

TOPIC: University of Maryland Eastern Shore: Doctor of Philosophy in Pharmaceutical Sciences

**<u>COMMITTEE</u>**: Education Policy and Student Life

# DATE OF COMMITTEE MEETING: June 3, 2014

<u>SUMMARY</u>: The UMES School of Pharmacy Doctor of Pharmacy program was awarded full accreditation by the Accreditation Council for Pharmacy Education (ACPE) on June 26, 2013. ACPE standards state that the factor of greatest significance in assurance of the educational quality in a school of pharmacy is the excellence of its faculty and staff. Thus ACPE guideline 8.4.2 specifies that faculty scholarship be demonstrated by productive research, contributions to the scientific and professional literature, or other evidence of scholarly accomplishment such as the publication of books and reviews (https://acpe-accredit.org/standards/standards3.asp). The proposed graduate program in pharmaceutical sciences (PS) supports the SOP compliance with ACPE standards and the UMES/SOP goal of attracting, developing and retaining high quality faculty.

The proposed Doctor of Philosophy in Pharmaceutical Sciences will be an academic, researchoriented program that offers multidisciplinary training in the areas of Drug Design & Discovery and Drug Delivery & Clinical Pharmacology. Students who fulfill the academic criteria of course work and original research culminating in a dissertation will earn the Doctor of Philosophy (Ph.D.) degree.

The two areas of specialization were created to develop a curriculum that is multi-interdisciplinary and on the cutting edge of the ever advancing field of pharmaceutical sciences, thus stimulating cross-exchange of the educational experience for the student. The DDD track will offer students the ability to gain knowledge and conduct research in the areas of drug design and synthesis, biosynthesis of natural products, neuropharmacology and immunology. The DD&CP track will offer the students the ability to gain knowledge and conduct research in the areas of new drug delivery systems with a focus on the use of nanomedicine in targeted drug delivery. The DD&CP track will also offer the opportunity for students to train in the area of clinical pharmacology by acquiring advanced pharmacokinetic and pharmacodynamic analysis skills and the use of modeling and simulation techniques.

The program will prepare students for careers in academia, government and advanced scientific research in the pharmaceutical and biotechnology industries. The proposed program fulfills the USM stated goal of strengthening and expanding the capacity of HBIs to provide high quality and unique educational programs. The proposed program is aligned with the 2013 Maryland State Plan for Postsecondary Education "Maryland Ready" program that include investing in health care programs. According to the bureau of labor statistics, medical scientists have one of the fastest growing job outlooks (2010-2020) at 36% (http://www.bls.gov/ooh/life-physical-and-social-science/medical-scientists.htm). Projected national employment for life scientists is expected to increase by 16.5 % by 2016. Maryland occupational projections (2010-2020) show a total of 5150 openings for life scientists by 2020. (http://www.dllr.state.md.us/lmi/iandoproj/occgroup19.shtml).

There is currently one graduate program in pharmaceutical sciences in the State of Maryland, offered by the University of Maryland School of Pharmacy (UMSOP) in Baltimore. The proposed program in Pharmaceutical Sciences at UMES will be unique as well as complementary to the program currently offered by the UMSOP. The Drug Design and Discovery specialization area is similar to the Chemical Biology track offered by the UMB SOP's program. However the proposed program will be unique regionally being the only graduate Pharmacy program of its kind serving the eastern shore of Maryland and the Delmarva peninsula. The "Drug Delivery and Clinical Pharmacology (DD&CP)" track of the proposed program is also unique as it is not currently offered by the UMB School of Pharmacy (although there are some elective courses offered in this area). The DD&CP track will educate and train researchers in critical drug delivery and nanomedicine research areas where advances and improvements are needed, such as animal and computer based predictive models, biomarkers for safety and effectiveness, and new clinical evaluation techniques. This track will also train researchers in the advanced pharmacokinetic/dynamic analysis, phase I clinical trial design, and translational research to validate new pharmacological targets. The core faculty of the UMES SOP has the expertise in these areas to educate and train students and post-doctoral fellows to pursue careers in industry, academia, regulatory agencies and the emerging trillion dollar nanobiotechnology industry.

ALTERNATIVE(S): The Regents may not approve the program or may request further information.

**FISCAL IMPACT**: No additional funding is necessary. The program will be supported through tuition and a one-time allocation for facilities renovation.

<u>**CHANCELLOR'S RECOMMENDATION**</u>: That the Committee on Education Policy and Student Life recommend that the Board of Regents approve the proposal from the University of Maryland Eastern Shore to offer the Doctor of Philosophy in Pharmaceutical Sciences.

COMMITTEE RECOMMENDATION: A	DATE: June 3, 2014			
BOARD ACTION:		DATE:		
SUBMITTED BY: Joann Boughman	301-445-1992	jboughman@usmd.edu		

UNIVERSITY SYSTEM OF MARYLAND INSTITUTION PROPOSAL FOR

New Instructional Program

Х Substantial Expansion/Major Modification

**Cooperative Degree Program** 

Within Existing Resources, or

**Requiring New Resources** 

University of Maryland Eastern Shore Institution Submitting Proposal

Doctor of Philosophy in Pharmaceutical Sciences **Title of Proposed Program** 

Ph.D.

