The University of Georgia
College of Pharmacy
Office of Public Service and Outreach

Masters of Science in Pharmacy (with an emphasis in Regulatory Affairs)

Addendum for Distance Education Delivery

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Addendum for Distance Education Delivery

Institution: The University of Georgia (UGA)
College/School/Division: College of Pharmacy
Department: Office of Postgraduate Continuing Education and Outreach
Degree: Master of Science in Pharmacy
Major: Regulatory Affairs
CIP Code:
Proposed State Date: First cohort beginning June 2006 (Summer Semester 06)
Proposed End Date: Ongoing

Introduction

In order to comply with UGA's Curricular Office Policies, this document outlines the proposed delivery of an existing degree (Master of Science in Pharmacy) using distance learning modalities. Distance education delivery is proposed for eligible students pursuing the Master of Science in Pharmacy, with an emphasis in Pharmaceutical and Biomedical Regulatory Affairs. In general, the curriculum will cover comprehensive FDA regulations of pharmaceutical, biotechnology, and device industries, food and drug laws, current good manufacturing practices and bioethics. Course work will follow the traditional academic pace, but will use extensive and technologically demanding internet-based means to produce streaming video and audio presentations as well as video conferencing on top of slide and manuscript presentations, on-line discussions, projects, and exams., The delivery mechanisms are intended to facilitate the needs of working adult students.

Based on present interests, the Regulatory Affairs Program expects to enroll between eight and twelve students for its initial masters level courses. These students will most likely be from within Georgia and the surrounding states and currently employed in the pharmaceutical and biomedical industries. However, over time, the program will draw students nationally because of the limited number of regulatory programs nationwide. In most cases it is expected that these working professional students will participate on a part-time basis while they maintain their current positions.

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1. Description of the Delivery System

The primary delivery mode will be computer-based internet instruction using WebCT course management platform provided by the University of Georgia; however, approximately 20% of instruction will occur during on-site weekend sessions that could be broadcast to multiple sites. The WebCT software can be used to create entire courses using text, images, video, and audio presentations. Courses can be accessed through a web browser such as MS Internet Explorer and Netscape Navigator. Student and Instructor interaction will take place through the bulletin boards, for threaded synchronous discussions, and though the built-in email feature. Chat rooms may be used for synchronous real-time discussions. HorizonLive, HorizonWimba, and other platforms also will be used to facilitate the real-time discussion.

2. Assessment of Societal Need and Demand for Distance Education

Pharmaceutical and Biomedical Regulatory Affairs professionals are employed in industry, government and academia and provide a range of support services related to the product development, manufacturing and marketing of pharmaceuticals, medical devices, in vitro diagnostics, biologics, biotechnology, nutritional products, cosmetics, and veterinary products. Due to the rapidly expanding biotechnology industry, there is a substantial need for additional highly trained professionals ready to perform the work required within this specialized industrial sector. Education and professional development are critical to the regulatory affairs professional, who must keep up-to-date with laws, regulations and regulatory guidance documents for one or more product lines as well as maintain an understanding of the scientific and technical background of new products.

The need for a distance delivery program was determined after researching the most conducive ways to deliver the regulatory affairs content. Industry representatives indicated that it would be most beneficial if their employees could participate, but not have their jobs interrupted by traditional class attendance. Considering that students in the UGA Regulatory Affairs program will be working adults, distance education methodologies and weekend sessions are best suited for these learners, who must juggle job demands, location, or family responsibilities. Moreover, web-based instruction provides a new avenue to attract a greater pool of students into this program.

The need for a regulatory affairs program in Georgia was determined following a study commissioned by The Board of Regents in 2003, which found 35 immediate openings among life sciences companies in Georgia. Additionally, the Chamber of Commerce identified several projects (companies) that have recently considered Georgia; but, the absence of quality and regulatory professionals was an important consideration in their decision not to relocate to Georgia.

