathematics relevant to the pharmaceutical sciences
  - b. Demonstrate an understanding of pharmaceutics, physiology, pharmacology, toxicology, medicinal chemistry, and pharmacokinetics.
  - c. Demonstrate the ability to solve problems by integrating multi-disciplinary scientific knowledge.
  - d. Develop a wide range of technical skills in various laboratory techniques.

Outcome Measurement: Student will pass CHEM, BIOL, PHYS, MATH and PMCY courses with grades of "C" (2.0) or better. Problem solving skills will be developed through the use of integrative problem sets and creative projects in the various pharmaceutical sciences courses. Technical skills are developed in PSCI 3200L, PSCI 4500, PSCI 4510, PSCI 4900, 4910 and other science-based laboratory coursework.

2. An understanding of drug discovery and development
  - a. Demonstrate a comprehensive understanding of the key stages in drug discovery, and development.
  - b. Demonstrate an ability to relate applicable scientific disciplines to each stage of drug discovery and development.
  - c. Identify the legal and regulatory issues that affect: 1) development, 2) conduct of research studies used in each phase of drug product development 3) post marketing surveillance of drug products.

- d. Identify questions addressed by research studies used in each phase of drug product development and the decision-makers who use this information.
- e. Synthesize this information to create a preliminary drug development research plan for all phases of a new compound's life cycle.
- f. Identify the potential roles of BS Pharmaceutical Sciences graduates in drug discovery and development.

Outcome Measurement: Student will pass PMCY 4500, 4510 with a grade of "C" or better.

3. Effective written and oral communication skills

- a. Demonstrate proficiency in technical writing and presentations
- b. Demonstrate knowledge and proficiency with current audio-visual presentation technologies.
- c. Demonstrate an ability to communicate scientific knowledge in non-expert terms .
- d. Develop examples of scientific communications (e.g., abstracts, manuscripts, reports, posters).
- e. Demonstrate an ability to critically and constructively evaluate the presentations of others.

Outcome Measurement: Student will pass ENGL 3590 with a grade of "C" (2.0) or better. Presentations of final project in poster and oral format will occur at a research day at the end of PMCY 4510. Successful completion of the final project in PMCY 4510 will be a requirement to pass this course. Finally, successful completion of research hours will involve presentations both oral and written at group meetings. Involvement in technical writing and critical review of data is expected during the research course (PMCY 4900 and 4910). Additionally, presentations at scientific meetings are highly desirable.

4. An ability to contribute in various roles on effective teams to solve problems

- a. Demonstrate an understanding of the interconnection between the scientific, clinical and filing processes that constitute the backbone of pharmaceutical development.
- b. Demonstrate a general understanding of how different areas of expertise must come together in order to discover and develop pharmaceutical products at the level of multi-participant collaboration.
- c. Demonstrate an ability to engage in productive professional/technical interactions with others and be able to actively and skillfully participate in team-based projects related to pharmaceutical development.
- d. Develop interpersonal skills such as negotiating and working with others, conflict management and leadership skills.

Outcome Measurement: Student will pass SPCM 1100, PMCY 4900 and 4910 with a grade of "C" (2.0) or better. Laboratory portion of this course will have team projects which will simulate the scale of the typical drug development process. Students will also interact with M.S. Regulatory Affairs students who will be conducting projects using the current Good

Manufacturing Practices (cGMP) Laboratory. Throughout the year speakers from both industry and the government, such as the US Food and Drug Agency, will deliver lectures and answer questions concerning specialized topics in drug development.

5. Demonstrate ethical, social and scientifically responsible conduct
  - a. Demonstrate awareness of cultural and social diversity through interactions with others.
  - b. Demonstrate a sense of self, community and citizenship.
  - c. Demonstrate sensitivity to personal values and ethical principles in professional and social contexts.
  - d. Develop an understanding of social, economic, and professional responsibilities of the pharmaceutical industry.
  - e. Demonstrate the ability to conduct scientific research with the highest level of integrity.

Outcome Measurement: Students will satisfy many of these objectives by meeting the cultural diversity, environmental and history/government requirements. However, the program will expand and continue to improve these objectives by developing professional interactions with faculty, classmates and working professionals in the field. In addition, research opportunities would exposure students to ethical conduct of research.

#### **9. Administration of the program.**

The program will be housed within the Department of Pharmaceutical and Biomedical Sciences within the College of Pharmacy. The program will have a coordinator appointed by and reporting to the Department Head of Pharmaceutical and Biomedical Sciences. Appointment to this position will require approval by the Dean of Pharmacy. The title of this position will be the Coordinator of the BS in Pharmaceutical Sciences Program and they will have full time faculty status within the Department of Pharmaceutical and Biomedical Sciences. The Coordinator will act as the liaison between the program and other administrators both within and outside of the College of Pharmacy. The Coordinator will be a member of the Dean's Executive Committee and thereby will represent the needs and concerns of this program at the highest levels of the College of Pharmacy. The Coordinator will also report on the activities of the BS Program in both Departmental and Collegiate Meetings. Faculty time and programmatic budget will be assigned to the BS Program annually by the Department Head of Pharmaceutical and Biomedical Sciences. It will therefore be the duty of the Coordinator to oversee the day-to-day operations of the program. The Coordinator will be assisted by a Program Specialist who will keep all program records, provide minutes from the various program committee meetings, work with the College of Pharmacy Budget Office to monitor the program budget, provide information on the program to perspective students, clarify program regulations to faculty and students and to work with the Coordinator to advise students in the program. The program will also have several committees including internal and external advisory committees. The Coordinator will act as the chair of the internal advisory committee. The internal advisory committee will meet regularly and will work with the Coordinator to propose policies and strategic outcome measures regarding the BS in Pharmaceutical Sciences. The internal advisory committee will also evaluate programmatic assessment data, content of courses, learning objectives

and support relevant Departmental, Collegiate and University evaluation of the program. The internal advisory committee will be composed of faculty members assigned by the Department Head of Pharmaceutical and Biomedical Sciences. The external advisory committee will be chaired by the Dean of Pharmacy and will have participation by the Department Head of Pharmaceutical and Biomedical Sciences. Additional members of the external advisory committee will be appointed by the Dean of Pharmacy but are expected to include stakeholders from industry and faculty members from other institutions with BS programs in the Pharmaceutical Sciences. The external advisory committee will meet once a year and will provide a conduit for the exchange of information with the objective of promoting our program outside the University and to continuously improve the quality of our program.