Award to be Offered

Proposed HEGIS Code

Interim-Dean Dennis Killian

**Department Contact** 

410 651 8350 **Contact Phone Number** 

Signature of President or Designee

May 20, 2014 Date

Fall 2015

Projected Implementation Date

Proposed CIP Code

Pharmaceutical Sciences /School of Pharmacy Department in which program will be located

dmkillian@umes.edu Contact E-Mail Address

# MISSION

The University of Maryland Eastern Shore (UMES), the State's Historically Black Land-Grant Institution, is a teaching, research and doctoral institution that nurtures and launches leaders in a student-centered environment, particularly among ethnic minorities. Committed to providing high quality programs in an ethnically diverse environment, the University prepares students who will serve and shape the global economy. The 2010 assessment of Historically Black Colleges and Universities (HBCUs) by US News and World Report, continues to rank UMES in the "top tier" of HBCUs.

UMES is the only research and doctoral degree granting institution of the University System of Maryland on the Eastern Shore of Maryland. The University has developed and implemented freestanding doctoral degree programs in (a) Food Science & Technology, (b) Educational Leadership, (c) Organizational Leadership, (d) Marine-Estuarine-Environmental Sciences and (e) Toxicology. To respond to extensive regional and national health care needs, especially those in rural areas, UMES established the School of Pharmacy and Health Professions (consisting of the School of Pharmacy (SOP), the Departments of Physician Assistants, Physical Therapy, Exercise Science and Rehabilitation Services). The UMES School of Pharmacy Doctor of Pharmacy program was awarded full accreditation by the Accreditation Council for Pharmacy Education (ACPE) on June 26, 2013. ACPE standards state that the factor of greatest significance in assurance of the educational quality in a school of pharmacy is the excellence of its faculty and staff. Thus ACPE guideline 8.4.2 specifies that faculty scholarship be demonstrated by productive research, contributions to the scientific and professional literature, or other evidence of scholarly accomplishment such as the publication of books and reviews (https://acpeaccredit.org/standards/standards3.asp). The proposed graduate program in pharmaceutical sciences (PS) supports the SOP compliance with ACPE standards and the UMES/SOP goal of attracting, developing and retaining high quality faculty.

The UMES 2011-2016 Strategic Plan includes the goal of "expanding the capacity to offer unique and/or critical undergraduate, graduate, and professional academic programs that address regional workforce needs". The plan is committed "to identifying and implementing complementary healthcare programs; advancing medical and pharmacologic knowledge through research and training" (UMES Goal I). Additionally, the plan calls for UMES "to obtain and retain the Carnegie Doctoral Research University (DRU) Classification". The proposed graduate program in PS supports the goals of the UMES 2011-2016 Strategic Plan which are aligned with the USM 2020 goals and themes (http://www.umes.edu/cms300uploadedFiles/4-

ExeuctiveDivision/OfficeOfPresident/Strategic\_Planning/Strategic%20Plan%20for%20web.pdf)

The proposed graduate program in PS, with its emphasis on research and scholarship, is in keeping with the mission of the University in its commitment to meeting the economic development needs on the Eastern Shore. The reality of today's job market require highly trained skilled graduates to fulfill the current and future needs of pharmaceutical and biotechnology industries and is consistent with the workforce development needs of the State, international development priorities of the nation, and commercialization and entrepreneurial ventures of the University through engagement activities and partnerships.

# CHARACTERISTICS OF THE PROPOSED PROGRAM

The Pharmaceutical Sciences Graduate Program will be an academic, research-oriented program that offers multidisciplinary training in the areas of Drug Design & Discovery and Drug Delivery & Clinical Pharmacology. Students who fulfill the academic criteria of course work and original research culminating in a dissertation will earn the Doctor of Philosophy (Ph.D.) degree.

The Graduate Program in Pharmaceutical Sciences includes the following areas of specialization:

- Drug Design and Discovery (DDD)
- Drug Delivery and Clinical Pharmacology (DD&CP)

The two areas of specialization were created to develop a curriculum that is multi-interdisciplinary and on the cutting edge of the ever advancing field of pharmaceutical sciences, thus stimulating crossexchange of the educational experience for the student.

The DDD track will offer students the ability to gain knowledge and conduct research in the areas of drug design and synthesis, biosynthesis of natural products, neuropharmacology and immunology. The DD&CP track will offer the students the ability to gain knowledge and conduct research in the areas of new drug delivery systems with a focus on the use of nanomedicine in targeted drug delivery. The DD&CP track will also offer the opportunity for students to train in the area of clinical pharmacology by acquiring advanced pharmacokinetic and pharmacodynamic analysis skills and the use of modeling and simulation techniques.

