TOPIC: University of Maryland, Baltimore: Master of Science in Regulatory Science

COMMITTEE: Education Policy and Student Life

DATE OF COMMITTEE MEETING: January 16, 2013

SUMMARY: The proposed program prepares health care professionals and biomedical scientists for expanded career opportunities in regulatory science, including positions in industry, e.g. pharmaceutical and biotechnology companies, and government agencies such as the FDA and NIH. The program will feature areas such as chemistry manufacturing controls (CMC), clinical research, pharmacovigilance, and Phase IV research, e.g., pharmacoepidemiology.

Program graduates will possess knowledge and skills to contribute to drug regulation and pharmaceutical product lifecycles. The target student audience is working professionals who hold a BA or BS degree and who now work in – or seek to work in – regulatory science in industry or government. In most instances, candidates for admission who have a BA or BS degree in an area of science, health or policy, engineering, or business. To be conducted exclusively online, the program will utilize asynchronous lectures, web conferencing, and online active-learning instruction.

The program is proposed, in part, to address a specific and long-standing need that has been identified by stakeholders. Two stakeholders with interests in regulatory science are pharmaceutical companies and the Food and Drug Administration. Informally, over many years, individuals and alumni who work with these organizations have articulated the specific need for scientists with a background in regulatory science. Further evidence of the training needs is the recent establishment of the University of Maryland Center of Excellence in Regulatory Science and Innovation, an FDA-sponsored center to promote education and exchange between the University and the FDA. Other government agencies are also engaged in translational biomedical research and hence have regulatory science needs..

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.

CHANCELLOR'S RECOMMENDATION: That the Committee on Education Policy recommend that the Board of Regents approve the proposal from the University of Maryland, Baltimore to offer the Master of Science in Regulatory Science.

COMMITTEE RECOMMENDATION: DATE:

BOARD ACTION: DATE:

SUBMITTED BY: Joann A. Boughman   301-445-1992   jboughman@usmd.edu

UNIVERSITY SYSTEM OF MARYLAND INSTITUTION PROPOSAL FOR

_x_	New Instructional Program
_____	Substantial Expansion/Major Modification
_____	Cooperative Degree Program

University of Maryland Baltimore
_____
Institution Submitting Proposal

Regulatory Science
_____
Title of Proposed Program

Master of Science	Fall 2013
Degree to be Awarded	Projected Implementation Date
129958	**512002**
Proposed HEGIS Code	Proposed CIP Code
Pharmaceutical Sciences	James Polli
Department in which program will be located	Department Contact
410-706-8292	jpolli@rx.umaryland.edu
Contact Phone Number	Contact E-Mail Address
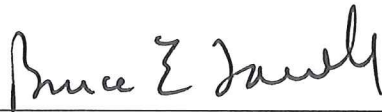
Bruce E. Jarrell
_____
Signature of President or Designee

12|21|12
_____
Date

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November 28, 2012

William E. Kirwan, Ph.D.
Chancellor & Chief Executive Officer
University System of Maryland
3300 Metzerott Road
Adelphi, MD 20783

Dear Chancellor Kirwan:
Enclosed please find a proposal that the University of Maryland Baltimore (UMB) will be sending to the Maryland Higher Education Commission (MHEC). This proposal requests authorization to create an MS in Regulatory Science. The proposed MS in Regulatory Science will prepare health care professionals and biomedical scientists for expanded career opportunities in regulatory science, including positions in industry (e.g., pharmaceutical companies, as well as device and biotechnology companies) and government (e.g., FDA, NIH). The program will feature areas such as chemistry/manufacturing/controls (CMC), clinical research, pharmacovigilance, and Phase IV research (e.g., pharmacoepidemiology). Conducted exclusively online, the program utilizes asynchronous (i.e., pre-recorded) lectures, web conferencing, and online active-learning instruction.

We are requesting your administrative review prior to our submission to MHEC.

In each course, students will be assessed via projects, online presentations, and mini-reviews. The library offers electronic access that will allow for student completion of these requirements (see http://guides.hshsl.umaryland.edu/distancestudents). The program is to be implemented within existing institutional resources. Regarding Section I of the proposal, the Health Sciences and Human Services Library is an excellent resource for students in the regulatory science program.

Regarding application item J, the physical facilities, infrastructure and instruction equipment are adequate to initiate the program. The program leverage existing at-a-distance instructional technologies. The program is to be implemented within existing institutional resources. Briefly, the School of Pharmacy's Audio Visual Services Department, in conjunction with the Office of Instructional Technology, offers excellent support for the Master's Program. The existing recording studio is highly functional and the School has developed capabilities to enable faculty to also record at their desk top computers.

There are three AV technicians who provide various support services including support of recording in the studio, minor editing and uploading of content.

