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University Council

April 20, 2018

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Dear Colleagues:

The attached proposal from the College of Pharmacy for a new Institute for International Biomedical Regulatory Sciences will be an agenda item for the April 27, 2018, Full University Curriculum Committee meeting.

Sincerely,

Alison Alexander

Alison F. Alexander, Chair
University Curriculum Committee

cc: Provost Pamela S. Whitten
Dr. Rahul Shrivastav

NAME

Institute for International Biomedical Regulatory Sciences

EXECUTIVE SUMMARY

The University of Georgia Institute for International Biomedical Regulatory Sciences will act as the nexus for education, research, and training in the regulatory sciences. The institute will focus on workforce development through graduate certificates, Master of Science degree programs, conferences, and workshops. Research programs will focus on global regulatory challenges that are central to the development and delivery of high quality biomedical products.

On March 9, 2017, the pharmacy faculty members participating from the Division of Nontraditional Education and Outreach voted 7-0 to support the reorganization described in the proposal and also to support the creation of the institute. Additionally, on December 12, 2017, the College of Pharmacy voted 46-0 to support both the reorganization of the College as described in the proposal as well as to support the creation of the institute.

MISSION

The institute will provide a venue for industry, government, and academia to improve and harmonize the worldwide safe use of pharmaceuticals, vaccines, medical devices, biologics, animal health products, and combination products through the regulatory sciences. We will achieve this through collaborative partnerships, integrative research, education, training, and outreach.

CONTEXT

There is a constant struggle to balance the needs of patients for new and improved lifesaving therapeutics and procedures while ensuring both safety and efficacy. The regulatory sciences encompass the need to continuously encourage innovative biomedical research and development with the realities of our shared responsibility for the safe implementation of these discoveries. However, these continual advances in healthcare face ever increasing challenges that need to be studied and understood in order to bring the highest quality of life to mankind. These include the following areas which have been identified by the U.S. FDA as critical research needs:

- Develop better, faster, and less expensive toxicology assessment methods to enhance product safety
- Stimulate innovation in clinical evaluations and personalized medicine to improve product development and patient outcomes
- Improve product manufacturing and quality through automation, better analytical methods, quality by design and new approaches to reduce microbial contamination.
- Ensure the readiness of companies and regulatory agencies to accept and evaluate innovative emerging technologies

- Increase the use of “big” data from diverse sources to improve health outcomes
- Strengthen social and behavioral science to help consumers and professionals make informed decisions about regulated products.
- Develop medical countermeasures to protect against pandemics and medical terror threats to global health and security.
- Strengthen the global product safety net to protect against contaminated, adulterated and counterfeit drugs posing threat to the public health.

Advances in technology and our understanding of diseases create new opportunities to positively impact the health and well-being of patients. However, these advances are often accompanied by changes in our understanding that may impact our previous approaches to the treatment of a disease or demonstrate that there are larger unknowns in our knowledge of a specific topic than we previously believed. The regulatory sciences are responsible for the integration of these new innovations in science, technology, engineering, informatics, and other related disciplines into guidelines that can be broadly understood and operationalized.

There is an absolute need for this explicit framework to assess medical products. Innovation is stifled when there is a lack of clarity in what is needed in order to develop new products and also to maintain the availability of current products. In our society these products will move throughout the world. Under these circumstances, there becomes an intense need to understand the nuances that different countries expect in order for these products to be utilized within their boundaries. In addition, our global economy creates complex supply and distribution systems that pose significant challenges toward maintaining patient safety.

The University of Georgia established graduate training in regulatory affairs and clinical trials management in 2005. This program had an initial focus toward improving the education of working regulatory professionals in a wide variety of biomedical product areas involving pharmaceuticals, biologics, medical devices, and animal health products. This included a strong focus on an understanding of the regulations of the U.S. Food and Drug Administration and also extended to other government agencies such as the U.S. Department of Agriculture and the U.S. Environmental Protection Agency.

The University of Georgia, via the Colleges of Pharmacy, Engineering, Veterinary Medicine, and Arts and Sciences, has assembled a faculty with extensive experience in addressing the various parts of this interdisciplinary field. The regulatory sciences provide a common interest and intellectual framework for coordinating these various highly interdisciplinary activities; an institute will provide the procedural structure for implementing these shared interests.

INSTITUTE GOALS

Over the next few years, federal agencies, foundations, municipalities, and industry will invest hundreds of millions of dollars to support research, education, training, and outreach related to the regulatory sciences. In response to these challenges from the various regulatory agencies and their affiliated industries, the goals of the institute are to:

- Increase the quality and quantity of interdisciplinary research in the many disciplines that form the basis of the regulatory sciences, and to procure external support for that research;

- Synergize the existing strengths at UGA to be able to respond comprehensively as an institution to significant research and development opportunities;
- Proactively develop interdisciplinary publications and modular research proposals focused on the regulatory sciences prior to announcements of significant funding opportunities;
- Enhance the visibility of UGA by establishing a national presence in the regulatory sciences;
- Attract high-quality students and faculty and provide them with effective mentoring in the regulatory sciences;
- Increase financial support and educational opportunities for students pursuing training in the regulatory sciences;
- Strengthen our existing relationships with major regulatory agencies to advance the regulatory sciences through research, training, and outreach activities.

ADDED VALUE OF THE NEW INSTITUTE

There is a pressing need for UGA to take an interdisciplinary approach to the significant opportunities and challenges represented by the regulatory sciences. This institute will bring together faculty who are already individually successful in their own areas to serve as a foundation for larger groups that are needed to tackle problems in the regulatory sciences. It will also connect UGA researchers across campus and build collaborations with complementary efforts at other institutions to serve as a campus nexus for interdisciplinary research, education, and training leadership. Success in this area is critical to Georgia, the nation, and the world.

By synergizing UGA's diverse strengths in pharmacy, engineering, veterinary medicine, and life science, the Institute for International Biomedical Regulatory Sciences will be positioned to make a lasting impact at multiple scales by attracting significant external research support. The institute will also be attractive to a new generation of pharmaceutical scientists, engineers, animal health, and biomedical researchers who are seeking to develop the skills needed to address the complex issues facing the development, approval, and continuing supply of critical life-saving medical advances. Further, underrepresentation in STEM disciplines can be countered with curricula in this area as they are inherently rich in interdisciplinary content and subjects of social concern.