#### Pharmaceutical Sciences Graduate Curriculum

Model Plan for the Drug Design and Discovery (DDD) Track				
Ph.D. Degree				
<u>Core Courses</u>	<u>Cr.</u>			
PSGP 801 Drug Design and Discovery I	3			
PSGP 803 Advanced Drug Metabolism I	3			
PSGP 805 Dosage forms and Advanced Drug Delivery Systems	3			
CHEM 421 Instrumental Analysis	3			
PSGP 809 Seminar, Journal Club	4X1			
PSGP 601 Responsible conduct of research: research ethics	1			
PSGP 810 Grant proposal, Scientific writing, Academic Development	3			
CSDP 604 Computer methods in statistics	3			
Subtotal	23			
Electives	18			
PSGP 899 Research/Dissertation				
Total	53			
Flective Courses*				
PSGP 804 Advanced Drug Metabolism II	з			
PSGP 812 Advanced Bioorganic Chemistry	3			
PSGP 814 Advanced Neuropharmacology	3			
	-			

PSGP 816 Advanced Molecular Pharmacology	3
PSGP 602 Oral Solid Dosage Forms	3
CHEM 670 Advanced Biochemistry I	3
TOXI 601 Advanced Toxicology I	3
TOXI 688D Molecular Genetics and DNA Damage	3
AGRI 684 Recombinant DNA Technology	3
AGSC 605 Statistics in Agriculture Research	3

\*Electives are offered for both M.S. and PhD degree tracks and can be selected in consultation with major advisor and are not limited to the above list or course descriptions below.

#### Model Plan for the Drug Delivery and Clinical Pharmacology (DD&CP) Track

Ph.D. Degree				
<u>Core Courses</u>	<u>Cr.</u>			
PSGP 801 Drug Design and Discovery I	3			
PSGP 821 Clinical Pharmacology & Drug Development	3			
PSGP 805 Dosage forms and Advanced Drug Delivery Systems	3			
CHEM 421 Instrumental Analysis	3			
PSGP 809 Seminar, Journal Club	4X1			
PSGP 601 Responsible conduct of research: research ethics	1			
PSGP 810 Grant proposal, Scientific writing, Academic Development	3			
CSDP 604 Computer methods in statistics	3			
Subtotal	23			
Electives	18			
PSGP 899 Research/Dissertation	12			
Total	53			
Elective Courses*				
PSGP 819 Modeling and Simulation Methods in Quantitative Clinical Pharmacology	R			
PSGP 814 Advanced Neuronbarmacology	3			
PSGP 816 Advanced Molecular Pharmacology				
PSGP 602 Oral Solid Dosage Forms	2			
TOXI 601 Advanced Toxicology I				
AGSC 605 Statistics in Agriculture Research	3			

\*Electives are offered for both M.S. and PhD degree tracks and can be selected in consultation with major advisor and are not limited to the above list or course descriptions below.

Non PharmD students applying for the graduate program may enroll in no more than 6 credit hours of PharmD 500/600 level classes as electives. These PharmD classes will have additional requirements for the enrolled graduate students as designated by the course instructor. Graduate students in the PSGP who are PharmD graduates are not allowed to take any course in the PharmD program with the exception of elective classes approved by the major advisor.

# All-Areas (Drug Design and Discovery and Drug Delivery and Clinical Pharmacology)

# Core Courses

# PSGP 801 - Drug Design and Discovery I (3 credit hours)

In depth consideration and correlation of molecular structure to biological activity of organic medicinal agents, the synthesis, chemical and pharmacological properties, current theories and their application to medicinal chemistry.

# PSGP 803 - Advanced Drug Metabolism I (3 credit hours)

A study of the metabolism and disposition of drugs and drug metabolites. Topics include in-depth discussions of Phase I and II biotransformation pathways, pharmacogenetics, biotransformation and toxicity, in vitro/in vivo techniques for evaluating drug metabolism and scale-up of drug metabolism data.

# PSGP 805 – Dosage Forms and Advanced Drug Delivery Systems (3 credit hours)

This course is designed to study the various dosage forms and drug delivery systems. Emphasis will be placed on novel dosage forms and drug delivery systems.

# CHEM 421 Instrumental Analysis (3 credit hours)

This course is designed to provide the student with an advanced knowledge in modern analytical chemistry and instrumental methods of analysis. Application will be on the use in the pharmaceutical sciences. Emphasis will be on chromatographic techniques, NMR, IR and Mass Spectroscopy.

# PSGP 809/TOXI 618 - Seminar/Journal Club (1 credit hour)

Presentations, reading and discussions on the pharmaceutical sciences/toxicology.

# PSGP 810- Grant proposal, Scientific Writing and Academic Development (3 credit hour)

A course designed to detail the processes involved in writing a proposal in the area of specialization. This course will also include a critical review of published manuscripts and those submitted for publication.

# PSGP 601 Responsible conduct of research (RCR): Research Ethics (1 credit hour)

All graduate students in the Pharmaceutical Sciences Program are required to satisfy the RCR requirement. The Responsible Conduct of Research (RCR) course is intended to provide students with information on pertinent federal and University guidelines and regulations pertaining to the responsible conduct of research as well as to instruct them in a method of utilizing moral reasoning skills in responding to ethical dilemmas in research.