If you need further information or wish to discuss, do not hesitate to contact me.

Sincerely,

Bruce E. Jarrell, MD, FACS
Senior Vice President
Chief Academic and Research Officer

November 28, 2012

The Honorable Danette Gerald Howard
Secretary, Maryland Higher Education Commission
6 N. Liberty Street
Baltimore, MD 21201

Dear Secretary Howard:

The University of Maryland School of Pharmacy, a national leader in regulatory science research, recently entered into a cooperative agreement with the Food and Drug Administration (FDA) yielding the UM Center of Excellence in Regulatory Science and Innovation. Regulatory Science as defined by the FDA, is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products [reference: Advancing Regulatory Science at FDA. Food and Drug Administration. August, 2011].

Collectively, the FDA, industry, and academic scientists all recognize the need for new tools in order to ensure safety and development efficiency in the evaluation of new drugs and medical devices. Regulatory scientists play critical roles at pharmaceutical companies (e.g., regulatory affairs departments) and within the FDA, NIH and DOD, however they are typically trained in broader biomedical and professional programs that do not feature regulatory science education.

The University of Maryland School of Pharmacy is requesting authorization to create an MS in Regulatory Science. The proposed program will prepare health care professionals and biomedical scientists for expanded career opportunities in regulatory science, including positions in industry and the federal government. The program will feature areas such as clinical research, chemistry/manufacturing/controls (CMC), pharmacovigilance, and Phase IV research (e.g., pharmacoepidemiology). This non-thesis, part-time program will be taught exclusively online. The program will consist of five courses that are each six credits, for a total of 30 credits. Ideally, we would like to launch this program in Fall 2013.

In each course, students will be assessed via projects, online presentations, and mini-reviews. The library offers electronic access that will allow for student completion of these requirements (see http://guides.hshsl.umaryland.edu/distancestudents). The program is to be implemented within existing institutional resources. Regarding Section I of the proposal, the Health Sciences and Human Services Library is an excellent resource for students in regulatory science.

Regarding application item J, the physical facilities, infrastructure and instruction equipment are adequate to initiate the program. The program leverage existing at-a-distance instructional technologies. The program is to be implemented within existing institutional resources. Briefly, the

School of Pharmacy's Audio Visual Services Department, in conjunction with the Office of Instructional Technology, offers excellent support for the Master's Program. The existing recording studio is highly functional and the School has developed capabilities to enable faculty to also record at their desk top computers. There are three AV technicians who provide various support services including support of recording in the studio, minor editing and uploading of content.

Enclosed please find our formal program proposal.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Bruce E. Jarrell, MD, FACS
Senior Vice President
Chief Academic and Research Officer

A.   Centrality to institutional mission statement and planning priorities:
Provide a description of the program, including each area of concentration (if applicable),
and how it relates to the institution's approved mission. Explain how the proposed
program supports the institution's strategic goals and provide evidence that affirms it is an
institutional priority.

Mission of University of Maryland Baltimore: The University of Maryland Baltimore is the
state's public academic health and law university devoted to excellence in professional and
graduate education, research, public service and patient care. We educate leaders in health care
delivery, biomedical science, social services and the law. We carry out internationally
recognized research to cure disease and to improve the health, social functioning and treatment
of the people we serve. We are committed to ensuring that the knowledge we generate provides
maximum benefit to society.

The Food and Drug Administration (FDA) indicates that regulatory science is the science of
developing new tools, standards, and approaches to assess the safety, efficacy, quality, and
performance of FDA-regulated products [reference: Advancing Regulatory Science at FDA.
Food and Drug Administration. August, 2011.
http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm]. The
proposed MS in Regulatory Science prepares health care professionals and biomedical scientists
for expanded career opportunities in regulatory science, including position in industry (e.g.
pharmaceutical companies, as well as device and biotechnology companies) and government
(e.g. FDA, NIH). The program will feature areas such as chemistry/manufacturing/controls
(CMC), clinical research, pharmacovigilance, and Phase IV research (e.g.
pharmacoepidemiology). The proposed program is consistent with the campus mission of
graduate education in health care and biomedical sciences.

Program graduates will possess knowledge and skills to contribute to drug regulation and
pharmaceutical product lifecycles. A non-thesis, part-time program, the program requires 30
credits of coursework and is exclusively taught online. The target student audience is working
professionals who are BS graduates and who now work in (or seek to work in) regulatory science
in industry or government. In most instances, candidates for admission who have earned a BA or
BS degree in an area of science, health or policy, engineering, or business from an accredited
U.S. or international institution possess adequate preparation for the graduate program, provided
they satisfy other admission requirements. Conducted exclusively online (i.e. students need not
attend in person in Baltimore), the program utilizes asynchronous (i.e. pre-recorded) lectures,
web conferencing, and online active-learning instruction.