- 10. Waiver to Degree-Credit Hour (if applicable): If the program exceeds the maximum credit hour requirement at a specific degree level, then provide an explanation supporting the increase in hours.**

Not applicable

- 11. Accreditation: Describe disciplinary accreditation requirements associated with the program (if applicable).**

Accreditation of the BS in Pharmaceutical Sciences would fall under University accreditation of degree programs by the Southern Association of Colleges and Schools (SACS). The next accreditation cycle occurs in 2020.



**Appendix 1: Support Letters**



16 December 2010

Re: Support for proposed degree B.S. in Pharmaceutical Sciences

As CEO of an HIV vaccine company, I find this to be a rather interesting concept for a nontraditional degree, but one with a particular focus which adds to its appeal. In my own career, my biomedical engineering degree, itself nontraditional, has served me well. When I led clinical research departments in the biotech industry, individuals with the B.S. degree in Biomedical Engineering were a perfect match for the job. Ideal candidates for this position required someone with the basic technical skills honed to a focus in medical products and systems who could understand the interaction of implantable products, run preclinical trials, converse with clinicians during regular trials, conduct research, and interpret the technical data. While early acceptance of this degree took time, the industry gradually recognized the field to where now, in some engineering degree programs, Biomedical Engineering is first or second in engineering discipline enrollment. I imagine a B.S. degree in Pharmaceutical Sciences would take much the same course as it matures into a recognized degree.

From an industry perspective, to offer such a degree program is both logical and attractive. With the complexity of drug development, whether in the oral or vaccine category, industry requires a multitude of disciplines, the full degree program for leadership and research expertise combined with bachelor level degrees fulfilling the work required to run the routine experiments. Until this degree becomes available, science majors had generic backgrounds, which required training to focus a small subset of the generic degree to developing drugs. Then, there are the facets of the job that the science bachelor degree does not address. Topics such as regulatory affairs and quality are integral to the job, but never included in traditional degree curriculums, for the very good reason that these programs are designed to be generic and not specific for a particular job function such as pharmaceutical drug development. The proposed curriculum goes further by including didactic training specific for the degree to include: membranes and organ systems, pharmaceutical science, technique and analysis.

My support for this degree grows as I explore its potential as a useful degree supporting the medical industry in Georgia. One of scientific objectives for the state is vaccine development. This coupled with the assorted medical products round out a vibrant industry for the state. Solvay (now Abbott), Merial, Ciba Vision (Novartis), Dendreon, Shionogi (formerly Sciele and recently moved), McKesson, Kimberly Clark, Bard, Porex, CryoLife, Immucor, and UCB Pharma form the major companies. These together with a list of much smaller companies, employ over 10,000 people in the state. Not included in this count are the numerous employees at area research universities and the CDC. Therefore, I believe UGA is proposing a very useful degree.

Sincerely,

A handwritten signature in cursive script that reads "Robert T. McNally".

Robert T. McNally, Ph.D.  
President and CEO  
GeoVax Labs, Inc.



January 11, 2011

Michael G. Bartlett, Ph.D.  
Professor  
Department of Pharmaceutical and Biomedical Sciences College of Pharmacy University of Georgia  
Athens, GA 30602-2352  
PH - (706) 542-5390  
FAX - (706) 542-5358  
[bartlett@rx.uga.edu](mailto:bartlett@rx.uga.edu)

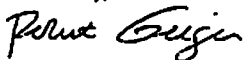
Dear Sir/Madam:

It is my pleasure to write a letter in support of BS In Pharmaceutical Sciences being submitted to the University of Georgia. For the last thirteen years of my career, I have worked in quality for Chemical and Pharmaceutical companies. We have always had a challenge hiring new graduates for our quality divisions. The challenge we face is the lack of knowledge or hands on experience with quality and regulatory guidelines. My companies have invested thousands of dollars training chemists/ biologists/ engineers in the area of quality. If the University of Georgia is able to implement this new BS program, this will save companies many hours and dollars in training. This program will also allow graduates advancement into higher level positions with Chemical, Pharmaceutical, and Biotech companies.

The biggest challenge my current company faces is adding new employees in the area of Quality/Regulatory. We recently filled an opening for Director of Quality/Regulatory after 8 months of extensive interviews. We hope that the University of Georgia is able to develop and implement this new program. We look forward to hiring future graduates from the University of Georgia.

In conclusion, I fully support the efforts of Dr. Bartlett to implement this program designed to train and educate students in all aspects of the Pharmaceutical Sciences. Any programs that can help our workforce make better decisions during the drug development process will benefit patients, doctors, and the community at large.

Sincerely,



Robert Geiger, Ph.D., MBA  
Vice President of Quality  
AmbioPharm, Inc.

# GEORGIA BIO™

The Life Sciences Partnership

January 24, 2011

Michael G. Bartlett  
Professor  
Department of Pharmaceutical and Biomedical Sciences  
College of Pharmacy  
University of Georgia  
Athens, GA 30602-2352

Dear Dr. Bartlett:

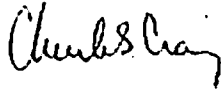
This letter is in support of the new Bachelors Degree program in the Pharmaceutical Sciences that is being proposed by the University Of Georgia's College Of Pharmacy.