Some of the opportunities that exist that would become goals of the institute would include:

- U.S. Food and Drug Administration Centers for Excellence in Regulatory Science Innovation
- National Institute for Innovation in Manufacturing Biopharmaceuticals
- National Institutes of Health

Each of these major national funding agencies has extramural programs that are aimed at research and workforce development in the regulatory sciences. A major benefit of the IIBRS would be its ability to act as a central organizational body for these larger funding opportunities and also to demonstrate the institutional commitment that UGA has made to support the regulatory sciences.

Several units across the UGA campus (as well as off-campus partners) will benefit from the integrative and strategic activities of the institute. The following units have been involved in

planning the institute and will contribute to its mission:

College of Engineering
College of Pharmacy
College of Public Health
College of Veterinary Medicine
Franklin College of Arts and Sciences

A list of participating faculty and letters of support from these units are provided in the appendices. It is anticipated and desired that additional academic units will become involved as the activities of the institute continue to develop.

RESEARCH FOCI AND AREAS OF EXPERTISE

Advances in science create new challenges and opportunities in the regulatory sciences. The institute will allow UGA to purposefully address how new discoveries both here at UGA and elsewhere will change the pathways to both the approval and continual delivery of health care. Faculty members initiating the institute represent many academic units (Appendix 2) and bring a tremendous depth and breadth of expertise. During the development of this proposal, we have identified several intersecting research themes and topics that synergize existing strengths and align with forthcoming opportunities for significant research support, including:

Biopharmaceutics

- Development of new therapeutics from proteins, oligonucleotides, cells, and tissues
- New methods of producing biopharmaceutical therapies
- New methods for assessing the quality of biopharmaceutical therapies
- Assess the ability of current regulatory systems to accommodate new and emerging technologies and approaches
- Identify best practices for the integration of new and emerging biopharmaceuticals into current health care systems

Biocompatible Materials

- Development of new materials for use in drug delivery systems and medical devices
- Methods to assess biocompatibility
- Methods to manufacture biocompatible materials
- Methods to assess the quality of biocompatible materials

Combination Products

- Development of products that involve more than one major classification of medical products (drugs, medical devices, biologics, animal health products)
- Assess the ability to accommodate combinations of traditional and emerging technologies within the current regulatory systems
- Identify best practices within current regulatory systems to accommodate new and emerging technologies that involve complex approval pathways

Risk Assessment

- Risk modeling for manufacturing and distribution systems
- Risk assessment of batch and continuous manufacturing processes
- Development of new methods to assess product risk

Quality Systems

- Develop new methods to assess the quality of biomedical products
- Assess the effectiveness of quality systems to protect patients
- Develop new methods for the rapid identification of microbial contamination in biomedical products and facilities
- Identify best practices for the implementation of quality systems and for the assessment of the integrity and quality of data

Security of Biomedical Products

- Develop systems that can be used to ensure the integrity of biomedical products
- Develop systems that can be used to effectively track biomedical products and their constituent parts from their origin to their point of use
- Assess the effectiveness of current practices to ensure the security and supply of medical products

We envision subsets of these topics being organized into focus areas within the institute as a result of conferences, workshops, writing retreats, and other activities.

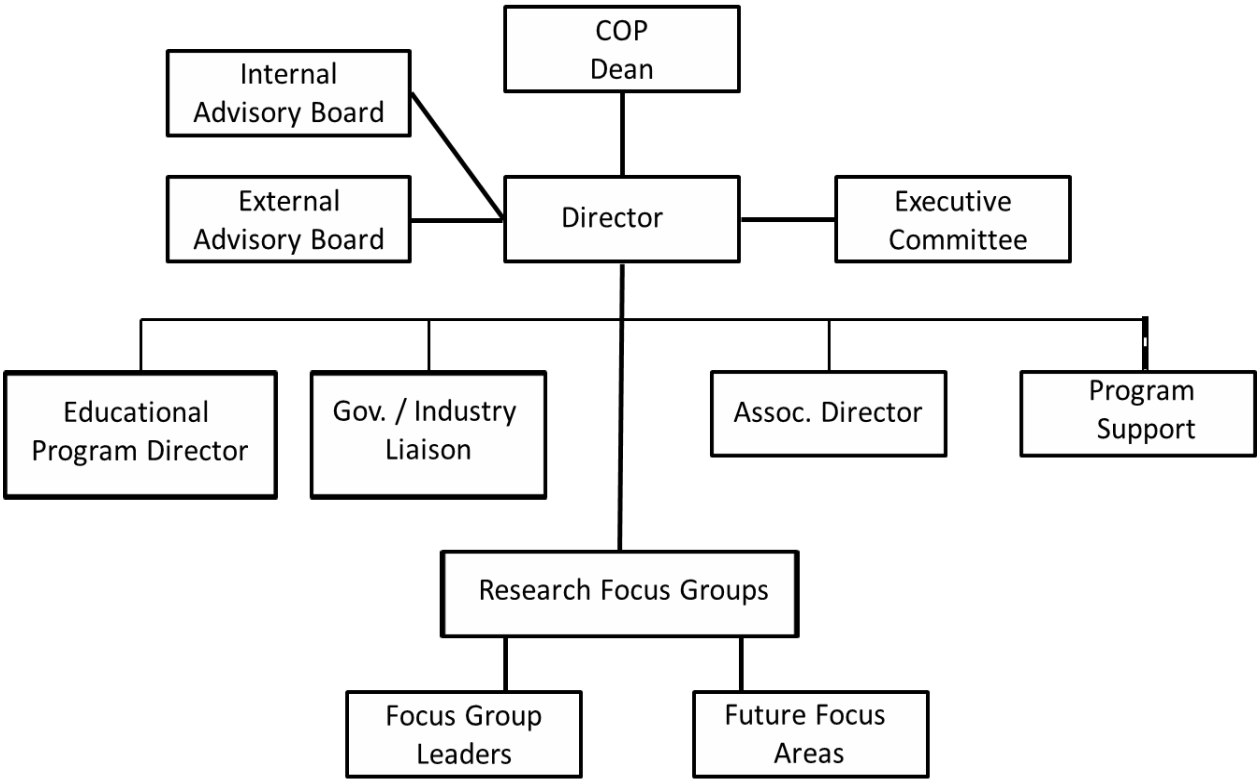
ORGANIZATIONAL STRUCTURE

The institute will be located administratively in the College of Pharmacy Dean's Office and will report to the Dean of Pharmacy. The Director will be appointed by the Dean of Pharmacy. The appointment of the Director will be reviewed annually. Participation of faculty in the institute will be voluntary and by agreement with the institute Director. UGA faculty members with relevant research interests can apply for affiliation with the institute by completing a web-based application form. Faculty applications will be evaluated by the Executive Committee (described below). The institute will maintain a cadre of faculty members whose primary academic duties will be with the institute. Their academic appointments current reside in the College of Pharmacy's Division of Nontraditional Education and Outreach. However, as part of this reorganization, that academic division within the College of Pharmacy will be dissolved and these faculty lines will move to the College of Pharmacy Dean's Office. A list of these faculty members can be found in Appendix 1. These faculty members will carry the majority of the educational mission of the institute. In addition, there will also be a significant number of participating faculty members who will maintain their existing appointments in their home academic units. Responsibilities of all participating faculty representing the various units are to:

- Attend institute meetings and proposal development retreats
- Collectively discuss and recommend institute strategic directions
- Actively participate in specific institute research and development and educational, training, and outreach activities

- Provide knowledge and guidance on priorities and relevant areas in their field of expertise
- Promote the strengths of the institute in supporting future regulatory decisions to their sponsors and collaborators

A diagram depicting the basic organization of the institute is provided below.



This chart represents the general framework within which the institute will grow. With input from the various advisory boards, the Director and leadership team comprised of the Associate Director, Government/Industry Liaison, and Educational Program Director will work to refine and advance the goals of the institute with the affiliated faculty and the Research Focus Groups that represent particular strengths and may be externally funded via major grants.

The founding Director of the institute is Dr. Michael Bartlett. The Director is responsible for providing both scholarly and administrative leadership for the institute such that the value of the institute grows for all its constituencies. The Director chairs the Executive Committee, organizes the Advisory Boards, and is responsible for establishing the leadership team of the institute (Associate Director, Government/Industry Liaison, and Educational Program Director) as the institute matures and grows.

The institute Associate Director is David Mullis. He has been a faculty member in the College of Pharmacy since 2004, serving as the Director of the COP Regulatory Sciences Graduate Programs. As the Associate Director he shares the leadership and management responsibilities of the institute with the Director. He will also work with the Director of Educational Programs to ensure that the institute meets its educational obligations. The Associate Director will work with the Director in executing the mission of the institute. Dr. Mullis also currently serves on the Board of Directors of the Association for Graduate Regulatory Education (AGRE), a group that represents the majority of the 12-15 Regulatory Science graduate programs that exist

across the United States.

The Executive Committee will be responsible for recommending and codifying the policies of the institute, providing input on priorities for institute research and educational activities and will be responsible for recommending spending priorities for infrastructure support based on input solicited from all faculty members affiliated with the institute. The Executive Committee consists of the Director, Associate Director, Program Chair, Government/Industry Liaison, and at least five additional faculty members broadly representing the diverse academic units participating in the institute. The Executive Committee is convened and chaired by the Director. The general responsibilities of the Executive Committee include:

- Establishing policy for the institute (the Director has final say for policy; disputes between the Director and the executive committee may be taken to the Internal Advisory Board or Dean of the College of Pharmacy)
- Evaluating faculty applications for membership to the institute
- Advising the Director

The External Advisory Board will be appointed by the Dean of Pharmacy in coordination with the Director and is comprised of outside technical experts from industry and outside academic institutions who are recommended by the institute leadership team. The External Advisory Board will elect its own chair who will serve a two-year term. The External Advisory Board will provide input on the institute's strategic research direction, educational programming, and progress toward goals and make recommendations regarding any needed course corrections and future directions. The External Advisory Board must meet as a group at least once a year.

The Internal Advisory Board will be appointed by the Dean of Pharmacy and is comprised of University administrators to assist in resolving issues that arise due to academic/university organizational structure that inhibit the institute from achieving its potential. The Internal Advisory Board will be chaired by Associate Provost Russell Mumper.

The Industry/Government Liaison will be Mr. Alexander Jacks. Mr. Jacks joined the College of Pharmacy as a part-time faculty member in 2015. In this role he will be responsible for the development of marketing materials for the institute to industry and government, working with the development office and corporate relations to garner their financial support, developing and coordinating industry and government involvement with faculty and students, and assisting the institute with the translation of research for the public good.

The Educational Program Director is Ms. Johnna Hodges. Ms. Hodges has been serving as the Assistant Director of the COP Regulatory Affairs Graduate Certificate and M.S. degree programs since 2004. The Educational Program Director will be responsible for the implementation and coordination of the institute's educational programs (e.g., courses, certificates, graduate programs, and short courses). The Educational Program Director will be assisted and supported by other faculty (permanent institute faculty and staff as well as affiliated faculty members) in the execution of the institute's programs.

The Program Support is Ms. Cindy Davenport and Ms. Arvinder Makkar. Ms. Makkar supports the institute's web site and social media presence and supports the students and faculty with course content development and course management. Ms. Davenport acts as the Program Coordinator for the UGA Gwinnett Campus and provides faculty and student support for this

campus and for the institute as a whole. The Program Support Staff will report to the Educational Program Director.

Institute faculty members anticipate developing centers of focus under the broader umbrella of the institute. The Executive Committee will initially take the lead in identifying focus areas that align with both research strengths of the university and also are funding priorities for federal agencies. The goal is for these focus areas to grow and eventually become UGA Centers within the Institute.

CURRICULA

The institute will initially have a primary focus on training and education while building research focus groups. The institute will have two approved graduate certificates (International Biomedical Regulatory Sciences and Clinical Trials Design and Management) and both thesis and non-thesis options for a Master's in Pharmacy with an Area of Emphasis in International Biomedical Regulatory Sciences. In addition, the Master's in Biomanufacturing and Bioprocessing offers a track in Regulatory Sciences as one of their three concentration options. These existing programs are briefly summarized below.

Clinical Trials Design and Management Certificate Program: This program provides a foundation for preparing candidates to lead and to manage the development and implementation of scientifically valid clinical study designs, including monitoring of clinical trials and directing daily clinical trial operations. The interdisciplinary program encompasses core competency areas integral to the drug product development and medical device design validation required for federal regulatory clearance. This certificate program requires the completion of 17 credit hours of coursework.