This proposal for a new program to enroll students in fall 2013 is endorsed by Dean Eddington,
the department of pharmaceutical sciences, the department of pharmaceutical health services
research, and the department of pharmacy practice and science.

Graduates will possess knowledge and skills to contribute to drug regulation and pharmaceutical product lifecycles, with an emphasis in drug discovery, drug development, clinical research, and post-approval drug regulation. The University of Maryland MS program in Regulatory Science mainly focuses on drugs, rather than devices or biologics, although some aspects of devices and biologics will be addressed. The program covers all major areas of drug product regulatory science, including chemistry, manufacturing, & controls (CMC), clinical research, and post-approval surveillance, as well as drug discovery. The target student audience is working professionals who are BS graduates and who now work in (or seek to work in) regulatory science in industry or government. Students need not attend in person in Baltimore. The program utilizes asynchronous (i.e. pre-recorded) lectures, synchronous lectures and review sessions, and online active-learning instruction. The MS in Regulatory Sciences is a non-thesis, part-time program that is taught exclusively online. The program is composed of five courses that are each six credits, for a total of 30 credits.

B.   Adequacy of curriculum design and delivery to related learning outcomes:
1.   Provide a list of courses with title, semester credit hours and course descriptions, along with a description of program requirements.

The proposed MS in Regulatory Science will be a non-thesis, part-time program, requiring 30 credits of coursework, and taught exclusively online. The program will mainly focus on drugs, rather than devices or biologics, although some aspects of devices and biologics will be addressed. Proposed program courses (five courses that are each six credits) are:
PHAR 603 Drug, Biologic, and Device Regulation (6 credits)
PHAR 614 Drug Discovery (6 credits)
PHAR 621 Clinical Research (6 credits)
PHAR 631 Drug Development (6 credits)
PHSR 641 Regulated Products in the Marketplace (6 credits)
The program utilizes asynchronous (i.e. pre-recorded) lectures, web conferencing, and online active-learning instruction. A student will be able to complete the program in two years (e.g. proposed first graduation in spring 2015, and admission for fall 2013). A tabulated course sequence is below. In each course, students will be assessed via projects, online presentations, and mini-reviews.

Table: Course sequence.

Fall year 1 (i.e. fall 2013) Drug, Biologic, and Device Regulation	Spring year 1 Drug Discovery	Summer year 1 Clinical Research
Fall year 2 Drug Development	Spring year 2 Regulated Products in the Marketplace	-

Drug, Biologic, and Device Regulation (6 credits)
This online course is designed to orient students of diverse professional backgrounds to several practical elements that underpin drug, biologic, and device regulation in the USA and around the world. It provides the core for the curriculum and is a pre-requisite for all other courses. Elements that are explored are the legal framework for drug regulation, including events that

have shaped today's framework; ethical issues in drug/biologic/device development and drug/biologic/device use; global regulatory guidance approaches; types of communications with Food and Drug Administration (FDA), including Investigational New Drug (IND) application, New Drug Application (NDA), and Abbreviated New Drug Application (ANDA) requirements, and 510(k) clearance and Premarket Approvals / Biologics Licensing Applications (PMA/BLA) approval requirements; chemistry, manufacturing, and control (CMC) issues; and post-marketing topics. This course is part of the proposed MS in Regulatory Science online program.

Drug Discovery (6 credits)
Pharmaceutical sciences are fundamental to the discovery of new medicines and impact clinical success. This online course is designed to orient students to the basic concepts in drug chemistry and functional groups, medicinal chemistry approaches to optimizing drug action, principles of pharmacology, biological and target considerations in drug design, and how drugs are metabolized and eliminated from the body. This course is part of the proposed MS in Regulatory Science online program.

Clinical Research (6 credits)
Well-designed clinical studies are essential in the development process of a medication or device and in generation of the knowledge base for evidence-based medicine and health policy. This online course is designed to uncover the ingredients of clinical research and to orient students to several important issues with current clinical research. Students will learn how to design and implement different clinical studies. The role of each clinical phase in drug/device development and their various study designs and regulatory issues will be explored. The course will also discuss the Principles of International Conference on Harmonization (ICH) GCP Guidelines and how to successfully manage clinical trials. Additionally, knowledge of personalized medicine and behavioral/social issues in drug use will be taught. This course is part of the proposed MS in Regulatory Science online program.

Drug Development (6 credits)
Drug candidates and active pharmaceutical ingredients (API) need to be successfully delivered and must exhibit acceptable toxicology. This course follows drug discovery and examines key aspects of drug development, including drug formulation and quality, stability testing, pharmacokinetic characterization, bioequivalence, preclinical toxicology, methods of bioanalysis, and non-clinical and clinical Good Laboratory Practices (GLPs). Aspects of biologics will also be discussed. This course is part of the proposed MS in Regulatory Science online program.