We have reviewed the curriculum, and feel that the degree will provide students with a strong background in the basic biosciences, combined with a thorough understanding of the drug development process and regulatory environment. The inclusion of a one-year research experience, along with cGMP training in a working facility, will provide students with a unique background for entering the workforce or for continuing their post-graduate education. We have reviewed this curriculum with several of our pharmaceutical executives, and they enthusiastically endorse the curriculum.

Pharmaceutical sciences are important to Georgia's economy. According to "Shaping Infinity 2009", our annual industry survey, Georgia's pharmaceutical and medicine manufacturing companies provide 3,262 jobs and close to \$300 million in wages (21.5 percent and 30.4 percent of the life sciences industry total. Cancer, infections, and neurological conditions are the most commonly cited targets for pharmaceutical, biopharmaceutical, and diagnostic firms. Biologics companies identified therapeutics, blood, vaccines, cell cultures, and research materials as their main products. The product pipeline to the FDA is fairly well stocked, which is likely to result in more marketed products in the coming years.

We look forward to these graduates entering the workforce and helping to meet the needs of Georgia's bioscience firms in the future.

Sincerely,



Charles S. Craig  
President  
Georgia Bio  
404-920-2043  
[charles.craig@gabio.org](mailto:charles.craig@gabio.org)

**R. EDWARD PERKINS  
1250 COVENTRY ROAD  
WATKINSVILLE, GEORGIA 30677**

January 31, 2011

**Dr. Michael G. Bartlett, Professor  
Department of Pharmaceutical and Biomedical Sciences  
College of Pharmacy  
University of Georgia  
Athens, GA 30602-2352**

**Re: University of Georgia Proposed BS in Pharmaceutical Science**

**Dr. Bartlett,**

I am writing to endorse establishing a Bachelor of Science degree program in Pharmaceutical Science at the University of Georgia. As President of a pharmaceutical division of Johnson and Johnson, a member of the Board of Directors of the Georgia Medical Center Authority, and a participant in various economic development efforts at the local and state levels, I see the value of the program and the void it would help to fill.

The development of pharmaceutical products is a unique balance of science, medicine, interaction with regulatory agencies, and organizational dynamics. The average compound takes over ten years from discovery to market and a cumulative investment of \$700 million to \$1 billion dollars. Where we used to see 80% of compounds in Phase 3 ultimately reach the market that number has fallen to under 50%. Professionals are needed to work in and improve this process who not only understand the traditional sciences (chemistry, biology, etc) but understand the development procedures, clinical trial development, and regulatory issues unique to our industry.

Georgia has a key economic development strategy to attract life science companies and to aggressively support life science startup companies spun off from our research universities. The proposed Pharmaceutical Science major will enhance our efforts by providing trained employees for target companies and resources to support the home grown start ups.

I applaud the initiative to establish the Pharmaceutical Science curriculum and would be happy to assist in any way that I can.

A handwritten signature in black ink, appearing to read 'R. E. Perkins', with a long horizontal flourish extending to the right.

R. E Perkins  
President, Noramco of Johnson & Johnson, retired  
Board of Directors, Georgia Medical Center Authority  
Board of Directors, Georgia Bio



1300 South Drive  
Gainesville, GA 30504  
T (770) 534 8239 F (770) 534 8247

February 9, 2011

Michael G. Bartlett, PhD, Professor  
Department of Pharmaceutical and Biomedical Sciences  
College of Pharmacy, University of Georgia

Dear Dr. Bartlett:

I appreciate the opportunity to review the proposed Bachelors Degree program in Pharmaceutical Science which is being considered by the College of Pharmacy.

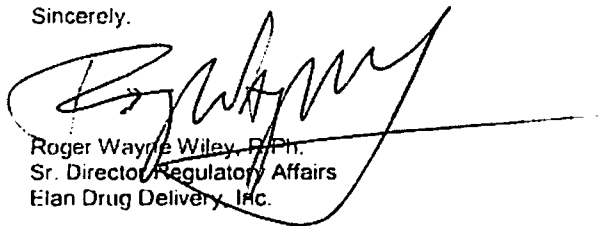
The Pharmaceutical Industry, especially in the Southeast Region and most notably the State of Georgia would undoubtedly benefit from the program you have proposed. As you are well aware, the metro Atlanta and surrounding areas, has yet to achieve or sustain a significant representation of the Pharmaceutical Industry. This fact stands as a stark contrast to the availability of a world class transportation system, affordable and economical business atmosphere and ready access to Universities and Medical facilities of significant reputation.

It is worth noting that within the past seven years the number of Schools of Pharmacy in Georgia has increased from two to four. Although most of those graduates will find ready employment in the more traditional Pharmacy settings, it is reasonable to expect that as the region is exposed to a greater number of the specialized disciplines represented by professionals who teach programs of the type you have proposed these programs (Pharmacology, Pharmacokinetics, Pharmaceutics, etc.) along with the research grants and programs supported by these institutions can only increase the awareness, capability and availability of professionals to the Atlanta and surrounding areas whom would be available to support business interests moving to the area.

The Pharmaceutical Science program you have proposed can only serve to enhance the interest and availability of graduates who could also lend support to business plans for the area. It is not hard to envision that a program of this design when added to the other curriculums offered by UGA (Doctorate of Pharmacy, Masters in Regulatory Affairs and the Doctorate program in Pharmaceutical Science), could easily help bring a critical mass of students and activities to the University and add to the building blocks and support UGA's drive to become a multi dimensioned center of excellence for these fields of study. One only need to look toward programs such as at the University of Maryland and its recognized center of excellence in Pharmacokinetics (supporting FDA) to realize the possibility of relationships with the leading medical institutions in the area.