# CSDP 604 Computer methods in statistics (3 credit hours)

Topics include (not limited to); principles and applications of probability and statistics needed in graduate studies in various academic areas and to the computer realization of these methods. Review of basic statistical principles. Pre-requisite: one semester of calculus.

# PSPG 821 Clinical Pharmacology and Drug Development (3 credit hours)

This course will focus on the early clinical drug development including the rationale and study design of studies needed for the clinical pharmacology section of new drug applications. Lectures will involve the challenges regarding discovery research, development, formulations and manufacturing and regulatory issues in the creation of new products for patient care. The course will require students to assimilate the information from pharmaceutics, pharmacokinetics, pharmacology and pharmacotherapy and be able to

write out and verbally present on drug development issues. The class will be an interactive format with student questions / discussion being fostered in class, along with student product presentation by each student.

#### PSGP 899 - Research/PhD Dissertation Writing (1-9 credit hours)

Research under faculty supervision in an area of specialization leading to the preparation and submission of a Dissertation in partial fulfillment of the graduation requirements.

#### Elective Courses

#### PSGP 802 - Drug Discovery II (3 credit hours)

A continuation of Drug Discovery I.

# PSGP 804 Advanced Drug Metabolism II (3 credit hours)

A continuation of Advanced Drug Metabolism I.

#### PSGP 811 Principles of Pharmacology (3 credit hours)

General principles of pharmacology including metabolism, action, interactions, side effects, toxicity and therapeutic use of drugs.

#### PSGP 812 Advanced Bioorganic Chemistry I (3 credit hours)

This course covers the biosynthesis of different classes of natural products drugs/drug candidates. The course begins with the introduction of organic reaction mechanisms relevant to the natural products biosynthesis. The biochemistry of carbohydrate and fat metabolism that provide building blocks for the biosynthesis of majority of classes of natural products are covered. Biosynthesis of selected classes of pharmaceutically important natural products -aminoglycosides, deoxysugars, and peptides (both ribosomal and non-ribosomal)- will be covered. Currently used drugs pertaining to these classes will be introduced.

# PSGP 813 Advanced Bioorganic Chemistry II (3 credit hours)

This course is built on the platform of the Advanced Bioorganic Chemistry I. Biosyntheses of polyketide drugs, recent advances on engineering of secondary metabolite pathways; shikimate pathway, shikimate-derived metabolites (cinnamic acids, lignans, benzoic acids, flavonoids, and aromatic amino acids) and alkaloids are covered. Mevalonate pathway, biosynthesis of terpenes, cyclization mediated structure diversification of terpenes, terpenes therapeutics, and natural product drugs of mixed biosynthetic origin are extensively covered in this course.

#### PSGP 814- Advanced Neuropharmacology (3 credit hours)

Advanced study of the central nervous system pharmacology and neurochemistry. Topics will include the actions of neurotransmitters in the central nervous system and the use of drugs which exert therapeutic action in the central nervous system.

#### PSGP 815 Clinical Chemistry (3 credit hours)

Clinical chemistry is an area of clinical pathology that uses chemical tests for various components in blood and urine for diagnostic, prevention, and prognostic information, and therapeutic purposes. This course provides an overview of various tests used in medical diagnostics and discusses the interpretations and limitations of the tests. The topic that will be covered include electrolytes, acid-base

disorder, kidney and liver function tests, enzymes and proteins, hemoglobinopathy and iron metabolism, endocrine (diabetes, bone markers, hypothalamus, pituitary, thyroid, adrenal, gonads, and pregnancy), cardiac disease and lipid disorders, therapeutic drug monitoring, alcohol, and clinical toxicology.

#### PSGP 816 – Advanced Molecular Pharmacology (3 credit hours)

Study of the actions of drugs at the molecular level.

#### PSGP 817 - Advanced Immunology (3 credit hour)

This course will discuss the current progress of areas related to immunology including tumor immunity, virus immunity, or auto-immune diseases. Each year will focus on one of these three topics. Contents include lectures by faculty, seminar by invited speakers, and article presentation by students.

#### PSGP 818 Advanced Pharmacokinetics and Pharmacodynamics (3 credit hours)

This course is designed to provide the student with the advance knowledge and skills necessary for problem solving technique related to the relationship between plasma concentration and effect, and clearance concepts as it relates to drug therapy. Emphasis will be placed upon a complete understanding of advanced, clinically applicable pharmacokinetic formulas and the assumptions that are involved with their use. This course will also utilize computer simulation programs to fit pharmacokinetic/pharmacodynamic parameters using different models.

#### PSPG 819 – Modeling and Simulation Methods in Quantitative Clinical Pharmacology (3 credit hours)

Quantitative methods are an essential part of clinical pharmacology, both in the pharmaceutical industry and academic/government settings. This course is designed to give the student hands-on experience in applying quantitative methods to problems in clinical pharmacology and drug development. The first few weeks will be a refresher in the use of the standard software used in pharmacometrics (NONMEM, R, and Madonna). The students will then be given weekly problems (derived from actual drug development work in the pharmaceutical industry) where quantitative methods must be used to answer specific questions around drug dosing, formulation development, first-time-in man dose finding, study design, and clinical trials simulation. The student will then be asked to present their solutions to the rest of the class.