Regulated Products in the Marketplace (6 credits)
FDA approval for the marketing of the drug or other regulated product (e.g. biologics, vaccines, medical devices, laboratory tests) is a major milestone in a product's lifecycle. But it doesn't stop there. Once on the market, how a drug is used and by whom, entry of competing products into the marketplace, and changes in medical care can change the benefit:risk balance. This course covers the breadth of clinical research and surveillance activities which take place in the post-approval phase of a regulated medical product's lifecycle. This includes pharmacovigilance and risk management activities, pharmacoepidemiology, pharmacoeconomics, comparative effectiveness, and drug utilization research. The course is designed to prepare students to communicate across the pre-/post marketing divide, evaluate the need for postmarketing studies

and to be able to critically interpret and apply the results of such studies. This course is part of the proposed MS in Regulatory Science online program.

Admission to the MS program is contingent upon satisfying admission requirements of the Graduate School. In most instances, candidates for admission who have earned a BA or BS degree in an area of science, health or policy, engineering, or business from an accredited U.S. or international institution possess adequate preparation for the graduate program, provided they satisfy other admission requirements. International students and applicants whose language of the home is other than English must provide current, official test score results from the Test of English as a Foreign Language (TOEFL) or the International English Language Testing System (IELTS).

Applications for admission are evaluated on the basis of the following:
a. Minimum 3.00 GPA and overall quality of academic transcripts if the applicant possesses less than two years of post-BA/BS experience
b. TOEFL scores for international applicants: minimum 600 for the paper-based test and 100 for the internet-based test; or, minimum score of 8 on the IELTS
c. Three letters of recommendation using the Graduate School form
d. A "Statement of Goals in Regulatory Science" that discusses career objectives pertaining to regulatory science, including relevant work experience.
e. Once admitted, students must comply with Graduate School Standards, policies and degree requirement including maintain a minimum of GPA of 3.0 at all times.

2. Describe the educational objectives and intended student learning outcomes.

Educational objectives of the program
Graduates of this program will become fluent in the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products. An emphasis is drug products, rather than devices or biologics. This fluency will provide graduates with a number of opportunities in drug research and development, including but not limited to:
• Regulatory science/affairs positions in pharmaceutical companies, as well as device and biotechnology companies;
• Regulatory science/affairs positions in government agencies such as the Food and Drug Administration, National Institutes of Health, Department of Defense, Biomedical Advanced Research and Development Authority, and the Centers for Disease Control;
• Admission into the PhD programs at UMB or comparable programs elsewhere;
• Admission to professional programs, such as pharmacy, medicine, and dentistry.

Individuals obtaining this degree may also use it to complement and enhance an already obtained advanced degree such as pharmacy, medicine, dentistry, nursing, or law. Graduates will be prepared to fill the increasing demand for skilled regulatory scientists at cutting-edge research facilities in academia, government, and industry. Graduates will be excellently trained for positions in chemist/manufacturing/controls, clinical research, pharmacovigilance, and Phase IV research.

Student learning outcomes (i.e. core competencies)

A graduate of the MS in regulatory science program will:

1. Understand global strategies for drug, biologic, and device development and evaluation [Drug, Biologic, and Device Regulation]

2. Know FDA and other region requirements for drug product development and registration [Drug, Biologic, and Device Regulation]

3. Understand principles of basic and applied pharmaceutical sciences in drug discovery and development [Drug Discovery and Drug Development]

4. Apply critical elements of chemisty, manufacturing, & controls (CMC) to drug development [Drug Development]

5. Understand principles of clinical research design and practices in clinical trial management [Clinical Research]

6. Apply critical elements of risk and utilization to post-marketing surveillance and pharmacoepidemiology, and understand economic factors that impact drug use [Regulated Products in the Marketplace]

3.   Discuss how general education requirements will be met, if applicable.
N/A

4.   Identify any specialized accreditation or graduate certification requirements for this program and its students.
None

5.   If contracting with another institution or non-collegiate organization, provide a copy of the written contract.
N/A

C.   Critical and compelling regional or Statewide need as identified in the State Plan:
1.   Demonstrate demand and need for the program in terms of meeting present and future needs of the region and the State in general based on one or more of the following:
o   The need for the advancement and evolution of knowledge;
o   Societal needs, including expanding educational opportunities and choices for minority and educationally disadvantaged students at institutions of higher education;
o   The need to strengthen and expand the capacity of historically black institutions to provide high quality and unique educational programs.
2.   Provide evidence that the perceived need is consistent with the Maryland State Plan for Postsecondary Education and the USM Strategic Plan.