I commend your efforts to start this program and as I have supported the Masters in Regulatory Affairs program I offer my support to this program as you go forward.

Sincerely,



Roger Wayne Wiley, D.Ph.  
Sr. Director Regulatory Affairs  
Elan Drug Delivery, Inc.



Elan Drug Delivery, Inc.  
a member of the Sanofi Group

John E. Nine  
11134 Estancia Way  
Carmel, IN 46032  
317-705-0641 Phone  
317-705-0642 FAX

Michael G Bartlett  
Professor  
Department of Pharmaceutical and Biomedical Sciences  
College of Pharmacy  
The University of Georgia  
Athens, GA 30602-2352

Dear Dr Bartlett,

The process of developing a BSPS Course of study in the Pharmaceutical Sciences Program at The University of Georgia College of Pharmacy will fill an unmet need the State of Georgia.

The latest year of 2010 Graduates in the BSPS Program at the College of Pharmacy at Purdue University is similar to last year to the past 3 years. The program have about 10 to 20 students each year.

The graduates this past year were offered Employment Offers as follows:

Graduates	11
Continuing Education	6
Employment	3
Interviewing	2

Industry Salary:       \$56.000 to \$61.000

The BSPS Program is significant in developing students who plan to continue for their PhD in Research.

The BSPS Program provides to develop a critical unmet need in the State of Georgia.

Sincerely,



John E Nine  
Pharmacy 1963  
Purdue University  
Schering Plough Retired





February 18, 2011

Dr. Michael G. Bartlett  
Professor  
Department of Pharmaceutical and Biomedical Sciences  
250 West Green Street  
College of Pharmacy  
University of Georgia  
Athens, GA 30602-2352

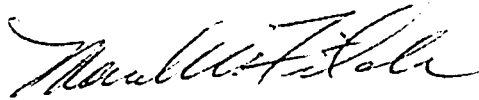
Dear Dr. Bartlett,

Thank you for contacting me in regards to the initiation of a curriculum at the University of Georgia for an undergraduate degree in Pharmaceutical Sciences. As we discussed, I was closely involved in the development of a similar program initiated approximately 12 years ago at Purdue University College of Pharmacy to confer a B.S. in Pharmaceutical Sciences (BSPS degree).

As a senior executive within the pharmaceutical industry, I recognized that there was an unmet need for technical employees, who were educated in the pharmaceutical sciences, to fill production and quality assurance support positions within our operations. Candidates with similar backgrounds were primarily PhD's and usually over-qualified for positions we were typically offering. The PharmD graduates had a strong background in pharmacology and very little education related to pharmaceuticals. Once the BSPS program was underway and producing graduates, we filled several of our technical and production management positions with these candidates. They immediately contributed to the operations and all have advanced rapidly through various career paths. In some cases, individuals went on to pursue advanced degrees in pharmaceuticals and were extremely successful, having had the solid undergraduate training in the subject.

A key aspect of the program was the mandatory inclusion of a summer internship in a pharmaceutical company or laboratory environment. Many of our permanent employees had been our interns prior to graduation. I believe there continues to be a need for this type of graduate within the pharmaceutical industry and I would support your internship program at the University of Georgia when you are successful at initiating this program.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark W. Fitch". The signature is fluid and cursive, with the first name "Mark" being the most prominent.

Mark W. Fitch  
Sr. V.P., Operations  
Nycomed US Inc.  
60 Baylis Rd.  
Melville, NY 11747-0103  
631-393-2306  
[mark.fitch@nycomedus.com](mailto:mark.fitch@nycomedus.com)

February 19, 2011

Dr. Michael G. Bartlett  
Department of Pharmaceutical and Biomedical Sciences  
College of Pharmacy  
University of Georgia  
Athens, GA 30602-2342

Dear Dr. Bartlett,

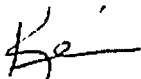
I have reviewed the proposed B.S. Program in Pharmaceutical Sciences at the University. I sincerely believe this kind of program is very much needed to train students in the science of drug development and registration.

Currently, about the only way to get this knowledge is hands-on experience, and this program will certainly provide an excellent foundation for the students. I am certain that this will be embraced by the Pharmaceutical Industry as well.

As former Head of Animal Health and Pharmaceutical Research and Development, first at Merck, then at Merial, and now Chief Scientific Officer and Executive VP of Animal and Human Health at TyraTech, I can assure you I will be following this program with big expectations.

Please let know if I can be of assistance in your program.

Sincerely,



Kevin T. Schultz, DVM, PhD



Georgia Institute of Technology  
311 Ferst Drive, NW, Mail Code: 0100  
Ford Environmental Safety & Technology Building, Room L 1326  
Atlanta, GA 30332-0100  
O: 404-385-7372; C: 404-569-0670  
Email: Shlevin@gatech.edu

February 25, 2011

Dr. Michael G. Bartlett, Professor  
University of Georgia  
Department of Pharmaceutical and Biomedical Sciences  
College of Pharmacy  
Athens, GA 30602-2352

Dear Professor Bartlett,

**RE: Proposed Bachelor Degree Program in Pharmaceutical Sciences**

I have reviewed the proposed program curriculum for your program in Pharmaceutical Sciences and offered suggestions to further enhance the course offerings. I strongly support the need for this new program as it helps assure a workforce educated in the industry required skills and aligns very nicely with a strategic priority of the State to build a vibrant life science industry in Georgia. A well trained scientific workforce is a critical element of the ecosystem needed to build a sustainable life science industry in Georgia.

I am currently engaged at ATDC as a manager and startup catalyst in helping GT faculty and other entrepreneurs across the State in forming and growing new bioscience companies. My past twenty-five years of experience in the global pharmaceutical, medical device and allied industries is perhaps more relevant to the importance of the course curriculum you are proposing. Therefore, I would like to share with you my experiences and the difficulties in Georgia of finding graduates with appropriate training relevant to the pharmaceutical industry.