# PSGP 820 – Translational Nanomedicine (3 credit hours)

Design considerations and applications of novel engineered nanomedicine in drug delivery and imaging will be discussed. The course will cover basic concepts in nanomedicine, physicochemical characterization techniques for engineered nanomaterials, applications of nanomedicine in diagnostics and therapy, translational aspects and safety and regulatory considerations. Students will assigned group activities to review contemporary research articles on nanobiotechnology applications and present their findings to the rest of the class.

# PSGP 602 - Oral Solid Dosage Forms (3 credit hours)

This course will focus on the process, equipment and technology associated with unit operation required for the manufacturing and packaging of tablets and capsules. The course will cover basic concepts of ingredient dispensing/formulation; blending; granulation; drying; compression/encapsulation; coating and packaging. The course will describe the oral solid dosage forms processing methods including direct compression, wet and dry granulation. Process monitoring/validation techniques will be discussed with an emphasis on scale-up and technology transfer.

# CHEM 632 - Advanced Organic Chemistry (3 credit hours)

This course is a continuation of CHEM 211/211H and CHEM 212/212H. This course is built from three learning modules: advanced organic reactions (controlled radical processes, carbon-carbon bond formation, pericyclic reactions); advanced NMR analysis of organic molecules (one and two dimensional NMR methods, DEPT, COSY, HetCorr and others); reaction involving organometallic reagents (organometallic complexes and their structure, 18 electron rule, oxidative addition and reductive elimination, C-H bond activation and others).

# CHEM 670 Advanced Biochemistry I (3 credit hours)

The course covers the classification, chemistry, and metabolism of proteins, amino acids, carbohydrates, and lipids. Prerequisites: One semester of Biochemistry.

# BCHM 671 Protein Chemistry and Enzymatic Catalysis (3 credit hours)

The course involves the study of the structures and functions of proteins. Emphasis will be placed on the application of the structure-function relationships to the development of experimental protocols for studies in biochemical research.

# CHEM 710 Polymer Chemistry: Environmental and Biomedical Aspects (3 credit hours)

Synthetic polymers have become an integral part of our lives and can be found in many everyday and advanced materials: rubber tires, bullet-proof vests, paints, fibers, contact lenses, drug delivery vehicles and many others. This course will cover the basics of polymer synthesis, including traditional polymerization techniques, such as free-radical and anionic chain polymerizations, and step-growth polymerization. Newer methods of polymer synthesis, such as ring-opening metathesis polymerization and living free-radical polymerizations will also be discussed. Fundamentals of structure and physical properties of polymers and methods of characterization will also be covered. For each type of polymers, the influence of toxic additives and impurities on environment will be discussed. In addition, such important topics as ecological aspects of polymer waste management, accidental and controlled polymer burning; fire retardants, replacing toxic plastics by similar nontoxic ones, biodegradable and biocompatible polymers will be discussions. The recommended text book is: Odian, *Principles of Polymerization*, Wiley, 4th ed., 2004. The course is Blackboard supported.

The course is built in such a way that each common theoretical polymer topic is followed by the topic covering the environmental and/or biomedical aspect related to this theoretical topic. You are required to attend all lecture and discussion classes.

# TOXI 601 & 602 Toxicology (3 + 3 credit hours)

A two-semester course covering basic principles of toxicology and mechanisms by which chemicals cause diseases and environmental damage. Topics include target organ toxicity, major classes of toxic agents, and mechanisms of cell injury and cell death. The course is offered in sequence in fall and spring semesters.

# TOXI 688G (3 credit hours)

This course will provide areas of toxicology where significant advances are being made on molecular mechanisms. Emphasis on alterations in function caused by toxic substances, and by genetic and metabolic diseases. The course will focus on new advances in biochemical and molecular biological experimental techniques that would help understand the precise effects of xenobiotics on living organisms at the molecular, cellular, and organismal levels. Emphasis on linking molecular pathways to more general biomedical context.

# TOXI 688D (3 credit hours)

The course provide an understanding of the basic genetic mechanisms that govern gene expression, understanding of the basic genetic mechanisms that govern transmission of genetic information and cell cycle control mechanisms that determine the timing of cell division as well as the analysis of how environmental factors alter normal genetic pathways.

# AGSC 605 Statistics in Agricultural Research (3 credit hours)

Emphasis is placed on techniques and application of statistical and experimental design, data acquisition, analysis, interpretation and presentation as applied to Agricultural Sciences.

# ANPT 622 Analytical Laboratory Methods (2 credit hours)

The application of analytical laboratory techniques used in biomedical research will be explored.

# AGRI 684 Recombinant DNA Technology (3 credit hours)

This is a laboratory course to introduce the basic principles of gene cloning, give essential background on working with E. coli, utilize different cloning systems and employ methods utilized for DNA sequencing.

# **Education Objectives and Student Learning Outcomes**

The goals of the graduate program in pharmaceutical sciences are two-fold.