Elements of the USM Strategic Plan 2010-2020 are a stronger innovation economy and a higher quality of life. Graduates of this program will become fluent in the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products, with an emphasis on drugs. Headquartered in Maryland, the FDA is responsible for advancing the public health by helping to speed innovations that make medicines safer and more effective. Pharmaceutical companies and patients benefit from advances in regulatory science by making better medications available. The program will contribute to such organizations and societal outcomes.

D.   Quantifiable & reliable evidence and documentation of market supply & demand in the region and State:
1.   Present data and analysis projecting market demand and the availability of openings in a job market to be served by the new program.
2.   Discuss and provide evidence of market surveys that clearly provide quantifiable and reliable data on the educational and training needs and the anticipated number of vacancies expected over the next 5 years.
3.   Data showing the current and projected supply of prospective graduates.

Motivation for this program is, in part, to address a specific and long-standing need that has been identified by stakeholders. Two stakeholders with interests in regulatory science are pharmaceutical companies and the Food and Drug Administration. Informally, over many years, individuals and alumni who work within these stakeholder institutions have articulated the specific need for scientists with a background in regulatory science. Regulatory scientists play critical roles at pharmaceutical companies (e.g. regulatory affairs departments) and the Food and Drug Administration, although are typically trained in broader biomedical and professional programs that do not feature regulatory science education. Further evidence of the training needs in regulatory science is the recent establishment of the University of Maryland Center of Excellent in Regulatory Science and Innovation (www.cersi.umd.edu), an FDA-sponsored center to promote education and exchange between the University of Maryland and the FDA. Other government agencies are also engaged in translational biomedical research and hence have regulatory science needs (e.g. NIH, DoD). We anticipate the 25 program graduates each year from this exclusively online program, with a target of 15 Maryland residents, will benefit from specific education in drug development and regulation, largely through greater opportunities with their current employers. The program is targeted to be a two year program, such that we will target 50 enrolled students at any one time.

E.   Reasonableness of program duplication:
1.   Identify similar programs in the State and/or same geographical area. Discuss similarities and differences between the proposed program and others in the same degree to be awarded.
2.   Provide justification for the proposed program.

The University of Maryland is a national leader in regulatory science research and has recently entered into a cooperative agreement with FDA, yielding the University of Maryland Center of Excellent in Regulatory Science and Innovation. An academic program in regulatory science will synergistically benefit from, as well as enhance, on-going regulatory science at University of Maryland.

A few out-of-state universities have recently established masters or certificate programs in regulatory science (e.g. Northwestern U, USC), which also favor related areas (e.g. drugs, devices).   There are no similar degree programs in the region. Hood College has a certificate program in Regulatory Compliance. JHU has a Master of Science in Bioscience Regulatory Affairs which emphasizes biotechnology products, which is not an area of proposed emphasis. The proposed program will be exclusively online.

F.   Relevance to Historically Black Institutions (HBIs)
1.   Discuss the program's potential impact on the implementation or maintenance of high-demand programs at HBI's.
2.   Discuss the program's potential impact on the uniqueness and institutional identities and missions of HBIs.
There is no duplication of a similar program at any HBI.

G.   If proposing a distance education program, please provide evidence of the Principles of Good Practice (as outlined in COMAR 13B.02.03.22C).

The proposed program's faculty has extensive teaching experience in teaching across two campuses (i.e. PharmD program in Baltimore and Shady Grove). Below is a description of elements of planned good practices in distance education.

Curriculum and Instruction. The program will be established and overseen by faculty with expertise in regulatory science, with an emphasis on drugs. Faculty has expertise in chemistry/manufacturing/controls (CMC), clinical research, pharmacovigilance, and Phase IV research (e.g. pharmacoepidemiology). The curriculum and course sequence are coherent and cohesive, and would not differ if the offered in a traditional instructional format. The above learning outcomes are appropriate for the rigor and breadth of a proposed MS program, which we believe will be more science-oriented compared to other programs.

The program will employ both real-time and delayed interaction between faculty and students. A majority of instruction will be presented through asynchronous lectures (i.e. pre-recorded lectures). About every other week, at the end of each course unit, each course will hold a web conference (i.e. real-time interaction). Proposed course faculty spans several departments and are working with distance education specialists in the Dean's Office, as well as Computer and Network Services in course design, along with the Health Sciences and Human Services Library. Two distance education rubrics that we are employing in course design are the Quality Matters standards for 2011-13 (http://www.qmprogram.org/files/QM_Standards_2011-2013.pdf) and the Blackboard Exemplary Course Program Rubric. Dr. Polli would also like to thank Dr. Theo Stone (UMUC) for guidance.

In addition to asynchronous lectures and web conferences, each program course will include active-learning instruction sessions (e.g. include a combination of online videos, online reading references, and online discussions, two projects, six presentation assignments, and three written minireviews. Assignments are due almost weekly in each course.