I moved to Atlanta in 1991 as a founder and senior manager of CIBA Vision Ophthalmics, a start-up specialty ophthalmic pharmaceutical company. At that time, it was virtually impossible to find scientists in the local area that had a background of experiences and skills relevant to the pharmaceutical industry. While we could find excellent undergraduate and graduate educated students in the major science disciplines, we could not find job candidates that had industry-relevant practical experience. By relevant pharmaceutical industry experience, I mean knowing how to operate a laboratory under cGMPs, how to develop, characterize and develop a new drug formulation, how to scale bench formulations into a pilot or manufacturing facility, how to problem solve stability and other issues in pharmaceuticals, etc. Also, while excellent scientists, students from Georgia universities had minimal to no exposure to the drug discovery and development process. As a result, we found ourselves having to import experienced talent into the area to staff our science positions in pharmaceutical chemistry, formulations, characterization, quality assurance, pharmaceutical manufacturing, etc. This was extremely expensive and time consuming.

In 1996, I joined Solvay Pharmaceuticals as Sr. VP of R&D and Business Development and subsequently served as their CEO. At Solvay, we found ourselves having to deal with a nasty FDA compliance situation. The root cause of this problem was a long-standing lack of appropriate industry skills and

**Enterprise Innovation Institute**

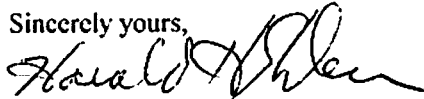
*A Unit of the University System of Georgia An Equal Employment Opportunity Institute*

experience of our scientific staff. To address this situation, we had to upgrade the quality of our scientific staff particularly in the areas of pharmaceutical sciences, quality assurance and regulatory affairs. Thanks largely to efforts to improve work-force development in life sciences, such as those at UGAs extension division of the School of Pharmacy and some educational efforts that Solvay and UCB undertook with Kennesaw State, the pool of available talent and their industry knowledge base was better than when I moved to Georgia in 1991. However, there was still a need for further improvement in the practical and industry-specific skills available in recent undergraduate students looking for entry level jobs.

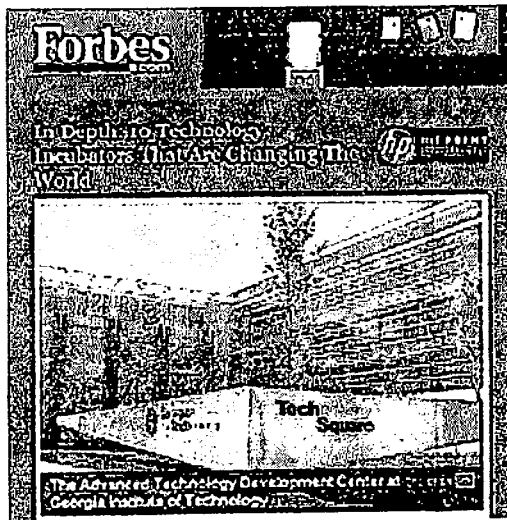
I believe your new program will fill an unmet need in providing a pool of talent which will be of value to the life science industry here and across the nation. In many respects, the program is somewhat similar to and builds upon the program at Purdue. The Purdue program has proven highly successful in supplying students well positioned with practical experience and knowledge for careers in the industry and many graduates of Purdue's program have become senior leaders in the industry. I would expect successful graduates of your new program to be offered similar career opportunities.

I applaud your efforts to build this new program into your curriculum and would be glad to help in any ways that would be helpful.

Sincerely yours,



Harold H. Shlevin, PhD  
Manager & StartUp Catalyst  
Advanced Technology Development Center – Biosciences  
Georgia Institute of Technology



**Appendix 2: Topical Outlines of Pharmaceutical Sciences Courses**

**PMCY 3010: Membranes and Organ Systems**

Alternate titles PMCY 3010: Cell and Organ Function

PMCY 3010: Pharmaceutical Physiology

PMCY 3010: Concepts in Pharmaceutical Sciences

**Course Description:** Human Physiology with an emphasis on cell membranes/transporters and organ systems as targets and modifiers of drug action.

**Prerequisites:** BIOL 1107L, CHEM1211/CHEM1212

**Coreq:** BCMB3100

**Length/credit hours:** 15 weeks/4 credits

**Format:** 4 x 50 minutes didactic/active

**Student assessment:** 4 unit exams (3-4 Q per lecture), each worth 15% of final grade (total 60%)  
Integrative problem solving set, worth 10% of final grade  
Comprehensive final or Creative Project, worth 25% of final grade  
Participation, worth 5% of final grade