Course Title	Brief Description	Credit Hours
PHAR 6010, Pharmaceutical, Biotechnology and Device Industries	Foundational knowledge of the pharmaceutical, biotechnology, and medical device industries. Emphasis on organization, product development, new product applications and commercialization-associated activities, including drug discovery, chemical synthesis, laboratory practices, quality assurance, regulatory affairs, manufacturing, design control, marketing, and post-marketing surveillance.	4
BIOS(PHAR) 7100E, Biostatistical Applications for the Pharmaceutical and Biotechnology Industries	Biostatistical issues regarding the introduction and regulatory agency (FDA) approval of new drugs, biologics, medical devices, and combination products, and their post market surveillance are considered. Data quality assurance, experimental design, clinical trials, power and sample size determination, uncertainty assessment, regression, survival analysis, and variable and model selection are considered.	3
PHRM(HPAM) 7230, Ethical Issues in Research	Ethics of research in animals and human subjects, fraud, scientific misconduct, and conflicts of interest.	3

PHAR 6200, Clinical Trials Design and Management	Fundamentals of the clinical trials environment, study design and management. Emphasis on the initiation, administration, coordination, and management of clinical research studies for the development of new drugs, biologics and other clinical products.	4
PHAR 6210E, Project Management in Clinical Trials	Concepts, practicalities, and realities of project management. Practical guidance from trial set-up to delivering targets, the problems of performing clinical trials and how to deal with project teams, deadlines, budgets, and resources.	3
		17 Total

International Biomedical Regulatory Sciences Certificate Program: This program provides an opportunity for active regulatory professionals to round out their experiences and also provides a foundation for individuals looking to transition into entry level regulatory positions. The program is designed to provide the specialized scientific and technical content required to support regulatory issues pertaining to both new and existing products. The program consists of 14 credit hours of coursework.

Course Title	Brief Description	Credit Hours
PHAR 6010, Introduction to the Pharmaceutical, Biotechnology and Device Industries	Foundational knowledge of the pharmaceutical, biotechnology, and medical device industries. Emphasis on organization, product development, new product applications and commercialization-associated activities, including drug discovery, chemical synthesis, laboratory practices, quality assurance, regulatory affairs, manufacturing, design control, marketing, and post-marketing surveillance.	4
PHAR 6020, Food and Drug Law	Overview of laws and regulations governing development, manufacturing, and commercial distribution of drugs, biologic and medical device products and how they relate to the pharmaceutical, biotechnology, and medical device industry. Domestic and international regulatory requirements and various regulatory agencies and their jurisdiction.	3
PHAR 6030, Current Good Manufacturing Practices	Current Good Manufacturing Practice regulations implemented to assure quality and safety of marketed products. Inspection techniques used by the FDA to ensure best practices within a manufacturer's organization, personnel, facilities, equipment, control systems, production, process controls, laboratory procedures and records, and clinical testing.	4
PHRM(HPAM) 7230, Ethical Issues in Research	Ethics of research in animals and human subjects, fraud, scientific misconduct, and conflicts of interest.	3
		14 Total

Pharmacy (M.S.) with an Area of Emphasis in International Biomedical Regulatory Sciences: The Master's in Pharmacy with an Area of Emphasis in International Biomedical Regulatory Sciences assures a strong professional background for administrative positions and specialized areas required for this applied profession. This program provides a comprehensive background in regulatory requirements for pharmaceutical, biologics, medical devices, animal health products, international regulations, and combination products. The Master of Science program requires 38-39 credit hours of coursework, depending on whether an individual chooses the Thesis or Project option. The program begins with the 14 credit hours required for the completion of the regulatory affairs certificate program. The additional required core courses for this program are described below.

Course Title	Brief Description	Credit Hours
PHAR 6120, Process Control and Validation	Broad coverage of validation and control processes for the pharmaceutical, biologic, and medical device industries.	3
PHAR 6100, Quality Control and Quality Assurance	Principles to understand and establish quality control/quality assurance processes, procedures, and compliance reports for the production of biologics, drugs, and devices.	3
BIOS(PHAR) 7100E, Biostatistical Applications for the Pharmaceutical and Biotechnology Industries	Biostatistical issues regarding the introduction and regulatory agency (FDA) approval of new drugs, biologics, medical devices, and combination products, and their postmarket surveillance are considered. Data quality assurance, experimental design, clinical trials, power and sample size determination, uncertainty assessment, regression, survival analysis, and variable and model selection are considered.	3
PHAR 6130E, U.S. Marketing Applications for New Drugs, Biologics, Medical Devices, and Animal Health Products	Theory and practical considerations associated with preparing new medical product applications with a focus on the regulations that govern specific applications and strategic/tactical issues to consider.	4

In addition to the courses above which total 27 hours, students are required to take an additional 6 hours of research and thesis or seminar and project depending on the track they choose. This leaves the student with 2 additional elective courses needed to complete the program. These courses are selected from the list below.

Course Title	Brief Description	Credit Hours
PHAR 6310E, Good Clinical Practice Regulations for Drugs, Biologic Products, and Medical Devices	Review of the United States and European Good Clinical Practices regulations that apply to conducting clinical trials for drugs, biologic products, and medical devices involving human subjects. Knowledge and understanding of the regulations and compliance challenges associated with conducting human clinical studies from a regulatory affairs perspective.	3

PHAR 6320E, Understanding the Role and Function of the United States Food and Drug Administration	In-depth examination of the FDA organization and how it functions on day-to-day basis. Organizational structure of FDA is explored. Historical organizational changes are studied. Relationships between organizational elements of the agency are examined. The relationship between organizational structure and decision making within the agency are discussed.	3
PHAR 6200, Clinical Trials Design and Monitoring	Fundamentals of the clinical trials environment, study design and management. Emphasis on the initiation, administration, coordination, and management of clinical research studies for the development of new drugs, biologics and other clinical products.	4
PHAR 6210E, Project Management for Clinical Trials	Concepts, practicalities, and realities of project management. Practical guidance from trial set-up to delivering targets, the problems of performing clinical trials and how to deal with project teams, deadlines, budgets, and resources.	3
PHRM 7210, Combination Products	Special topics in pharmacy covering biomedical products that are considered combination products and the special requirements involved in their manufacturing, quality systems and approval pathways.	3
PHRM 7210, EU Medical Device Approval Process	Special topics in pharmacy covering the classification of medical devices within the European Union and the regulations that govern their approval.	3
PHRM 7210, Latin American Regulatory	Special topics in pharmacy covering the regulations for the approval of biomedical products within Latin America.	3
PMCY 4500/6500-4500L/6500L, Pharmaceutical Drug Development	Overview and underlying principles of drug development in the United States. Primary focus on understanding and assessing various phases in drug development, including preclinical and clinical investigations, manufacturing, and other general considerations of the drug development process.	4
PMCY 4510/6510-4510L/6510L, Advanced Drug Delivery System	Assessment of the major issues and stages in drug development, including regulatory, economic, and legal issues associated with the drug development process.	4

Masters in Biomanufacturing and Bioprocessing (M.B.B.), Pharmaceutical Track: The M.B.B. program has three tracks for students to choose from after fulfilling their core courses. These tracks require four additional courses.