Role and Mission. As described above, the distance education program is consistent with the institution's mission. Proposed program faculty has extensive teaching experience in distance education. The program will employ existing exceptional technology to produce and deliver pre-recorded lectures (e.g. recording studio), to conduct web conferences (e.g. BlackBoard Collaborate), and to design and deliver active-learning instructional sessions.

Faculty Support and Learning Resources. Faculty is routinely trained in distance instructional technology. This training is conducted through both the Dean's Office and departments. The Dean's office includes both Academic Affairs (e.g. including an Assistant Dean for Instructional

Technology) and Computer and Network Services. Resources are available to faculty in the design and implementation of distance education lectures, active-learning sessions, and courses. As discussed above, library resources for distance education students are excellent.

Students and Student Services. The program will make use of established mechanisms in the Graduate School and School of Pharmacy to provide students with clear, complete, and timely information on the curriculum, course and degree requirements, nature of faculty/student interaction, assumptions about technology competence and skills, technical equipment requirements, learning management system, availability of academic support services and financial aid resources, and costs and payment policies. For example, course materials will be available through BlackBoard, a web-interface with which faculty have many years of experience, including with current programs.

Accepted students will have the background, knowledge, and technical skills needed to undertake a distance education program. In most instances, candidates for admission who have earned a BA or BS degree in an area of science, health or policy, engineering, or business from a U.S. or international institution possess adequate preparation for the graduate program, provided they satisfy other admission requirements. The target student audience is working professionals who are BS graduates and who now work in (or seek to work in) regulatory science in industry or government. Recruitment and admissions materials about the program will represent the program and the services available (e.g. need for students to have access to computer that meets the minimum system requirements, broadband internet access, and a headset microphone for participation in web conferences).

Commitment to Support. Policies for faculty evaluation already include consideration of teaching and scholarly activities related to ongoing distance education programs. We are committed to continuation of the program for a period sufficient to enable students to complete the MS degree.

Evaluation and Assessment. The School of Pharmacy has a culture and support structure to assess program educational effectiveness. For example, the Dean's Office includes an Assistant Dean for Assessment. Ongoing assessments will be applied to the proposed program. At course completion, courses and individual faculty will be evaluated by student using an anonymous web-based survey. Collected by the Dean's Office, such evaluations are reviewed immediately by the course manager and graduate program director, and annually by the department chair and vice-chair.

A steering committee will be appointed by the department chair and will function to serve as an admission committee and a curriculum committee, which will review each course and the program annually. Students will have a faculty advisor. The graduate program director and advisors will track individual student progress each semester. The program director will work with the Graduate School in enforcing Graduate School policies for academic standing.

H.   Adequacy of faculty resources (as outlined in COMAR 13B.02.03.11).
Provide a brief narrative demonstrating the quality of program faculty. Include a summary list of faculty with appointment type, terminal degree title and field, academic title/rank, status (full-time, part-time, adjunct) and the course(s) each faulty member will teach.

Faculty from the School of Pharmacy is excellent. Faculty contribute to teaching (e.g. PharmD program, graduate program in pharmaceutical sciences, graduate program in pharmaceutical health services research), research, and service. The faculty has significant experience in employing at-a-distance instructional technologies, such as through the PharmD program, which operates at both Baltimore and Shady Grove. Faculty members below have full-time (FT), regular appointments and hold the PhD degree. We anticipate adding adjunct faculty with expertise in regulatory science (e.g. FDA scientists) if topics in areas that evolve.

Drug, Biologic, and Device Regulation

James Polli, PhD, Professor	pharmaceutical science	FT
Susan DosReis, PhD, Associate Professor	pharmaceutical health services research	FT
Joga Gobburu, PhD, Professor	pharm. science; pharm. practice and science	FT
Stephen Hoag, PhD, Professor	pharmaceutical science	FT
C. Daniel Mullins, PhD, Professor	pharmaceutical health services research	FT
Frank Palumbo, PhD JD, Professor	pharmaceutical health services research	FT
Fadia Shaya, PhD, Professor	pharmaceutical health services research	FT
Peter Swaan, PhD, Professor	pharmaceutical science	FT
Jia Bei Wang, PhD, Professor	pharmaceutical science	FT
Sheila Weiss, PhD, Professor	pharmaceutical health services research	FT
Ilene Zuckerman, PhD PharmD, Professor	pharmaceutical health services research	FT