Project Name	**Scope of Project**	**# Of Employees in quality/regulatory affairs**
Project Rain	Georgia was pre-selected by Deloitte and Touche Consulting, who conducted a global screening for the CA-based biomanufacturing company. A total of 250 employees and an investment of $130 million planned.	70 BA/BS at $40.00/hr.
Project Orca	Project is considering a site in Gainesville for protein fermentation manufacturing. A	100 at $25-$40 / hr.

	total of 750 jobs with an overall investment of $550 million over 10 years.	
Project Cactus	Project is considering sites in Georgia for biomanufacturing. Ultimately, client will employ 500 with an investment of $200-$300 million.	50-75 in quality assurance

3. Readiness of Institution to Offer the Program

a. Institutional Mission and Relevance to Other Programmatic Offerings

The implementation of an extended education Masters of Science in Pharmacy degree program (with an emphasis in regulatory affairs) by the College of Pharmacy augments the University of Georgia's mission to provide a teaching/learning environment for interested students coming from diverse backgrounds with a focus on high achievement, excellent instruction quality. A comprehensive program of regulatory education through computer–based and distance education instruction is better able to maximize UGA's commitment to reach students in areas not currently served by the University, the area of Regulatory Affairs.

b. Faculty Inventory with Delivery Expertise

UGA's College of Pharmacy has been a leader in distance learning instruction. Currently, the college has two web-based academic programs for professional students, The Nontraditional Doctor of Pharmacy Degree (with over 150 enrolled students) and The Regulatory Affairs Graduate Certificate Program, which began January 2005 (with over 20 students enrolled). The Masters Program will employ many of the resources already established for these programs. Currently, the College employs two fulltime instructional managers for online programs who provide expertise in adult and distance learning methodologies and directly assist each faculty member with course development and implementation. Moreover, these managers are assisted by two program specialists, having computer and web skills for faculty and student support.

Prior to teaching an online course, faculty members will be instructed in the area of distance education delivery so as to develop each online course. The university provides training in WebCT for all faculty members involved in distance education activities as well as technical assistance for faculty and students. Course design is supported by the WebCT Template, which guides the faculty member through the development of coursework.

c. Facilities

Except for the regular upgrading of computers for faculty members, there are no modifications of existing facilities to establish and maintain the alternative delivery of the program. Currently, the administrative base for this program is located at University of Georgia at Gwinnett, Lawrenceville, Georgia. This site was selected because of its proximity to the Atlanta area.

d. Instructional Support

The University of Georgia and the College of Pharmacy have extensive resources to support students enrolled in distance learning activities. Students may apply for admission to the program and to the Graduate School online as well as register for classes. The program is utilizing the Department of Adult Education's Distance Learning Self-Assessment to determine each student's readiness and skills level for success in the online learning environment.

Students will be advised and counseled by their academic advisor through e-mail or telephone, and when feasible, through face-to-face meetings. Student/instructor interaction will take place through WebCT's bulletin board for threaded asynchronous discussions, chat rooms for synchronous real-time discussions, e-mail, and telephone calls.

All courses will be approved though the CAPA process and course materials will be delivered either electronically or mailed between the students and instructors. Grades will be determined by the quality and quantity of online discussions, class assignments, projects, papers, online activities and on-site assignments. Evaluation of each course will be an ongoing process based on course requirements and student interaction and satisfaction. Moreover, proctored exams at official testing centers will be utilized for written culminating exams. Oral examinations will be conducted, as needed, by committee. Evaluation of the course and the instructor will be completed at the end of each course according to university guidelines.

e. Student Services

The University of Georgia and the College of Pharmacy have extensive resources to support faculty and students enrolled in distance learning activities. Through Student E-Services, students have access to information about the bookstore, e-mail accounts, and access to technology support services. Students registered for courses at the university may gain access to the library system by following the instructions at http://libs.uga.edu/galileo.html. In addition, students will have access to the Gwinnett University Center Library.

f. Cooperative links with the Community

This program will go far to fill gaps in both life sciences education and economic development in Georgia. Over the next decade, we believe this program could add hundreds of jobs to the state's emerging life sciences industry. The curriculum for this program is modeled after several existing programs outside of Georgia; but, in developing our curriculum, we have worked very closely with industries in Georgia and the surrounding states.

Two key advisory groups have been assembled to help management set the strategic direction for the regulatory affairs program and will serve to focus the masters curriculum in practical ways. These groups are comprised of management and 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.

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
William Hearn, M.B.A.