**Course Outline:**

- Week 1: Intro to cells & Biological Membranes; Membrane Transport I; Membrane Transport II
- Week 2: Membrane Transport III (Ion channels); Membrane Potential & Action Potential; Excitable Cells, Synapses & Neuromuscular junction
- Week 3: Muscle I (power stroke/EC coupling); Muscle II (mechanics, metabolism, smooth muscle); Motor System
- Week 4: Integration of Motor Function; Autonomic Nervous System; CNS Learning & Memory
- Week 5: Group problem solving I; **EXAM 1 (Intro – Motor function, 10)**; Sensory systems I (overview, mechanosensation, thermosensation, nociception)
- Week 6: Sensory systems II (vision); Sensory Systems III (hearing/balance/taste/smell); Cardiac I (Overview, Anatomy, electrophysiology)
- Week 7: Cardiac II (electrophysiology); Cardiac III (pump); Cardiac IV (output)
- Week 8: Group Problem solving II; **EXAM 2 (ANS – Cardiac IV, 9)**; Circulation I (peripheral/microcirculation)
- Week 9: Circulation II (blood pressure/regulation); Renal I (overview/anatomy & filtration); Renal II (tubular reabsorption)
- Week 10: Renal III (secretion & urine concentration); Renal IV (fluid, acid-base balance); GI I (motility)
- Week 11: GI II (digestion/absorption); GI III (liver function); GI IV (liver & drug metabolism)
- Week 12: Group Problem solving III; **EXAM 3 (Circ I – GI IV, 10)**; Pulmonary I (overview-ventilation & mechanics)
- Week 13: Pulmonary II (blood flow); Pulmonary III (ventilation-perfusion & gas exchange); Pulmonary IV (O<sub>2</sub> & CO<sub>2</sub> transport, regulation)
- Week 14: Endocrine I (pituitary/hypothalamus/growth?); Endo II (thyroid/adrenal/ pancreatic?); Endo III (female reproduction/pregnancy/male reproduction)
- Week 15: Skin; Group problem solving IV; **Exam 4 (Pulm I – Skin, 8)**

**Exam week:** Comprehensive Final Exam OR Creative Project Submission

## **PMCY 3100: Introduction to the Pharmaceutical Sciences**

**Course Description:** Presentation of the basic concepts of physical pharmacy and the pharmaceutical sciences with an emphasis of drug delivery systems.

**Prerequisites:** BCMB 3100, CHEM 3110, MATH 2250

**Length/credit hours:** 15 weeks/3 credits

**Format:** 3 x 50 minutes didactic/active

**Student assessment:** 4 unit exams each worth 15% of final grade (total 60%)  
Integrative problem solving set, worth 10% of final grade  
Comprehensive final or Creative Project, worth 25% of final grade  
Participation, worth 5% of final grade

### **Course Outline:**

**Week 1: States of Matter**

**Week 2: Pharmaceutical Thermodynamics; Physical Properties of Molecules**

**Week 3: Physical Properties continued; Nonelectrolyte Solutions**

**Week 4: Electrolyte Solutions; Ionic Equilibria**

**Week 5: Solubility and Distribution; Complexation and Protein Binding; Exam 1 (weeks 1-4)**

**Week 6: Complexation and Protein Binding continued; Diffusion**

**Week 7: Introduction to Biopharmaceutics**

**Week 8: Drug Release and Dissolution**

**Week 9: Chemical Kinetics and Stability; Exam 2 (weeks 5-8)**

**Week 10: Interfacial Phenomena**

**Week 11: Colloidal Dispersions; Coarse Dispersions**

**Week 12: Micromeritics**

**Week 13: Rheology; Exam 3 (weeks 9-12)**

**Week 14: Pharmaceutical Polymers; Oral Solid Dosage Forms**

**Week 15: Oral Solid Dosage Forms continued; Exam 4 (weeks 13-15)**

**Exam week: Comprehensive Final Exam OR Creative Project Submission**



**PMCY 3200L: Pharmaceutical Techniques**

**Course Description:** Laboratory of major techniques used to support pharmacology and drug development in the pharmaceutical sciences.

**Prerequisites:** CHEM 2212, BCMB 3100

**Credit Hours:** 1 credits

**Format:** 1 x 3 hr laboratory per week

**Student Assessment:** Laboratory Reports

**Course Outline:**

**Week 1: Gel Electrophoresis**

**Week 2: Southern and western blot analysis**

**Week 3: qPCR**

**Week 4: Cell and Organelle Staining**

**Week 5: Microscopy**

**Week 6: Karl-Fischer Titration**

**Week 7: Shear force / Shear stress (Rheology)**

**Week 8: Dissolution Testing**

**Week 9: Partition Coefficients**

**Week 10: Infrared Spectroscopy**

**Week 11: Gas Chromatography**

**Week 12: High Performance Liquid Chromatography**

**Week 13: Nuclear Magnetic Resonance Spectroscopy**

**Week 14: Mass Spectrometry**

**Week 15: Liquid Chromatography – Mass Spectrometry**

## PMCY 3500: Pharmaceutical Analysis

**Course Description:** Techniques applicable characterization and determination pharmaceutical agents.

**Prerequisites:** CHEM 2212

**Credit Hours:** 3 credits

**Format:** 3 x 50 min didactic lectures

**Student Assessment:** 4 exams, homework, comprehensive final exam or creative project, class participation

### Course Outline:

**Week 1:** Quality Control - Accuracy and Precision; Linearity; Method Validation; SOPs; Basic Calculations

**Week 2:** Physical & Chemical Properties – pKa; H-H; %Ionization; Dissolution; Partition Coefficients; Stereochemistry; Optical Rotation; Stability

**Week 3:** Physical & Chemical Properties – Gravimetric; Surface Area; Polymorphs; Calorimetry

**Week 4:** Titrations – Acid/Base; Non-aqueous; Redox; Potentiometric; Karl-Fischer

**Week 5:** UV/Vis Spectroscopy – Instrumentation; Beer's Law; Diode Array; Interpretation; Difference Spectrophotometry; Derivative Spectra

**Week 6:** IR Spectroscopy – Instrumentation; Interpretation; Polymorphs; Near-infrared Spectroscopy; Exam 1 (covers weeks 1-4)

**Week 7:** Molecular Spectroscopy – Instrumentation; Molecules that Fluoresce; Quenching; Raman Spectroscopy; Interpretation

**Week 8:** NMR – Instrumentation; Proton; Carbon; 2-D; Interpretation

**Week 9:** Mass Spectrometry – Instrumentation; Ionization; Interpretation; MS-MS

**Week 10:** Chromatography – Capacity Factor; Efficiency; Partitioning; Band Broadening; Peak Shape; Exam 2 (covers weeks 5-8)