Drug Discovery

Paul Shapiro, PhD, Associate Professor	pharmaceutical science	FT
Andy Coop, PhD, Professor	pharmaceutical science	FT
Alex MacKerell, PhD, Professor	pharmaceutical science	FT
Hongbing Wang, PhD, Associate Professor	pharmaceutical science	FT
Peter Swaan, PhD, Professor	pharmaceutical science	FT
Ed Moreton, PhD, Professor	pharmaceutical science	FT
Patrick Wintrode, PhD, Associate Professor	pharmaceutical science	FT
Steve Fletcher, PhD, Assistant Professor	pharmaceutical science	FT
Sudha Veeraraghavan, PhD, Associate Professor	pharm. science	FT
Sarah Michel, PhD, Associate Professor	pharmaceutical science	FT
Angela Wilks, PhD, Professor	pharmaceutical science	FT
Maureen Kane, PhD, Assistant Professor	pharmaceutical science	FT
Fengtian Xue, PhD, Assistant Professor	pharmaceutical science	FT
Yan Shu, PhD, Assistant Professor	pharmaceutical science	FT
C.S. Raman, PhD, Associate Professor	pharmaceutical science	FT

Clinical Research

Yan Shu, MD, PhD, Assistant Professor	pharmaceutical science	FT
Joga Gobburu, PhD, Professor	pharm. science; pharm. practice and science	FT
Jia Bei Wang, MD, PhD, Professor	pharmaceutical science	FT
Hongbing Wang, PhD, Associate Professor	pharmaceutical science	FT
Francoise Pradel, PhD, Associate Professor	pharmaceutical health services research	FT

Drug Development

James Polli, PhD, Professor	pharmaceutical science	FT

Richard Dalby, PhD, Professor	pharmaceutical science	FT
Stephen Hoag, PhD, Professor	pharmaceutical science	FT
Maureen Kane, PhD, Assistant Professor	pharmaceutical science	FT
Anjan Nan PhD, Assistant Professor	pharmaceutical science	FT
Gerald Rosen, PhD, Professor	pharmaceutical science	FT
Audra Stinchcomb, PhD, Professor	pharmaceutical science	FT
Hongbing Wang, PhD, Associate Professor	pharmaceutical science	FT
Patrick Wintrode, PhD, Associate Professor	pharmaceutical science	FT

Regulated Products in the Marketplace

Susan dosReis, PhD, Associate Professor	pharmaceutical health services research	FT
Julie Zito, PhD, Professor	pharmaceutical health services research	FT
Ilene Zuckerman, PhD, Professor	pharmaceutical health services research	FT
Robert Beardsley, PhD, Professor	pharmaceutical health services research	FT
Francis Palumbo, PhD, Professor	pharmaceutical health services research	FT
Françoise Pradel, PhD, Associate Professor	pharmaceutical health services research	FT
Eberechukuwu Onukwugha, PhD, Assistant Professor	pharm. health services research	FT
Linda Simoni-Wastila, PhD, Professor	pharmaceutical health services research	FT
Fadia Shaya, PhD, Professor	pharmaceutical health services research	FT
Bruce Stuart, PhD, Professor	pharmaceutical health services research	FT

I.   Adequacy of library resources (as outlined in COMAR 13B.02.03.12).
The Health Sciences and Human Services Library is an excellent resource for students in regulatory science.   In each course, students will be assessed via projects, online presentations, and mini-reviews. The library offers electronic access that will allow for student completion of these requirements (see http://guides.hshsl.umaryland.edu/distancestudents). The program is to be implemented within existing institutional resources.

J.   Adequacy of physical facilities, infrastructure and instructional equipment (as outlined in COMAR 13B.02.03.13)
The physical facilities, infrastructure and instruction equipment are adequate to initiate the program. The program leverage existing at-a-distance instructional technologies. The program is to be implemented within existing institutional resources. Briefly, the School of Pharmacy's Audio Visual Services Department, in conjunction with the Office of Instructional Technology, offer excellent support for the Master's Program. The existing recording studio is highly functional and the School has developed capabilities to enable faculty to also record at their desk top computers. There are three AV technicians who provide various support services including support of recording in the studio, minor editing and uploading of content.

K.   Adequacy of financial resources with documentation (as outlined in COMAR 13B.02.03.14)
No new general funds are required. Initially, several existing school faculty member's effort will be redirected to support the program. These faculty members are funded from the School's existing State Appropriation. Over time (by year three), as indicated in the financial plan, new tuition revenues will cover the expenditures for all faculty including new few faculty to be hired to directly support the program. Existing equipment from our newly constructed building will

support the program. Tuition revenues will offset/cover administrative staff and AV/technical staff.

L.   Resources and Expenditures
The program will initially start with 10 students but grow to 50 part time students by year three (with 30 total students in year two). The school will initially use existing faculty (supported by existing state appropriations) until year three when new tuition revenues will easily support all of the program's expenditures. We have a collaborative agreement in regulatory science with the FDA, and industrial stakeholders and federal employees have indicated interest in this new program. As the program will be offered online, we anticipate being able to attract more students than we can enroll into the program. Interest has been expressed from the PharmD students for a dual degree program, which would be considered after program implementation.