Course Title	Brief Description	Credit Hours
PHAR 6010, Pharmaceutical, Biotechnology and Device Industries	Foundational knowledge of the pharmaceutical, biotechnology, and medical device industries. Emphasis on organization, product development, new product applications and commercialization-associated activities, including drug discovery, chemical synthesis, laboratory practices, quality assurance, regulatory affairs, manufacturing, design control, marketing, and post-marketing surveillance.	4

PHAR 6030, Current Good Manufacturing Practices	Current Good Manufacturing Practice regulations implemented to assure quality and safety of marketed products. Inspection techniques used by the FDA to ensure best practices within a manufacturer's organization, personnel, facilities, equipment, control systems, production, process controls, laboratory procedures and records, and clinical testing.	4
PHAR 6120, Process Control and Validation	Broad coverage of validation and control processes for the pharmaceutical, biologic, and medical device industries.	3
IDIS 8900, Mammalian Cell Culture Principles	Intensive study, under the direction of staff members, on approved problems in medical microbiology.	3

Additional Opportunities: One of the great strengths of the regulatory sciences courses is that they are all on-line. That means that they have great flexibility to be used by other programs as supplements to enhance training. We believe that additional opportunities exist with many programs across UGA and at other institutions to use either the existing graduate certificates or other combinations of these courses to create regulatory science tracks in a similar manner to the Master's in Biomanufacturing and Bioprocessing. For example, engineering graduate students with an interest in medical devices or biocompatible materials would benefit from such a combination. Professional pharmacy students with an interest in compounding pharmacy would benefit, especially in light of the dramatically increased scrutiny that this industry is current receiving from the U.S. FDA. Students associated with the UGA New Materials Institute, Centers for Vaccine Research, Regenerative Medicine, Tropical and Emerging Global Infectious Diseases, or Drug Discovery would benefit from a more complete understanding of the approval, quality, and risk management issues associated with these products. Finally, through the Georgia Clinical and Translational Science Institute (CTSI) these courses could be offered to students at Emory University, Georgia Tech, and the Morehouse School of Medicine using the University System of Georgia's FastTrack Initiative which allows students access to these courses since they do not exist at their institution. We have had a few Emory and Georgia Tech students complete the graduate certificates in the past but by engaging the Georgia CTSI we believe that this will dramatically increase the visibility of these unique offerings. It also would become a base for building shared research interests between UGA and these institutions.

B.S./M.S. Programs: In 2017 the College of Pharmacy launched a B.S./M.S. dual degree program between the undergraduate program in pharmaceutical sciences and the M.S. in Pharmacy with an emphasis in either Pharmaceutical and Biomedical Sciences or International Biomedical Regulatory Sciences. This program has 8 students currently enrolled, with significant interest from undergraduates that will become eligible in the coming years. This dual degree pathway would be attractive for undergraduates in many life science and engineering disciplines. This option will be evaluated in conjunction with the College of Engineering and Franklin College of Arts and Sciences for future additional programs.

FACILITIES

The UGA International Biomedical Regulatory Sciences Graduate Programs are primarily housed on the UGA Gwinnett Campus in Lawrenceville, Georgia. The building is conveniently located

just off I-85 at the Old Peachtree Road exit. The International Biomedical Regulatory Sciences graduate program has 1727 square feet of space that includes four faculty offices (including the Associate Director, the Educational Program Director, and two additional faculty members), a video conference room, cubicle space attached to the suite (for two staff members), and a large storage area.

The video conference room is equipped with state of the art Cisco video equipment. This includes a 55-inch monitor and voice detection camera and a touchscreen control panel. The room can comfortably fit up to six people. The equipment is mobile and can be relocated if needed.

Both student and faculty services are provided on the Gwinnett campus. This site is equipped with secure internet services from Peachnet, the statewide communications network supporting all University System of Georgia Information Technology Services efforts. This allows direct and immediate access to GALILEO and The University of Georgia's Libraries, EITS, the College of Pharmacy IT Department, and the Center for Teaching and Learning. The network's speed and reliability are apt for the development of online content. Videos and other large file sizes are easily and quickly uploaded to Desire2Learn. Web conferencing through Blackboard Ultra is nearly seamless.

The Director, the Industry / Government Liaison, and several training facilities are located on the main UGA campus in the RC Wilson College of Pharmacy. This includes office space for two faculty members and over 4000 sq. ft. of laboratory space which can be used for both research and training. The laboratory facilities are also used for training students in the B.S. and M.S. programs in the pharmaceutical sciences. One lab is equipped for the pilot scale manufacturing of solid dosage forms (tablets, capsules) along with the associated quality testing facilities. The other lab is currently being renovated and equipped for the pilot scale manufacturing of biopharmaceuticals along with aseptic filling technology and the associated quality testing facilities.

In addition to being used for student training and the equipment being used to support research, the facilities are also used for industry-focused training programs in areas such as quality, process validation, and manufacturing. These courses have accompanying coursework which covers both the basic scientific theory and the regulatory statutes, with trainees receiving hands-on experience in best practices for implementation.

BUDGET

The institute would initially be composed of two full-time faculty, 7 part-time faculty, and 2 full-time staff members, all from the College of Pharmacy. The institute generates income through three sources: (1) credit hour generation from regulatory sciences courses (generally from existing UGA Graduate Students on TA/RA that are also completing one of the graduate certificate programs but do not pay the e-rate tuition), (2) e-rate tuition from on-line regulatory sciences courses ($ 750.00 per credit hour), and (3) conferences and workshops.

