



The University of Georgia®

University Council
Athens, Georgia 30602

April 21, 2017

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Graduate Student Representative – Ms. Ashley E. Fallaize

Dear Colleagues:

The attached proposal for the following name changes from the College of Pharmacy will be an agenda item for the April 28, 2017, Full University Curriculum Committee meeting:

From: Graduate Certificate in Pharmaceutical and Biomedical Regulatory Affairs
To: Graduate Certificate in International Biomedical Regulatory Sciences

From: Area of Emphasis in Pharmaceutical and Biomedical Regulatory Affairs under the major in
Pharmacy (M.S.)
To: Area of Emphasis in International Biomedical Regulatory Sciences under the major in Pharmacy (M.S.)

Sincerely,

Alison F. Alexander, Chair
University Curriculum Committee

cc: Provost Pamela S. Whitten
Dr. Rahul Shrivastav

Committee on Facilities, Committee on Intercollegiate Athletics, Committee on Statutes, Bylaws, and Committees, Committee on Student Life,
Curriculum Committee, Educational Affairs Committee, Executive Committee, Faculty Admissions Committee, Faculty Affairs Committee,
Faculty Grievance Committee, Faculty Post-Tenure Review Appeals Committee, Faculty/Staff Parking Appeals Committee,
Human Resources Committee, Program Review and Assessment Committee, Strategic Planning Committee,
University Libraries Committee, University Promotion and Tenure Appeals Committee

An Equal Opportunity/Affirmative Action/Veteran/Disability Institution

NAME CHANGE JUSTIFICATION FORM

School/College Name: College of Pharmacy

Department: College of Pharmacy

Certificate Name Changes:

Current Certificate Name:

Proposed Certificate Name:

Graduate Certificate in Pharmaceutical and
Biomedical Regulatory Affairs

Graduate Certificate in International Biomedical
Regulatory Sciences

Area of Emphasis Name Changes:

Current Area of Emphasis Name:

Proposed Area of Emphasis Name:

Area of Emphasis in Pharmaceutical and
Biomedical Regulatory Affairs under the
major in Pharmacy (M.S.)

Area of Emphasis in International Biomedical
Regulatory Sciences under the major in
Pharmacy (M.S.)

JUSTIFICATION:

The Graduate Certificate in Pharmaceutical and Biomedical Regulatory Affairs and the Area of Emphasis in Pharmaceutical and Biomedical Regulatory Affairs under the major in Pharmacy (M.S.) were created in 2004 in response to the significant need for education and training in this area. During the past 13 years, the program has evolved from its initial focus on pharmaceuticals to covering other biomedical regulated product areas such as medical devices, vaccines, and proteins and other advanced therapeutic medicinal products, animal health products, and combination products that cross several of these categories. In addition, due to the complex global markets that these products exist within, our program has advanced from its initial focus on U.S. Food and Drug Administration policies and procedures to include those that impact product approval filings and product compliance in other regions of the world, such as Europe, Asia, South America, and Latin America. As part of our commitment to expanding our coverage of the regulations outside of the U.S., we have hired our first two internationally-based faculty members. These are part-time UGA employees who actively work as regulatory professionals in these diverse markets. They have enormous real-world experience in both the U.S. and many other global markets, and therefore are acutely aware of the subtle (although sometimes striking) yet meaningful differences in the application of the regulatory sciences in these countries. The focus of these efforts is to enhance the international regulatory science content of all of our courses.

This makes our program extremely unique when compared to the 15-20 other programs around the country. We cover a wider range of medical product categories than any other program. Only a handful of programs even cover two of the areas mentioned above. In addition, no other program has expanded into covering international regulations, which are critical since most companies are global in nature and their regulatory professionals must interface with many different regulatory agencies. Many therapeutics are first approved outside of the United States, so an understanding of these pathways to market approval are extremely important, especially for small to medium-sized companies that do not have specialists in these global and emerging markets.

We believe that this change in program name from Pharmaceutical and Biomedical Regulatory Affairs helps us accomplish three major goals. First, it moves us from the more dated term Regulatory Affairs to the more broad scoped and more widely accepted term Regulatory Science. Second, it removes the implied focus of our program on pharmaceuticals, which is likely creating a barrier to students looking for training in other areas, such as medical devices, biological therapies, and animal health products. Third, by adding international to our title, it will allow for more immediate recognition of the fact that our program has content specific to regions of the world outside of the United States.

The Biopharma Regulatory Affairs Program faculty met on March 9, 2017. The faculty approved the name change of the program by a vote of 6 to 0.

Approvals on File

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To: Area of Emphasis in International Biomedical Regulatory Sciences under the major in Pharmacy (M.S.)

Department: College of Pharmacy

College: College of Pharmacy

Proposed Effective Term: Semester following approval

School/College:

- College of Pharmacy Associate Dean, Dr. George Francisco, 3/28/2017
- College of Pharmacy Dean, Dr. Svein Øie, 4/13/2017

Graduate School:

- Graduate School Dean, Dr. Suzanne Barbour, 4/20/2017