M.   Adequacy of provisions for evaluation of program (as outlined in COMAR 13B.02.03.15).
Discuss procedures for evaluating courses, faculty and student learning outcomes.

The program will be reviewed every seven years under the Graduate School Guidelines for Purpose, Procedures and Self-study Guidelines. Procedures for evaluating courses, faculty and student learning outcomes will follow well-develop procedures in the School of Pharmacy. At course completion, courses and individual faculty will be evaluated by student using an anonymous web-based survey. Collected by the Dean's Office, such evaluations are reviewed immediately by the course manager and graduate program director, and annually by the department chair and vice-chair. Student grading is based upon the course syllabus.

A steering committee will be appointed by the department chair and will function to serve as an admission committee and a curriculum committee. Other issues will be addressed by the Graduate Program Director and the department chair.

Students will be able to request a faculty advisor. If the student does not make a specific request one, they will be assigned a faculty advisor. Program orientation will include a series of web conferences that will include a description to available online library resources. Overall student progress will be monitored by the program director, who will work with the Graduate School in enforcing Graduate School policies for academic standing.

N.   Consistency with the State's minority student achievement goals (as outlined in COMAR 13B.02.03.05 and in the State Plan for Postsecondary Education).
Discuss how the proposed program addresses minority student access & success, and the institution's cultural diversity goals and initiatives.

Consistent with the State's minority student achievement goals, the proposed program will work with the FDA Office of Minority Health, an on-going collaborator with the University of Maryland Center of Excellent in Regulatory Science and Innovation (www.cersi.umd.edu). Efforts will also be made to represent diversity with current students attending Open House and participating in the interview process.

The institution's strategic goals and initiatives for cultural diversity are consistent with the State's minority student achievement goals. As the state's only public academic health, law, and human services university, the University is determined to build the capacity to value diversity, conduct self-assessment, manage the dynamics of difference, and acquire and disseminate cultural knowledge.

O.   Relationship to low productivity programs identified by the Commission:
If the proposed program is directly related to an identified low productivity program, discuss how the fiscal resources (including faculty, administration, library resources and general operating expenses) may be redistributed to this program.
N/A

TABLE 1: RESOURCES					
Resource Categories	Year 1 FY 14	Year 2 FY 15	Year 3 FY 16	Year 4 FY 17	Year 5 FY 18
1. Reallocated Funds Note 1	$296,945	$53,845			
2. Tuition/Fee Revenue (C + G Below)	$109,050	$327,150	$545,250	$545,250	$545,250
a. # F T Students	10	30	50	50	50
b. Annual Tuition/Fee Rate	$10,905	$10,905	$10,905	$10,905	$10,905
c. Annual Full Time Revenue (A X B)	$109,050	$327,150	$545,250	$545,250	$545,250
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					
4. Other Sources					
Total (Add 1-4)	$405,995	$380,995	$545,250	$545,250	$545,250

Note 1 Reallocated funds are state appropriations supporting faculty effort & staff for the 1st two
years of the program. IMPACT: Educational Technology/AV Resources will be stretched.
Faculty productivity should not be adversely impacted (several will be involved).

Note 2 Tuition Revenue Exclude Fees that go to the campus

TABLE 2: EXPENDITURES					
Expenditure Categories	**Year 1** FY 14	**Year 2** FY 15	**Year 3** FY 16	**Year 4** FY 17	**Year 5** FY 18
1. Total Faculty Expenses (b + c below)	$207,900	$207,900	$277,200	$277,200	$277,200
a. # FTE	1.5	1.5	2.0	2.0	2.0
b. Total Salary	$165,000	$165,000	$220,000	$220,000	$220,000
c. Total Benefits	$42,900	$42,900	$57,200	$57,200	$57,200
2. Total Administrative Staff (b + c below)	$77,550	$77,550	$77,550	$77,550	$77,550
a. # FTE	1.0	1.0	1.0	1.0	1.0
b. Total Salary	$55,000	$55,000	$55,000	$55,000	$55,000
c. Total Benefits	$22,550	$22,550	$22,550	$22,550	$22,550
3. Total Support Staff Expenses (b + c below)	$34,545	$34,545	$34,545	$34,545	$34,545
a. # FTE	0.65	0.65	0.65	0.65	0.65
b. Total Salary	$24,675	$24,675	$24,675	$24,675	$24,675
c. Total Benefits	$9,870	$9,870	$9,870	$9,870	$9,870
4. Equipment					
5. Library					
6. New or Renovated Space					
7. Other Expenses	$86,000	$61,000	$61,000	$61,000	$61,000
Total (Add 1-7)	$405,995	$380,995	$450,295	$450,295	$450,295

Excess Revenues over Expenditures $0 $0 $94,955 $94,955 $94,955