- The educational objectives are to provide the best training for students interested in pursuing careers in biopharmaceutical drug development; to conduct high-quality research relevant to pharmaceutical and biotechnology industries; to offer innovative educational programs; and to support the biopharmaceutical industry, especially in Maryland.
- 2) The intended student learning outcomes are for students to attain high ability for scholarship, research and leadership skills that contribute to the pharmaceutical sciences; for students to engage in the conduct of original research focusing on the contemporary issues facing the drug industry; to prepare students to be professionals in careers that require training at the highest level in life sciences pertaining to pharmaceutical sciences; and to prepare students for careers in academia and advanced scientific research in the pharmaceutical and biotechnology industries.

# **Evaluation of the Program**

The PSGP will be evaluated every five years. The following factors will be considered:

- Number of applications; success rate in enrolling students
- Overall quality of students enrolled in the program as indicated by undergraduate grade point averages, scores on the Graduate Record Examination, letters of reference, publications, and quality of undergraduate alma mater
- Grades of the students in didactic courses
- Time to degree
- Retention rate in the program
- Number of publications and poster or oral presentations of trainees and their advisors
- Success rate of students in securing predoctoral fellowships
- Breadth of training experienced by students with respect to disciplines

- Success rate of dissertation advisors in securing extramural funding
- Placement of students after obtaining the PhD

Three external reviewers who are experts in the field with an interest in graduate training will be selected by the Dean of the Graduate School and the Dean of SOP at UMES in consultation with experts outside of the leadership of the program. The external reviewers will assess data described above concerning the program and conduct a site visit to the campus to interview students and participating faculty as well as administrators at UMES. The results of the review will be submitted in writing to the Dean of the Graduate School and the Dean of SOP at UMES.

# **Consistency With The State's Minority Student Achievement Goals**

The June 2012 report from NIH on biomedical research workforce working group makes the statement that increasing diversity of trainees and the workforce is critical to the future of biomedical research in the US, particularly as the share of the US population comprised of underrepresented groups increases. (<u>http://acd.od.nih.gov/Biomedical research wgreport.pdf</u>). The proposed graduate program in PS will make available educational opportunities in advanced pharmaceutical sciences that are not available on the Delmarva peninsula. In keeping with its mission as a HBU, UMES is committed to providing access to high quality, values-based, educational experiences, including individuals who are first-generation college students of all races, while emphasizing multicultural diversity and international perspectives. In addition, the University is committed to meeting the economic development needs of the Eastern Shore; workforce development needs of the State; international development priorities of the nation; and commercialization and entrepreneurial ventures of the University through engagement activities and partnerships.

# Critical and compelling regional or Statewide need as identified in the State Plan

The graduate program in PS will prepare students for careers in academia, government and advanced scientific research in the pharmaceutical and biotechnology industries. The proposed program fulfills the USM stated goal of strengthening and expanding the capacity of HBIs to provide high quality and unique educational programs. The proposed program is aligned with the 2013 Maryland State Plan for Postsecondary Education "Maryland Ready" program that include investing in health care programs. According to the bureau of labor statistics, medical scientists have one of the fastest growing job outlooks (2010-2020) at 36% (http://www.bls.gov/ooh/life-physical-and-social-science/medical-scientists.htm). Projected National employment for life scientists is expected to increase by 16.5 % by 2016. Maryland occupational projections (2010-2020) show a total of 5150 openings for life scientists by 2020. (http://www.dllr.state.md.us/lmi/iandoproj/occgroup19.shtml).

A 2012 salary survey from the American Association of Pharmaceutical Scientists reports the mean annual base salary from principal employment earned by those employed full-time in the US as of July 1, 2012, was \$138,400 (US\$) with a standard deviation of \$55,900. This represents a 4.2% increase from 2011 results of \$132,800 (s.d. \$53,300); the CPI inflation rate from July 2011 to July 2012 was 1.4%. Employment in academic positions in colleges of pharmacy typically exceed the availability of adequately and appropriately trained individuals. There is a severe shortage of pharmacy faculty in the U.S. based on the results of a survey by the American Association of Colleges of Pharmacy (AACP).

# **Reasonableness of program duplication**

There is currently one graduate program in pharmaceutical sciences in the State of Maryland, offered by the University of Maryland School of Pharmacy (UMSOP) in Baltimore. The proposed program in

Pharmaceutical Sciences at UMES will be unique as well as complementary to the program currently offered by the UMSOP. The Drug Design and Discovery specialization area is similar to the Chemical Biology track offered by the UMB SOP's program. However the proposed program will be unique regionally being the only graduate Pharmacy program of its kind serving the eastern shore of Maryland and the Delmarva peninsula. The "Drug Delivery and Clinical Pharmacology (DD&CP)" track of the proposed program is also unique as it is not currently offered by UMB School of Pharmacy (although there are some elective courses offered in this area). The DD&CP track will educate and train researchers in critical drug delivery and nanomedicine research areas where advances and improvements are needed, such as animal and computer based predictive models, biomarkers for safety and effectiveness, and new clinical evaluation techniques. This track will also train researchers in the advanced pharmacological targets. The core faculty of the UMES SOP has the expertise in these areas to educate and train students and post-doctoral fellows to pursue careers in industry, academia, regulatory agencies and the emerging trillion dollar nanobiotechnology industry.