**Week 11:** Gas Chromatography – Instrumentation; Column Chemistry; Derivatization; Detectors; Residual Solvent Analysis

**Week 12:** HPLC – Instrumentation; Column Chemistry; Secondary Equilibrium; Detectors; Method Development

**Week 13:** HPLC – Ion-Pair; Ion-exchange; Size-exclusion; Affinity; Normal Phase; HILIC; Exam 3 (Covers weeks 9-11)

**Week 14:** Other Separations – Thin Layer Chromatography; Electrophoresis; Capillary Electrophoresis;

**Week 15:** Hyphenated Techniques: GC-MS; LC-MS; LC-MNR; Exam 4 (Covers weeks 12-15)

**Exam Week:** Comprehensive Final Exam or Creative Project Submission

## **PMCY 3800 Introduction to Pharmacology**

The goal of this course is to develop understanding of the molecular and organ system basis for the therapeutic use of the major classes of drugs in the treatment of disease. This course covers basic pharmacological principles and specific therapeutic actions of major drug classes commonly used in clinically significant disease states. The first two sections of the course cover general principles in molecular and systemic Pharmacology, and will provide a framework for sections 3-7, which will cover specific drugs and therapeutic applications. In each of the drug sections (3-7), we will review the physiology of the organ system affected in the disease state, discuss the mechanism of action of the drug(s), and identify significant adverse effects and toxicological aspects.

Explores principles of drug action on biological systems,

- 1) **Basic Principles**
  - a) **Pharmacodynamics**
    - i) **Receptor classes**
    - ii) **Dose-response curves**
  - b) **Pharmacokinetics**
    - i) **ADME**
  - c) **Toxicology**
    - i) **Adverse effects**
    - ii) **Drug safety and screening**
    - iii) **Therapeutic effects of chemotherapeutics**
- 2) **Autonomic Pharmacology**
  - a) **Neurotransmitter function and regulation**
  - b) **Cholinergic transmission overview**
    - i) **Major transmitters, receptors, and physiologic effects**
    - ii) **Therapeutic use of cholinergic activators and inhibitors**
  - c) **Adrenergic transmission overview**
    - i) **Major transmitters, receptors, and physiologic effects**
    - ii) **Therapeutic use of adrenergic activators and inhibitors**
- 3) **Therapeutics that target the Cardiovascular System:**
  - a) **Anti-hypertensives**
  - b) **Angina therapeutics**
  - c) **Heart Failure therapeutics**
  - d) **Anti-Arrhythmia**
  - e) **Diuretics**
- 4) **Therapeutics that target the Central Nervous System:**
  - a) **Sedatives**
  - b) **Anti-seizure drugs**
  - c) **General anesthetics**
  - d) **Local anesthetics**

- e) Muscle relaxants
  - f) Anti-Parkinsonism drugs
  - g) Anti-Psychotics
  - h) Anti-depressants
  - i) Analgesics
- 5) Therapeutics that target the Circulatory and Inflammatory systems:
- a) Anti-histamines
  - b) Anemia
  - c) Anti-inflammatories
  - d) Anti-coagulants
- 6) Therapeutics that target the Endocrine Systems:
- a) Hypothalamic and pituitary hormones
  - b) Thyroid hormones
  - c) Corticosteroids
  - d) Pancreatic hormones
  - e) Gonadal hormones
- 7) Chemotherapeutics
- a) Anti-bacterials
  - b) Anti-virals
  - c) Anti-fungals, anthelmintic, antiprotozoal, etc.
  - d) Cancer chemotherapy

**PMCY 4100: Biopharmaceutics and Pharmacokinetics**

**Course Description:** Biopharmaceutical and pharmacokinetic principals will be discussed with an emphasis on evaluation of dosage formulations and drug development

**Prerequisites:** PMCY 3010, PHYS 1211, PMCY 3100

**Length/credit hours:** 15 weeks/3 credits

**Format:** 3 x 50 minute didactic lectures/problem based learning

**Student Assessment:** Three exams and a comprehensive final, active learning exercises, and problem sets

**Course Outline:**

**Dosage Formulations and Drug Absorption (5 lectures)**

**Bioavailability and Bioequivalence (2 lectures)**

**Drug Distribution (3 lectures)**

**Drug Metabolism (4 lectures)**

**Drug Transport: Absorption, Distribution and Elimination (2 lectures)**

**Drug Excretion (2 lectures)**

**Compartment Model Kinetics (8 lectures)**

**Non-Compartmental Analysis (2 lectures)**

**Computer Analysis of Data (2 lectures)**

**Design of PK Studies for Investigational Compounds (3 lectures)**

**Small molecule vs. large molecule (2 lectures)**

**Pharmacogenomics (2 lectures)**

**Exams (3 lectures)**

**Problem based /active learning (5 lectures)**

## **PMCY 4200 Medicinal Chemistry**

### **Objectives**

The student should be able to:

1. Identify the drug or drug class given the structure of the drug or a drug prototype
2. List the indications for a drug or drug class
3. Discuss the side effects of a given drug and the mechanism of these side effects
4. Describe the mechanism of action and the pharmacological action of a given drug or drug class
5. Describe the physicochemical (biological stability) and pharmaceutical (chemical stability) properties of a given drug or drug class
6. Describe the structure-activity relationship for a given drug class.
7. Describe the ADME characteristics of a given drug or class
8. Describe how physiological and pathophysiological conditions affects the Absorption, distribution, metabolism and elimination (ADME) of a drug.
9. Describe how other drugs influence the ADME characteristic of a given drug