The credit hour and e-rate tuition covers the salaries for 1 full-time, 5 part-time faculty, and the two staff positions. The salary for the other full-time faculty member is for the Director who also serves as the Associate Dean of the College of Pharmacy and is provided by the Dean

of Pharmacy. The two remaining part-time faculty members are funded via revenue generated from the conferences and workshops.

The institute will organize two major annual international conferences that are co-sponsored with the U.S. FDA. The International Good Manufacturing Practices Conference has been held each spring in Athens since 1976, with roughly 20-25 speakers and between 250-300 attendees. The Medical Device Regulations Conference is held each fall in Athens or Atlanta since 2013, with roughly 8-10 speakers and between 75-125 attendees. There are also workshops held in conjunction with the conferences each year that provide additional training opportunities for the industry attendees.

The conferences and workshops generate roughly $125,000-150,000 per year. This revenue is used to fund the two part-time instructor positions in the program, provide operational funds for the graduate program in the regulatory sciences, and provides summer salaries for some UGA faculty members who provide coursework for the regulatory sciences program. There is significant opportunity to further expand the workshops/training courses by engaging GeorgiaBIO, the Georgia Chapter of the Regulatory Affairs Professional Society (RAPS), or the Atlanta District Office of the US FDA to identify emerging industry needs.

PROGRAM REVIEW

To ensure that the institute is fulfilling its mission and stated goals, periodic review will be performed by the internal and external evaluators. These will include annual updates on the institute metrics to be prepared by the Executive Committee and presented to the External Advisory Board. The institute will be reviewed internally every three years by the Dean of Pharmacy. As part of this review process, the institute will produce a report describing all educational program numbers, graduate and placement data, research funding efforts, and scholarly productivity of the faculty participating in the institute. Measureable outcomes to be quantified by the institute and evaluated in these reviews are listed below. The baselines for each of these metrics will be established upon creation of the institute.
Course and program enrollment data

- Number of graduate certificates conferred
- Number of M.S. degrees conferred
- Research productivity of core faculty based on indicators of scholarly activity, such as number of journal articles published, conference presentations, invited presentations, books and book chapters, reports, and other indicators
- Number of research projects in the institute and level of involvement of institute faculty
- Number of grant and contract proposals submitted
- Number of grant and contract proposals funded
- Number of partnerships created with industry and government
- Success competing for National Center Grants (e.g., FDA, NIIMBL, NIH)

Review of the institute will also include an assessment of the following broader questions:

- Has the institute become a catalyst for interdisciplinary research, training, and curricular development?
- Is the institute successfully establishing a national and international reputation?
- Has the institute met its original milestones or adaptively moved to seize

opportunities to establish and achieve new milestones?
- Has the institute become self-sustaining?

The institute will also be reviewed by the UGA Office of Accreditation and Institutional Effectiveness as part of the UGA Program Review and Assessment Committee (PRAC) when the College of Pharmacy undergoes its normal review.

Each internal and external review will address any changes in strategy, resources, commitments, and/or operating agreements, and ultimately recommend or not recommend continuation of the institute. If continuation is not recommended, the Dean of Pharmacy will decide the process for dissolution.

Appendix 1

Faculty

Ron Arkin, M.S. – Instructor
Fran Akelewicz – M.S., RAC – Instructor
Johnna Hodges, M.Ed. – Academic Professional Associate
David Mullis, Ph.D., RAC – Associate Professor
Seppe De Gelas, M.S. – Academic Professional Associate
Robert Geiger, Ph.D. – Academic Professional Associate
Alexander Jacks, M.S. – Academic Professional Associate
Samuel Silva, Ph.D. – Academic Professional Associate

Staff

Cindy Davenport – M.L.S. – Administrative Specialist
Arvinder Makkar – M.B.A. – Program Coordinator

Appendix 2 – Initial Participating Faculty and their Research Areas

College of Pharmacy

Michael G. Bartlett, Georgia Athletic Association Professor – Bioanalytical chemistry
Gurvinder Singh Rekhi, Academic Professional Associate – Pharmaceutical manufacturing
Randall L. Tackett, Professor – Clinical trials management

College of Engineering

Larry Hornak, Professor – Photonic Devices
Jason Locklin, Associate Professor – Biocompatible materials
Hitesh Handa, Assistant Professor – Biocompatible materials and medical devices
K. Melissa Hallow, Assistant Professor – Computational modeling of physiology and pharmacology
Yajun Yan, Associate Professor – Metabolic engineering and synthetic biology for biosensors

College of Veterinary Medicine

Harry Dickerson, Professor – Microbial pathogenesis
Benjamin Brainard, Edward H. Gunst Professor – Coagulation diagnostics
Karen Burg – Harbor Lights Chair – Bioengineering and regenerative medicine

College of Public Health

Tim Hickman, Professor – Rural health and telemedicine
Stephen Rathbun, Professor – Biostatistics

College of Arts and Sciences

David Blum, Director – Biomanufacturing
Joy Doren Peterson, Professor – Biomanufacturing
Arthur Edison, GRA Eminent Scholar – Metabolomics

Emory University

Andrew West, Sr. Center Administrator GaCTSA
Carlton Dampier, Professor – Healthcare outcomes

Center for Regenerative Medicine

Steven Stice, GRA Eminent Scholar – Regenerative medicine

Appendix 3 – Support Letters

1 – Atlanta Clinical and Translational Science Institute
2 – UGA College of Engineering
3 – UGA College of Veterinary Medicine
4 – UGA Department of Biochemistry
5 – UGA Biomanufacturing and Bioprocessing Program
6 – UGA Office of Research
7 – UGA College of Public Health

ACTSI Executive Council

David S. Stephens, MD
Emory University

Elizabeth O. Ofili, MD, MPH
Morehouse School of Medicine

Andrés J. García, PhD
Georgia Institute of Technology

Greg S. Martin, MD, MSc
Emory University

Jeff M. Sands, MD
Emory University

Sandra Harris-Hooker, PhD
Morehouse School of Medicine

Linda A. McCauley, RN, PhD
Emory University

R. Paul Johnson, MD
Yerkes National Primate Research Center

Herman A. Taylor, MD, MPH
Morehouse School of Medicine

August 31, 2017

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

Professor Bartlett,

The new proposed Institute for International Biomedical Regulatory Sciences is an outstanding mechanism for promoting this well-known educational program. As you know the renewal of the ACTSI (to be called the Georgia Clinical and Translational Research Institute) included the involvement of the UGA regulatory science program. Moving forward I look forward to integrating your online course offerings into our Masters of Science in Clinical Research program and possibly with our training partners in Ethiopia and the country of Georgia. Our students will greatly benefit from this training which is critical to understand clinical trials and the development of new therapies. Even our PIs would certainly benefit from increasing their understanding of this rapidly changing field.