#### Relevance to Historically Black Institutions (HBIs)

Implementation of a graduate program in PS will have a favorable impact on UMES's ability as a HBI to strengthen its Doctor of Pharmacy program by enhancing the development and research capabilities of the SOP faculty in the area of PS. This will also lead to greater opportunities for biomedical research experiences for UMES's professional, graduate and undergraduate students.

The proposed program will also serve to support the mission of UMES. As an HBI, UMES is committed to providing access to high quality, values-based, educational experiences to all students, while emphasizing multicultural diversity. There are currently six HBIs in the USA with pharmacy schools, however only three of those include graduate programs. The inclusion of a graduate program in PS at UMES would therefore significantly expand the limited opportunities available to obtain an advanced degree in PS within the unique environment provided by an HBI.

# RESOURCES

# Faculty

The SOP Department of Pharmaceutical Sciences has a core of 11 full-time faculty members as listed below. Experience in teaching at the graduate level and mentoring graduate students already exists in the Department. Currently, Drs. Hsia and Martin each serve as major advisor for a Ph.D. student working in the SOP labs but enrolled through the Ph.D. Toxicology program at UMES. Dr. Hsia is also supporting one postdoctoral student in his lab. Dr. Martin taught graduate level courses and had 3 Ph.D. and 1 M.S students at his lab at the University of Vermont. Dr. Karara taught graduate level courses at the University of Louisiana-Monroe College of Pharmacy where he served a major advisor for 3 Ph.D. and 2 M.S. students. Dr. Nan has supervised 1 Ph.D. student and currently has one Ph. D student at another institution and served on the graduate committee of several graduate students. Dr. Simmons had full graduate faculty status at Biomedical Science graduate programs at other institutions since 1987. He taught numerous graduate courses, supervised 2 Ph.D. and served on 10 other graduate committees. Many faculty provide opportunities for research to Pharm D students enrolled in research elective modules. The faculty has a strong potential for generating extramural funding as evidenced by Dr. Hsia who has secured in 2012 an NIH R01 grant (\$750,000) to investigate the cellular and molecular mechanisms of herpes simplex virus (HSV) during lytic and latent infections. Recently, Dr. Jackson-Ayotunde secured a \$10,000 new investigator grant from the American Association of Colleges of Pharmacy to support her research in the area of anti-epileptic agents.

Name	Academic Rank	FTE	Field	Course
Victor Hsia, Ph.D.	Interim-Chair	1.0	Drug Design and Discovery-	PSGP 817
	Associate Professor		Cell biology, Immunology	PSPG 816
Patrice Jackson-	Assistant Professor	1.0	Drug Design and Discovery-	PSGP 801
Ayutounde, Ph.D.			Design and synthesis of therapy-	PSGP 802
			resistant partial antiseizure agents.	PSGP 803
				PSGP 804
James Junker, Ph.D.	Associate Dean ,	1.0	Drug Design and Discovery-	PSPG 811
	Professor		Pathophysiology and cell biology	PSPG 816
Adel H. Karara,	Associate Professor	1.0	Drug Delivery-Clinical	PSGP 602
Ph.D., FCP			Pharmacology	PSGP 818
			Pharmacokinetics	PSGP 821
Madan Kharel,	Assistant Professor	1.0	Drug Design and Discovery-	PSGP 801
Ph.D.			Discovery of microbial natural	PSCP802
			products as anticancer and anti-	PSGP 812
			infective agents	PSGP 813
Dennis Killian,	Interim Dean	1.0	Drug Delivery-Clinical	PSGP 818
Pharm D, Ph.D.			Pharmacology	
			Pharmaceutics	
Miguel Martin-	Associate Professor	1.0	Drug Design and Discovery-	PSGP 814
Caraballo, Ph. D.			Neurobiology/Cell biology	
Anjan Nan, Ph. D.	Assistant Professor	1.0	Drug Delivery-Clinical	PSGP 820
			Pharmacology	PSGP 805
			Nano-medicine	5

Mark A. Simmons,	Professor	1.0	Drug Design and Discovery-	PSGP 811
Ph. D.			Behavioral, cellular and molecular	PSGP 814
			neuropharmacology	PSGP 816
Fred Tejada, Ph.D.	Assistant Professor	1.0	Drug Design and Discovery-	PSGP 801
			Medicinal Chemistry	PSGP 802
				PSGP 803
				PSGP 804
				PSGP 815
Sean Vasaitis, Ph.D.	Assistant Professor	1.0	Drug Design and Discovery-	PSPG 811
			Pharmacology	PSPG 816

