The University of Georgia

University Council
Athens, Georgia 30602

December 6, 2004

UNIVERSITY CURRICULUM COMMITTEE - 2004-2005
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Veterinary Medicine - Dr. Sheila W. Allen
Graduate School - Dr. William K. Vencill
Graduate Student Representative – Ms. Angela McMellen
Undergraduate Student Representative – Ms. Meredith Wilson

Dear Colleagues:

Attached is a request from the College of Pharmacy to establish a Graduate Certificate Program in Regulatory Affairs. This request will be an agenda Item for the next Full University Curriculum Committee meeting.

Sincerely,

Jan Hathcote

Jan M. Hathcote, Chair
University Curriculum Committee

cc: Dr. Arnett C. Mace, Jr.
Dr. Delmer D. Dunn

OUTLINE FOR A CERTIFICATE PROGRAM

I. Basic Information

1. Institution The University of Georgia Date October 12, 2004

2. School / College The College of Pharmacy

3. Department/Division Office of Postgraduate Continuing Education & Outreach

4. Level (undergraduate or graduate) Graduate

5. Proposed starting date for program Spring Semester 2005 (January 2005)

6. Abstract of the program for the University Council's agenda:
Provide a one or two page summary of the proposed program that includes an overview and highlights of the response to the criteria in Section II.

7. Submit letters of support from the various academic unit heads involved in developing the program initiative or whose support is vital to its success.

SIGNATURES:

Department Head

Dean of School/College

Abstract

In 2004, The University of Georgia College of Pharmacy was awarded a Board of Regent's ICAPP grant to help support the development of a regulatory affairs graduate certificate program. The proposed Certificate Program consists of four previously approved graduate courses totaling 12-semester credit hours and will be delivered through a combination of classroom and distance learning technologies, with the face-to-face component located at the Gwinnett University Center.

The purpose is to help fill a vital workforce need in the rapidly expanding biotechnology industry in Georgia. Biotechnology, pharmaceutical, and medical device companies require the expertise of well educated regulatory affairs professionals, who must keep up-to-date with regulatory policies and procedures for one or more product lines as well as maintain an understanding of the scientific and technical background of new products.

There is a shortage of well trained regulatory professionals, especially as the life sciences industries are moving to the Southeast to establish or grow their businesses. Currently, there are no other graduate regulatory certificate programs in the Southeast and very few on the East Coast. We anticipate that our program will draw students regionally, nationally and perhaps internationally. We have benchmarked our program against other certificate programs that have been identified and complied by The Regulatory Affairs Professionals Society. They include California State University-Hayward, San Diego State University, Temple University, and Northeastern University.

Presently, the core teaching faculty are associated with the College of Pharmacy and The Interdisciplinary Toxicology Program. Additionally, to maintain a practical and current curriculum, a number of Nationally recognized individuals, who currently are employed in industry and at the FDA have expressed their desire to teach selected areas/lectures based on their expertise.

Purpose and Educational Objectives

In order to meet the developed and emerging needs for regulatory specialists in Georgia-based biotechnology, pharmaceutical, and medical device industries, a certificate program is being initiated to educate a knowledgeable workforce in the area of Regulatory Science. The proposed certificate program consists of 12-semester credit hours designed to produce skilled graduates to fill regulatory affairs management needs of current and future biotechnology, pharmaceutical, and medical device companies in the state. The certificate program will be delivered through a combination of classroom and distance learning technologies, with a face-to-face component that utilizes facilities at the UGA campus located at the Gwinnett University Center (GUC) in Lawrenceville, Georgia.

The broad educational objectives include:

Identifying product development and commercialization activities of pharmaceutical, biotechnology and medical device industries that require federal regulations.

Outlining product development processes of the Food and Drug Administration (FDA).

Deciphering the laws and regulations governing development, manufacturing and commercial distribution drugs, biologic and medical device products and how they relate to the pharmaceutical, biotechnology and medical device industry.

Interpreting Good Manufacturing Practice regulations for application that assures quality and safety of marketed products.

Applying a consistent decision making framework needed to predict and solve ethical dilemmas within the biotechnology field.