I also view the establishment of the Institute as critical toward successfully competing for one of the FDA Centers for Excellence in Regulatory Sciences and Innovation awards. This Institute would be another important step toward becoming FDA's Southeastern CERSI. The combination of the proposed Georgia CTSA and the Institute for International Biomedical Regulatory Sciences would be another excellent way to increase educational and research collaborations between Emory, Morehouse School of Medicine, Georgia Tech and UGA.

I look forward to continuing to work with your program and to being involved in the Institute for Biomedical Regulatory Sciences.

Sincerely,

David S. Stephens, M.D.
Stephen W. Schwarzmann Distinguished Professor of Medicine
Interim Dean, Emory University School of Medicine
Vice President for Research
Robert W. Woodruff Health Sciences Center
Emory University

Supported by a grant from the NIH/National Center for Advancing Translational Sciences (UL1TR000454)

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Phone: 404-727-9296 Email: actsi@emory.edu
www.ACTSI.org

UNIVERSITY OF GEORGIA
College of Engineering

September 25, 2017

Dr. Michael Bartlett
Pharmaceutical and Biomedical Sciences
College of Pharmacy

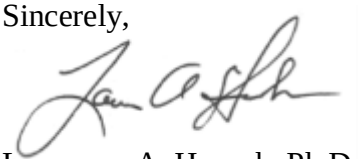
Dear Dr. Bartlett,

I am pleased to provide this letter of support from the College of Engineering for the proposed *Institute for International Biomedical Regulatory Sciences (IIBRS)*. Your proposed institute addressing the science and engineering that underpins and informs regulation has the potential for campus-wide interdisciplinary research impact in a cross-cutting area of critical importance to the health and well-being not only of the United States but the entire global community. Due to the importance of regulatory science, it is an area of significant interest to FDA as well as to the national manufacturing initiative institutes such as NIIMBL and the NIH. The proposal for the institute is timely and is an important step needed to bring the necessary science and engineering expertise of UGA together with the well-established educational programs in pharmaceutical regulatory science to properly position UGA for major extramural awards and an FDA Center of Excellence in Regulatory Science Innovation.

A core group of our engineering faculty have already expressed strong interest in working with you as you build the institute towards an FDA Center of Excellence. The College of Engineering over the past three years has organized its growing research enterprise around three clusters of activity, two of which have the potential to contribute to the IIBRS. Our *Material, Device and Cyber Tools Cluster* is in part the foundation for both the *New Materials Institute* and the *Georgia Informatics Institute*, both which can contribute to the biomaterials, data analytics and security component of the IIBRS. Faculty in this Cluster as well as our *Human Wellness, Cognition and Learning Cluster* are members of the Regenerative Biosciences Center (RBC) and participants in the newly announced *NSF Engineering Research Center for Cell Manufacturing Technologies* based at GT of which UGA is a key university site. We also see great potential for dual BS-MS Double Dawg programs between engineering and regulatory science.

In summary, the proposed institute is very synergistic with our College's strategic direction. Building strong collaborative groups with the IIBRS will enable us to add new dimensions to our growing biomedical materials, devices and systems research. We look forward with anticipation to the establishment of the IIBRS as a formal UGA institute.

Sincerely,



Lawrence A. Hornak, Ph.D.
Associate Dean for Research and Graduate Studies

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An Equal Opportunity/Affirmative Action Institute

The University of Georgia

Office of the Dean

College of Veterinary Medicine

Athens, Georgia 30602-7371
Telephone 706-542-3461
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August 29, 2017

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

Professor Bartlett,

I believe that the proposed Institute for International Biomedical Regulatory Sciences is a unique and exciting opportunity for the University of Georgia. The College of Veterinary Medicine has a long standing interest in maintaining the health of animals through the use of pharmaceuticals, medical devices and vaccines. As you know, animal health products have a very complex approval process involving input from such agencies as the US FDA, USDA and US EPA. Certainly products that would be available internationally would involve many other agencies from around the world. The International Biomedical Regulatory Sciences program is unique in that it is the only regulatory graduate program that covers animal health products and is also the only program that covers international regulatory approval processes. Graduate students and potentially even DVM students in the College of Veterinary Medicine would greatly benefit from exposure to these topics.

The Institute will also act to centrally coordinate activities related to the regulatory sciences across campus and across other institutions such as Emory and Georgia Tech. The translation of new technologies toward novel products is always accompanied by changes in the regulations to ensure the protection of patients both animal and human. The basic science faculty members are often not aware of the regulatory implications of their work and even the potential for funding opportunities for studying the regulatory impact of these advances in the biomedical sciences. The Institute will enable the faculty in the College of Veterinary Medicine, along with others at UGA, to compete for large external funding opportunities in the regulatory sciences and continue to strengthen our national reputation in this critical area.

I look forward to continuing to work with the International Biomedical Regulatory Sciences program and to future involvement in the Institute.

Sincerely,

Lisa K. Nolan, DVM, PhD
Dean

An Equal Opportunity/Affirmative Action/Veteran/Disability Institution

Christopher M. West
Professor & Head

The University of Georgia

Franklin College of Arts and Sciences
Department of Biochemistry and Molecular Biology
http://www.bmb.uga.edu

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Telephone 706-542-4259
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September 24, 2017

Michael Bartlett, Ph.D.
Georgia Athletic Association Professor in Pharmacy
Interim Assistant Dean for Nontraditional Education and Outreach
Wilson Pharmacy, Rm 420
University of Georgia
Athens, GA 30602

Dear Dr. Bartlett,

This letter is written in support of your plans to establish the International Institute for Biomedical Regulatory Sciences at the University of Georgia. As you are aware, students in the BioPharma Regulatory Affairs program currently intern with the Bioexpression and Fermentation Facility (BFF), a UGA Core Laboratory administered within the Department of Biochemistry & Molecular Biology, and very much look forward to continued collaborations. This collaboration has been beneficial for students learning bioprocess techniques as part of their degree program as well as for the BFF, which benefits through increasing the facility's overall knowledge base in regulatory affairs and evaluation of operations from a regulatory standpoint. In addition, there are potential future collaborations for establishment of workforce development programs through the National Institute for Innovation in Manufacturing Biopharmaceuticals. The Department of Biochemistry & Molecular Biology will enjoy the involvement between your programs and the BFF that will continue if not expand in association with your Institute status. From this perspective, we are pleased to support your goals and wish you the best of luck in your efforts.