#### Adequacy of library resources

The Frederick Douglas Library (FDL) presently houses over 283,128 volumes of books, 37,265 bound journal volumes and 11,193 unbound journal issues. There is also a new Sage e-journal package of 646 titles, in which Pharmacy, Health Sciences and Medicine are featured. The UMES School of Pharmacy currently has access through FDL to many print and electronic journals recommended in the American Association of Colleges of Pharmacy Core List of Journals for Libraries that serve Schools and Colleges of Pharmacy. Full text access is available for the majority of journals. Students and faculty may also take advantage of the library holdings housed at the twelve other universities of the University System of Maryland (USM), through inter-library loans in addition to access to electronic medical data bases. Students at the SOP have subscriptions to Access Pharmacy and American Pharmacists Association's Pharmacy Library electronic book collections. Recently, the FDL launched the EBSCO Discovery Service that allows researchers to simultaneously search a number of databases to find scholarly articles, books and other research resources via a single search engine. Educational programs have been presented and are made available of such new and current features for the students and faculty of the SOP. There is a dedicated library liaison to the SOP who meets bimonthly with Pharmacy faculty for a Library and Learning Resources Committee to discuss any needs or concerns. The current UMES/SOP library resources are adequate to support the implementation of the graduate program in PS.

# Adequacy of physical facilities, infrastructure and instructional

For graduate instruction, four conference rooms each approximately 400 sq. ft. are available. Each room holds up to 16 students. The rooms are provided with large flat screen monitors for projection and audio. Currently, the PS faculty conducts research in a 881 sq. ft. laboratory located on the second floor of Somerset Hall. In addition, an 1147 sq. ft. teaching lab that is not in continuous can be used to provide additional research space. Administration is working to locate additional space for the growing current needs and that space would be available for use by the PS graduate program. Additionally, the School of Pharmacy is vigorously working with university administrators to determine the plan of construction of a new Pharmacy building. The building is included in the University's Capital Improvement Plan.

No capital investment for new equipment is needed for the initial launch of the graduate program. Major equipment located in Somerset Hall includes: Waters Breeze 2 HPLC with UV detection and autosampler, Bio-Rad My iQ real-time PCR cycler, programmable thermal PCR cycler, Promega 20/20 luminometer, Bio-Rad Chemi-docl XRS imaging system and Nikon Eclipse Ti-E inverted fluorescence light microscope with quantitative analysis software.

# Adequacy of financial resources

The proposed program will be part of the School of Pharmacy and will utilize the existing resources of the School. UMES administration has allocated \$ 350,000 for expenditure on renovation of lab space during first two years of the program. It is expected that students would be taking didactic course work during the first two years of the program. New graduate level courses will be taught by existing department faculty. The revenue for financing the program is based on an estimate of tuition revenue, funds allocated to UMES, and the U.S. Department of Education Strengthening Developing institutions (Title III) funds. Starting the PS graduate program in is not contingent on receiving Title III funds. The UMES SOP faculty is actively seeking extramural training and research funding support from NIH such as T32 and/or R25. UMES is, therefore, not requesting additional state resources; consequently, grants, gifts, or contract funds would be used to fund the program.

TABLE 1: RESOURCES							
Resources Categories	(Year 1)	(Year 2)	(Year 3)	(Year 4)	(Year 5)		
1.Reallocated Funds <sup>1</sup>							
2. Tuition/Fee Revenue <sup>2</sup> (c+g below)	25700	26471	27265	56167	57851		
a. #F.T Students	5 <sup>(a)</sup>	5	5	10	10		
b. Annual Tuition/Fee Rate	5140 <sup>(b)</sup>	5294.2 <sup>(c)</sup>	5453	5616.7	5785.1		
c. Annual Full Time Revenue (a x b)	25700	26471	27265	56167	57851		
d. # Part Time Students							
e. Credit Hour Rate							
f. Annual Credit Hours							
g. Total Part Time Revenue (d x e x f)							
3. Grants, Contracts, & Other External Sources <sup>3</sup>							
4. Other Sources					E		
TOTAL (Add 1 - 4)	25700	26471	27265	56167	57851		

<sup>(</sup>a) This number represents the total number of students that will be enrolled every year. If there is some student attrition during years 1 and 2 we plan to achieve our goal of 5 students in year 3 by further recruitment. A new cohort of 5 new students can be enrolled starting on Year 4 for a total of 10 students for Years 4 and 5.

<sup>(</sup>b) Based on the Graduate School list of costs for 2012-2013. The numbers are based on tuition +mandatory fees for an in-state student.

<sup>(</sup>c) Based on a 3% annual increase in tuition rate.

TABLE 2: EXPENDITURES								
Expenditure Categories	(Year 1)	(Year 2)	(Year 3)	(Year 4)	(Year 5)			
1. Total Faculty Expenses								
(b + c below)								
a. # FTE								
b. Total Salary								
c. Total Benefits								
2. Total Administrative								
Staff Expenses (b + c below)				- - -				
a. # FTE								
b. Total Salary								
c. Total Benefits								
3. Total Support Staff								
Expenses (b + c below)	*							
a. # FTE								
b. Total Salary								
c. Total Benefits								
4. Equipment	:							
5. Library								
6. New or Renovated Space	175,000	175,000						
7. Other Expenses	4000 <sup>(a)</sup>	4120	4244	4371	4502			
TOTAL (Add 1 - 7)	179,000	179,120	4244	4371	4502			

(a) Other expenses include advertisement, recruitment and interviewing. The cost of those is expected to rise at an annual rate of 3%.