Presently, the core faculty are associated with the College of Pharmacy and The Interdisciplinary Toxicology Program. Additionally, in order to maintain a current and relevant curriculum, a number of individuals who currently are employed in industry and at the FDA will teach specific topics within courses.

Demonstrated need for the program

This program will be targeted for personnel working within economically important Georgia-based bioscience industries, who desire to obtain advanced training in regulatory science. Regulatory Affairs professionals are employed in industry, government and academia and are involved in a range of services related to the manufacturing and testing of pharmaceuticals, medical devices, in vitro diagnostics, biologics, biotechnology, nutritional products, cosmetics, and veterinary products. Due to the rapidly expanding biotechnology industry in Georgia, there is a substantial need for additional highly trained professionals to work within this specialized industrial sector. Education and professional development are critical to the regulatory affairs expert, who must keep up-to-date with regulatory policies and procedures for one or more product lines as well as maintain an understanding of the scientific and technical background of new products.

A study commissioned by The Board of Regents in 2003 found that there were 35 openings among life sciences companies in Georgia – some 20% of those positions are in the quality and regulatory areas. The same study showed that the absence of quality and regulatory programs in Georgia was an obvious hurdle in trying to attract new businesses in the life sciences and part of the reason these companies did not relocate to Georgia.

The Regulatory Affairs Certificate Program has received preliminary funding through a competitive grant in the total amount of $401,970 provided by the Board of Regents' Intellectual Capital Partnership Program (ICAPP). The purpose of the ICAPP Program is to promote economic development in Georgia through education for low supply, high need knowledge-based jobs. Corporate commitments have also been garnered and will assist in the funding of this program. To date, we have confirmed participation of eight Georgia Life Sciences Companies. These companies have pledged a total of $386,000 in cash and in-kind donations.

It is the expectation that over the next decade, this program will help provide the workforce required for the state's emerging life sciences industry.

Semester/Year of Program Initiation

The Regulatory Affairs Program is on track to enroll its first non-degree students in January 2005 (Spring Semester 2005). This program will follow the traditional academic pace, but will utilize web-based (WebCT) instruction with occasional use of GSAMS and other technologies for those participants who are unable to commute to Atlanta.

Based on present interests, the Regulatory Affairs Program expects to enroll between eight and twelve students for its initial courses. These students will be primarily from within Georgia and currently employed in the pharmaceutical or biomedical industries. It is expected that these working professional students will participate on a part-time basis, while they maintain their current positions.

Semester/Year Full Implementation of Program

We anticipate that this program will be fully implemented and underway by Fall Semester 2005.

Semester/Year First Certificate will be awarded

The Regulatory Affairs Certificate program is geared for working professionals. As such, we expect many of our students to take one or two courses per semester, year-round. With this in mind, we anticipate to award of our first certificate in December 2005.

Annual Number of Graduates Expected

The Regulatory Affairs Certificate program expects that it will graduate on average 8-12 students per academic year for the first 5-7 years.

Projected Future Trends for number of students enrolled in the program

The Regulatory Affairs Certificate program expects the initial number of student enrollment to be between 8-12 students. As our program develops and information about our program spreads, we expect the number to increase by 2-5 students over the next five years.

Student Demand

We anticipate three types of students to enroll in The Regulatory Affairs Certificate Program

1. Because the ICAPP grant mission is to enhance Georgia's work force, our first priority will be to enroll professionals in the health products industry within Georgia. These are people who have industry experience, but desire FDA Regulatory Education to assist their companies in getting products through the US market.

2. The second group will be professionals in the health products industry outside Georgia. Currently there are no other regulatory certificate programs in the Southeast and very few on the East Coast. We anticipate that our program will draw students regionally, nationally and perhaps internationally. One reason we believe our program can draw from elsewhere is because we are developing our curriculum for delivery by web-base instruction and condensed weekend workshops. Thus, it will be more easily accessible to others outside the state versus a traditional on-site program.

3. A third group will be traditional graduate students in pharmacy and in other academic fields, who wish to achieve the distinction of having regulatory education on their transcript.

The Regulatory Affairs Certificate Program has been developed to meet the human resource needs for regulatory affairs professionals in the health products industry within Georgia. As such, our program will recruit potential students and enroll them based on 1) current professional position within the regulatory affairs arena and/or 2) bachelor's degree in the sciences, if they are coming directly from an undergraduate program. Therefore, minority enrollment program will be proportionate to 1) minority employment in the health products industry and 2) minority student enrollment in science programs.