Sincerely,

Christopher M. West, Ph.D.
Professor and Head of Biochemistry & Molecular Biology

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Joy Doran Peterson, Ph.D
MBB Director and
Graduate Coordinator
Email: biomfg@uga.edu

Biomedical and Health Sciences Institute

Athens, Georgia 30602-7394
Tel: (706) 542-4845
Fax: (706) 542-5285

August 9, 2017

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

Professor Bartlett,

I am very excited by possibilities that would result from the proposed Institute for International Biomedical Regulatory Sciences. As you know we have long made use of your on-line regulatory courses in our Master of Biomanufacturing and Bioprocessing (MBB) Program. Our students have greatly benefited from this training which is critical to understand to manufacturing of cell-based products such as proteins and monoclonal antibodies that would be used for the treatment and diagnosis of disease. We are especially excited about the recent international expansion of the regulatory sciences program. Since biomedical products are distributed all over the world it is critical for our students to gain an understanding of the challenges involved in the registration and manufacturing of biologics throughout the world.

I look forward to continuing to work with your program and to being involved in the Institute for Biomedical Regulatory Sciences.

Sincerely,

Joy B. Doran Peterson

Joy Doran Peterson, Ph.D.
Professor
Department of Microbiology
Director and Graduate Coordinator
Master Biomanufacturing and Bioprocessing Program

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The University of Georgia

Office of the Vice President for Research

October 6, 2017

Michael Bartlett, Ph.D.
Professor and Director, B.S. Program, Pharmaceutical and Biomedical Sciences
Interim Assistant Dean for Nontraditional Education and Outreach
College of Pharmacy
University of Georgia
250 West Green Street
Athens, GA 30602

Dear Dr. Bartlett:

I am pleased to provide my strong support for the proposed Institute for International Biomedical Regulatory Sciences. In my role as Director of Industry Collaborations, I work to build strategic research partnerships between companies and faculty at the University of Georgia. As I interface with life science companies, I consistently get feedback about the regulatory challenges they face in bringing new drugs and medical devices to market. Whether they be small, local start-up companies or large, multi-national firms, these potential industry partners struggle with understanding the ever-changing and increasingly complex global regulatory landscape. The expertise and experience that you possess, along with those of the other faculty listed in this proposal, are critical in meeting the needs of these industry partners. The mission of the proposed institute is directly in line with the needs of the industry as a whole and the work of this institute will make a significant contribution to advancing medial sciences and improving the lives of others.

This proposal is especially timely, as The University of Georgia is significantly expanding its leadership role in biomedical research, ranging from medical devices to vaccines to biologics and cell-based therapies to advanced biomanufacturing. This growth is exemplified by our participation in two highly competitive and reknowned public-private partnerships in the area of biomanufacturing. The first, The National Institute for The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is funded by the Department of Commerce and brings together over 150 companies, educational institutions, research centers, and government bodies, all with a common goal of advancing manufacturing practices and workforce training in this emerging area of global importance. In addition, The University of Georgia is part of a recently announced NSF Engineering Research Center in the area of advanced cell manufacturing (CMaT). This center will address the complex issues associated scalable biomanufacturing practices for advanced cell therapies in order to bring affordable, curative therapies to those battling disease. The proposed Institute for International Biomedical Regulatory Sciences is a critical part of the University's participation in these two public-private

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The University of Georgia

Office of the Vice President for Research

partnerships – the expertise of the members of the Institute, the research efforts and the educational programs provide a foundation for leadership in these two consortia.

I appreciate your leadership in this endeavor and sully support the formation of this Insitute. I believe it will play a critical role in our partnerships with other academic institutions, government and especially the life science industry in bringing new medical devices, drugs and therapies to market. I look forward to working with you to make the Institute for International Biomedical Regulatory Sciences a focal point for research, outreach and educational activities in this highly important field.

Sincerely,

Crystal S. Leach, Ph.D.
Director, Industry Collaborations
Office of Research
University of Georgia

The University of Georgia

College of Public Health

October 6, 2017

Michael G. Bartlett, Ph.D.
Professor and Director-Bachelors of Science Program
Georgia Athletic Association Professor in Pharmacy
Interim Assistant Dean for Nontraditional Education and Outreach

Dear Dr. Bartlett:

I am writing to express our college's enthusiastic support for your proposed Institute for International Biomedical Regulatory Sciences. Your planned institute provides an outstanding opportunity for the University of Georgia to capitalize on a unique educational program with tremendous translational research opportunities. The University of Georgia's College of Public Health's mission of promoting human health and preventing disease is well-aligned with the goals of your institute. As you know, many of our college's research goals necessitate clinical studies which require regulatory approval. The International Biomedical Regulatory Sciences program is the only program that covers both the regulatory approval pathways across multiple major regulatory bodies but also the regulations involved in the approval and management of biomedical clinical trials. Graduate students in the College of Public Health would benefit from training in these areas.

The Institute would also act to coordinate both educational and research activities related to the regulatory sciences across UGA and also between UGA and other regional institutions such as Georgia Tech, Emory, and the Morehouse School of Medicine. Most basic science faculty members are unaware of opportunities that exist to evaluate the regulatory impact of their work. The Institute will enable faculty in the College of Public Health and others to compete for extramural funding in the regulatory sciences and further strengthen our position in this important area.

The College of Public Health genuinely hopes to collaborate with the Institute of International Biomedical Regulatory Sciences to make UGA the recognized leader in this field.

Sincerely,

Timothy G. Heckman, Ph.D.
Associate Dean for Research
Director, Health Informatics Institute
Professor of Health Promotion and Behavior
College of Public Health
University of Georgia

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Approvals on File

Proposal: Institute for International Biomedical Regulatory Sciences

College: College of Pharmacy

Proposed Effective Term: Fall 2018

School/College:

- Institute for International Biomedical Regulatory Sciences Director, Dr. Michael Bartlett, 4/9/2018
- College of Pharmacy Dean, Dr. Svein Øie, 4/9/2018