### **Topical Outline**

1. Introduction to Medicinal Chemistry and Drug Design
2. Drugs acting on the sympathetic and parasympathetic nervous system  
Direct cholinergic agent, indirect cholinergic agents, antimuscarinic agents, neuromuscular blocking agents, adrenergic agonists, adrenergic antagonists,
3. Antihistamines
4. Cardiovascular Agents  
Lipid lower agents, cardiac glycosides, diuretics, misc. vasodilators, anti-arrhythmic drugs
5. Prostaglandins and NSAIDS
6. Drugs of the endocrine system  
Steroids, thyroid agents, Insulin and oral anti-diabetic agents,
7. CNS agents  
Antidepressants, antipsychotic agents, antimigraine, parkinson's disease drugs
8. Antibiotics  
beta-lactams, macrolides, tetracyclines, aminoglycosides, miscellaneous agents
9. Antibacterial and antifungal agent  
Fluoroquinolones, sulfonamides, azoles, miscellaneous agents
10. Anticancer agents  
Anti-metabolites, natural products, antitumor antibiotics, alkylating agents, miscellaneous agents

## **PMCY 4500: Drug Development I**

**Course Description:** This course presents an overview and the underlying principles of biopharmaceutical drug development in the United States. It deals with understanding and assessing various phases in drug development, including preclinical and clinical investigations, manufacturing and other general considerations of the drug development process. The course also covers aspects of pharmacogenomics and drug-drug interactions particularly in the context of drug design, drug metabolism prediction, drug-interactions prediction and overall drug development.

**Prerequisites:** PMCY 3100, PMCY 3500, PMCY 3800

**Credit Hours:** 4 credits

**Format:** 1 x 3 50 min didactic lectures; 1 x 3 hr laboratory

**Student Assessment:** Exams, homework, comprehensive final exam, class participation, laboratory reports, creative project

### **Course Outline:**

**Week 1: General Concepts of Drug Development**

**Week 2: Phase 1 and 2 Studies, including principles and rationale**

**Week 3: Phase 3 and 4 Studies, including principles and rationale**

**Week 4: Selection of Lead Compounds; Preclinical Study Requirements**

**Week 5: Preclinical Studies Continued, Information Flow and Utility in Study Design**

**Week 6: Dose Escalation and Allometric Scaling**

**Week 7: First Dose in Humans; Clinical Testing**

**Week 8: Formulation Design and Testing; Routes of Administration**

**Week 9: Product Stability and Testing**

**Week 10: High-Throughput Screening**

**Week 11: Drug Target Selection and Validation**

**Week 12: Drug-Drug Interactions**

**Week 13: Drug-Drug Interactions Continued**

**Week 14: Pharmacogenomics**

**Week 15: Pharmacogenomics Continued**

**Exam Week: Comprehensive Final Exam or Creative Project Submission**

## **PMCY 4510: Drug Development II**

**Course Description:** This course will critically assess the major issues and stages in drug development, including regulatory, economic, and legal issues associated with the drug development process. In addition, other specialized areas in pharmaceutical and biopharmaceutical drug development, as a continuation of PMCY 4500 will be dealt. A multidisciplinary perspective will be provided by the faculties representing basic, clinical and management sciences. This course will be supplemented by outside speakers from the pharmaceutical industry or regulatory agencies (FDA etc ...).

**Prerequisites:** PMCY 4500

**Credit Hours:** 4 credits

**Format:** 1 x 3 50 min didactic lectures; 1 x 3 hr laboratory

**Student Assessment:** Exams, homework, comprehensive final exam, class participation, laboratory reports, creative project

### **Course Outline:**

**Week 1: General Regulatory Aspects of Drug Development**

**Week 2: General Regulatory Aspects of Drug Development Continued**

**Week 3: FDA Approval Process: IND, NDA**

**Week 4: FDA Interactions: Application Review and Final Approval; Guidance and White Papers**

**Week 5: Drug Delivery Devices**

**Week 6: Bioequivalence Testing**

**Week 7: Small Molecule Therapeutics**

**Week 8: Large Molecule Therapeutics (Antibodies, Growth Factors, Cytokines etc ...)**

**Week 9: Scale-up in the Pharmaceutical Industry**

**Week 10: Scale-up in the Pharmaceutical Industry Continued**

**Week 11: Biomarkers**

**Week 12: Post-Market Surveillance**

**Week 13: Pharmacovigilance and Clinical Data Pathways**

**Week 14: Pharmacoeconomics**

**Week 15: Patents and Exclusivity**

**Exam Week: Comprehensive Final Exam or Creative Project Submission**



**PMCY 4900: Pharmaceutical Sciences Research I**

**Course Description:** Undergraduate Research in the Pharmaceutical Sciences.

**Prerequisites:** BCMB 3100, PMCY 3200L, BIOL 1117L

**Credit Hours:** 2 credits

**Format:** 6 Hours of Laboratory Research per Week

**Student Assessment:** Performance of Laboratory Research, Participation in Group Meetings, Presentation of Results at Group Meeting, Preparation of Report Summarizing Research Efforts.

**Course Outline:**

**Week 1:** Right-to-Know Training, Chemical Safety Training, Other Necessary Laboratory Training

**Week 2 – 14:** Participate in Laboratory Research Project

**Week 15:** Laboratory Research Finishes and Presentation of Results

**Exam Week:** Written Laboratory Project Submission

**PMCY 4910: Pharmaceutical Sciences Research II**

**Course Description:** Undergraduate Research in the Pharmaceutical Sciences.

**Prerequisites:** PMCY 4900

**Credit Hours:** 2 credits

**Format:** 6 Hours of Laboratory Research per Week

**Student Assessment:** Performance of Laboratory Research, Participation in Group Meetings, Presentation of Research Poster, Preparation of Report Summarizing Research Efforts.

**Course Outline:**

**Week 1 – 14:** Laboratory Research Project

**Week 15:** Laboratory Research Finishes, Preparation of Poster and Final Report

**Exam Week:** Written Laboratory Project Submission, Presentation of Poster at Research Day