Design and Curriculum of Program

Curriculum Outline

Certificate: An FDA Regulatory Overview of Medical Products: Drugs, Biologics and Medical Devices (12 semester hours)

PHAR 6010 Pharmaceutical, Biotechnology, and Device Industries (3 semester hours)
PHAR 6020 Food and Drug Law (3 semester hours)
PHAR 6030 Current Good Manufacturing Practices (4 semester hours)
PHRM 7230 Ethical Issues in Research (2 semester hours)

Course Identification

All courses have been in approved by the College of Pharmacy, The Graduate School, and the University Curriculum Committee and are listed in CAPA

Model Programs

We have benchmarked our program against other certificate programs that have been identified and compiled by The Regulatory Affairs Professionals Society. They include California State University-

Hayward, San Diego State University, Temple University, and Northeastern University. Below is a list of UGA's Proposed Program and the other University Curricula:

UGA College of Pharmacy 12 sem hrs, as proposed	California State University Hayward 16 qrt hrs (~9.6 sem hrs)	San Diego State University 12 sem hrs	Temple University 15 sem hrs	Northeastern University 16 qrt hrs (~9.6 sem hrs)
Pharmaceutical, Biotechnology, & Device Industries (3) Food & Drug Law (3) Current Good Manufacturing Practices (4) Introduction to Bioethics (2)	Pharmaceutical, Biotech & Biodevice Industries (4) Introduction to Food & Drug Law (4) Current Good Manufacturing Practice for Drugs and Biologics (4) Elective Courses	Pharmaceutical Biotechnology & Medical Device Industry (3) Introduction to Food and Drug Law (3) Current Good Manufacturing Practice General Concepts (3) And <u>one</u> elective	Drug Development (3) Good Clinical Practices (3) Clinical Trial Management for Research Practitioners (3) Bioethics for Pharmaceutical Professionals (3) Clinical Data Management (3)	Biologics Development: A QA/Regulatory Overview (4) Medical Device Development: A QA/Regulatory Overview (4) New Drug Development: A QA/Regulatory Overview (4) RA 3203 - Food, Drug, & Medical Device Law: (4)

<u>Accreditation</u>
The Regulatory Affairs Professionals Society (RAPS) is the foremost worldwide member organization for regulatory affairs professionals serving to create and uphold standards of ethics, credentialing and education for the regulatory affairs profession within the health product sector. Our program is being modeled after RAPS core competencies. However, presently there is no accreditation required by RAPS or any other agency for regulatory affairs graduate based education.

Faculty Resources

David Mullis, Ph.D , R.A.C. has been appointed by the College to serve as Director for the Regulatory Affairs Certificate Program. Dr. Mullis holds the appointment of Associate Professor in the Department of Pharmaceutical and Biomedical Sciences with the College of Pharmacy and brings a wealth of experience in the area of Regulatory Affairs and clinical support services. He has 25 years of successful corporate management experience in Food and Drug Administration regulated industry directing US and international programs in regulatory affairs, clinical studies, quality assurance and marketing. Prior to his industry experience, Dr. Mullis served as the Executive Director of a physicians' professional standards review organization where he lead the firm from its start-up phase to a successful business level from 1977-1981. From 1973-1985, he held faculty positions at The University of Tennessee and Radford University and served as an adjunct professor at Metropolitan State University and St. Mary's University. His Curriculum Vitae is attached.

Presently, the core teaching faculty are associated with the College of Pharmacy and The Interdisciplinary Toxicology Program. Other College of Pharmacy faculty as well as faculty from other university departments and system schools have expressed an interest in participating as the program matures and expands. Additionally, a number of individuals who currently are employed in industry and at the FDA have expressed an interest in teaching in the new Regulatory Affairs Program.

Core faculty for graduate studies:

C. (Tony) Capomacchia, Ph.D., Associate Professor, Department of Pharmaceutical & Biomedical Sciences

Stuart Feldman, Ph.D., Professor, Department of Pharmaceutical & Biomedical Sciences and Associate Director for Biomedical and Health Science Institute

George Francisco, Pharm.D., Professor, Department of Clinical and Administrative Pharmacy and Associate Dean, College of Pharmacy

Robert Galen, M.D., Clinical Professor, Department of Clinical and Administrative Pharmacy

Saundra Granade, Ph.D. candidate, Department of Pharmaceutical & Biomedical Sciences

David Mullis, Ph.D., Associate Professor, Department of Pharmaceutical & Biomedical Sciences and Director, Regulatory Affairs Graduate Education Programs

Randall Tackett, Ph.D., Professor, Department of Clinical and Administrative Pharmacy

Public Service faculty for adult education management and outreach delivery:

Paul Brooks, Pharm.D., Public Service Associate and Director for Postgraduate Continuing Education and Outreach

Jayne Smith, M.Ed., Public Service Assistant and Assistant Director for Distance Learning

Johnna Hodges, M.Ed., Public Service Representative and Coordinator, Instructional and Student Resources

Steering Committees
Two key advisory groups have been assembled to help set the strategic direction and focus the certificate program curriculum in practical ways: an Advisory Board and a Curriculum Committee. These groups are comprised of regulatory affairs professionals from Georgia-based bioscience industries, the FDA, and UGA.

Regulatory Affairs Advisory Board:

University of Georgia Representatives:
Bob Boehmer, J.D.
Paul Brooks, Pharm.D.
Anthony Capomacchia, Ph.D.
J. Griffin Doyle, J.D.
Stuart Feldman, Ph.D.
George Francisco, Pharm.D.
William Hearn, M.B.A.

Industry Representatives:
David Dodd, M.S., CEO, Serologicals
Robert T. McNally, Ph.D., President, Cell Dynamics LLC
Alan Minsk, Esq., J.D., Arnall Goldman Gregory
Gary Dykstra, M.S., Regional Director, Food and Drug Administration
Patty Fritz, M.S., UCB Pharma

Regulatory Affairs Curriculum Committee:

University of Georgia Representatives:
Paul Brooks. Pharm.D.
Jayne Smith, Ed.D. candidate
David Mullis, Ph.D.
Johnna Hodges, M.Ed.
Saundra Granade, Ph.D. candidate

Industry Representatives:
Penny Northcutt, Ciba Vision
Sue Sutton Jones, M.S., VP RA/QA/C/Medical Affairs, Serologicals
Michael Vollmer, J.D., Esq.
Robin Hart, Ph.D., Director RA Merial
Robert Coleman, M.S., Drug Expert, Food and Drug Administration
Don Ruggirello, Ph.D, Solvay Pharmaceuticals
Wayne Wiley, R.Ph., Elan Drugs

Adjunct and Contract Instructors
A number of individuals who currently are employed in industry and at the FDA have expressed an interest in teaching areas of expertise in the certificate program. These include members of the steering committee and others who work in the biomedical industry and who have expertise in regulatory science.

Library, computer, and other instructional resources
Critical to the success of the Regulatory Affairs Program are library and electronic resources. The UGA-Gwinnett University Librarians, Dr. Gene Ruffin and Ms. Claudia Shorr, have assisted us in determining appropriate on-line and print-based resources that students can use, and have helped us research electronic and digital availability and costs. ICAPP funds are available to purchase reference resources, books, materials, DVDs, and CD ROMs. These materials come from the Regulatory Affairs Professional Society, the Food and Drug Law Institute and other publishers. Many of these resources will be housed in GUC's library. Others will be offered online by GUC for student access from off-site locations.
Our program will utilize a blended approach of distance learning and on-site workshop. Our primary instructional resource will be WebCT. The Office of Instruction Support and Development will provide the necessary support to both students and faculty for WebCT assistance.

Currently, faculty members have the necessary software, email and internet access to support the development of this program. There is sufficient infrastructure at the GUC to provide computer technical assistance, wireless network access, and internet access.

Physical Facilities
Physical Facilities necessary to fully implement the program include those at the Gwinnett University Center. Its proximity to Atlanta, which is where our target audience is, makes it an ideal location for conducting face-to-face synchronous instruction. There are many state-of-the art teaching classrooms at GUC for study and on-site sessions.

Proposed Budget

At present, the Regulatory Affairs program is being supported from a Board of Regents' (ICAPP) grant. Additionally, commitments of cash and in-kind support have been secured from Industry. This support will be available into 2007. Income to cover expenses for subsequent years will be generated from tuition return, program fees, industry support, and additional potential grant support. Below is a summary of projected expenses:

Year	First Year –FY 2006	Second Year-FY 2007	Third Year –FY 2008
(1) Personnel	$110,000	$115,000	$118,000
(2) Operating Costs	$ 11,000	$ 18,200	$ 19,400
(3) Capital Outlays	$ 7,000	$ 7,300	$ 7,600
(4) Library Acquisitions	$ 5,000	$ 2,500	$ 3,000
(5) Total	$133,000	$143,000	$148,000

Student Support

There are no scholarships or assistantships specific to this program. From our meetings with Industry officials, we have received their assurance that a number of companies will send their employees through this credentialing program. Some businesses offer a reimbursement upon completion of a semester, while others allow for $5,000 per year in educational expenses. In addition to these commitments, we have received in-kind and cash donations to assist with the general operating expenses of the program.

Admission, Retention and Administration of Program

Admission Criteria to the Certificate Program:

1. Georgia residents will be given priority. Those applying as Georgia Residents must complete Application for Georgia Residence Status.

2. A Bachelor's degree (or higher) is required. Preference will be given if applicant's degree is in sciences, healthcare, or engineering.

3. Preference will be given if applicant is employed in the pharmaceutical, medical device, biotechnology industries or related field. Applicants are encouraged to include in their application documents *a company support letter*.

4. Daily access to a computer with required specifications and a working knowledge of the Microsoft Windows Operating System, Microsoft Office Suite (including MS Word, Excel) Internet Explorer or Netscape Navigator and Adobe Reader.

Admission Process (a two-step process):

1. Complete the UGA Graduate School Application as Non-degree seeking student, providing The UGA Graduate School with
   a. Two official copies of academic transcript from the institution awarding the highest degree sent to Graduate School.
   b. A $50 application fee
   c. Graduate School application (on-line or PDF), noting non-degree status

2. Complete Regulatory Affairs Graduate Education Program Supplemental Application
   a. Two-page Personal Information Profile
   b. A Distance Learning Self-Assessment
   c. Professional résumé outlining applicant's regulatory affairs experience
   d. Two Letters of recommendation (using standardized criteria)
   e. Letter of Support from Employer, outlining how the program will advantage the potential student and the industry. (as applicable)

Admission to the certificate program is a distinct process offered for both non-degree and degree seeking students, who meet the criteria above. Non-degree seeking students must complete the

application process stated above and will not be required to submit a GRE score. Potential students who wish to apply for a graduate degree program of study and possibility utilize coursework taken in the certificate program, must complete a separate Graduate School Application as a degree-seeking student must follow the directions required of the Graduate School, which includes submission of an appropriate GRE score required of the program of study. In no way will students be offered an opportunity to "track-in" to a degree-granting program or achieve degree status without following the current policies and requirements set forth by The Graduate School for that purpose.

Retention

In order to remain in the certificate program, students will be required to maintain a minimum grade point average consistent with graduate school requirements. Every effort will be made to support students who are concerned about their academic standing. This includes additional tutoring and mentoring.

Administration

Currently, there are five faculty and one staff charged with the development and operation of this program. David Mullis, as Director, is charged with developing the course content and industry relationships so critical to the program's success. Johnna Hodges whose area of expertise include adult and distance education is charged with the online learning components and the day-to-day management of the program and support staff supervisor. Students will have support in the area of administration (such as assistance with registration) and technology from an Educational Program Specialist, Ms. Angie McVey. Additionally, Dr. Stuart Feldman Professor of Pharmacy, will oversee Graduate Faculty policies; Dr. Paul Brooks, will oversee overall University and Board of Regents policies; and, Ms. Jayne Smith will oversee overall Delivery and Instructional policies.

Office space for these personnel is provided at the College of Pharmacy Offices in Athens and at UGA-Gwinnett on the GUC campus. ICAPP funds have provided the necessary monies for computer and technology equipment and software, to support efficient and effective work.