Regulatory Affairs Curriculum Committee:

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

Industry Representatives:
Penny Northcutt, Ciba Vision
Michael Vollmer, J.D., Esq.
Felipe Doltz, DVM, Executive Director, Worldwide Regulatory Affairs, Merial
Robert Coleman, M.S., Drug Expert, Food and Drug Administration
Don Ruggirello, Ph.D, Solvay Pharmaceuticals
Wayne Wiley, R.Ph., Elan Drugs
Vacancy, to be filled by representative from Serologicals

g. Accreditation and Legal Issues

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 developed based on RAPS core competencies and plans to register for RAPS listing of nationally recognized program in regulatory affairs. However, presently there is no accreditation required by RAPS or any other accreditation agency for regulatory affairs graduate based education. The Regulatory Certificate Program recently underwent a University Program Review as part of an over assessment of the College of Pharmacy's graduate offerings. In their report, the Program Review committee supported the option of a distance learning master's degree in pharmacy (with an emphasis in regulatory affairs). The committee noted that such program "would offer advanced training in quality control and quality assurance, pharmaceutical process control and validation, and biostatistics related to clinical trials management. The committee feels this is a laudable ambition that will further the development of pharmaceutical and biomedical enterprises in Georgia."

4. Recruitment and Admission of Students

The Regulatory Affairs Graduate Education Program has been developed to meet the human resource needs for regulatory affairs professionals in the health products industry. As such, our program will recruit potential students and enroll those students based on 1) their current professional position within the regulatory affairs arena and/or 2) their bachelor's degree in the sciences if they are coming directly from an undergraduate program.

Admission Criteria to the Masters of Science in Pharmacy, with an emphasis in regulatory affairs:

- A Bachelor's degree (or higher) is required.
- The admissions committee will consider multiple criteria, such as, but not limited to, academic background and work experience in related fields of pharmaceutical and biotechnology

industries. Applicants are encouraged to include in their application documents *a company support letter*.

- 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 to the Masters of Science in Pharmacy, with an emphasis in regulatory affairs (a two-step process):

- Complete the UGA Graduate School Application as a degree seeking student for the Master of Science in Pharmacy, providing The UGA Graduate School with:
  - Two official copies of academic transcript from the institution awarding the highest degree sent to Graduate School.
  - **Official** copy of GRE score
  - A $50 application fee
  - Graduate School application (on-line or PDF)
- Complete Regulatory Affairs Graduate Education Program Supplemental Application
  - Two-page Personal Information Profile
  - A Distance Learning Self-Assessment
  - Professional résumé outlining applicant's regulatory affairs experience
  - Three Letters of recommendation (using standardized criteria)
  - Letter of Support from Employer, outlining how the program will advantage the potential student and the industry (as applicable)
  - Applicant essay describing student's purpose in pursuing graduate studies in regulatory affairs and relationship to personal and professional objectives.
- Applicant Interview with Program Faculty

5. Curriculum

The academic standards for this program are the same as those for on-campus delivery. Expectations concerning student readings, discussions, papers, and grades are consistent with departmental and CAPA standards. Assessment will be ongoing and will include proctored written exams and oral examinations by committee. All of the courses offered are appropriate for distance delivery. There are no laboratory requirements.

The following is a listing of courses and credit hours for the Master of Science degree in Pharmacy with an emphasis in Regulatory Affairs.

Master of Science in Pharmacy with an emphasis in Regulatory Science (37 semester hours)

Core (22 semester hours):

Completion of Certificate Courses (13 semester hours)

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

Additional Core Courses (9 semester hours):

PHAR 6100 Quality Control and Quality Assurance (3 sem hrs)

PHAR 6120 Process Control and Validation (3 sem hrs)
BIOS 7100 Biostatistical Applications for Pharmaceutical & Biotech Industries (3 sem hrs)

Electives (minimum of 9 semester hours):

Program Electives (must complete at least 6 semester hours of program electives)

Regulatory Affairs for the Pharmaceutical Industry (2 sem hrs)
Regulatory Affairs for the Biotechnology Industry (2 sem hrs)
Regulatory Affairs for the Medical Device Industry (2 sem hrs)
Clinical Trials Management (3 sem hrs)
Critical Issues in Regulatory Sciences (3 sem hrs)
Topics vary: Indepth analysis of major regulatory issue or regulated industry (e.g., Animal Health Products, Combinaton Products)
Comparative Global Regulations (3 sem hrs)
Internship in Regulatory Affairs (3 sem hrs)
PHRM 6800 Applied Project in Regulatory Affairs (3 sem hrs)

Other Electives: (* = with approval by home department)

PHRM 8660 Health Care Marketing (3 sem hrs)
*MGMT 7010 Developing Leadership Skills (1-3 sem hrs)
*MGMT 7220 Project Management (3 sem hrs)
*SPCM 6610 Health Communication (3 sem hrs)

Thesis (6 semester hours):

The master's thesis is either a basic or applied research project conducted by the student supervision of the student's advisory committee. A final oral examination is required.

PHRM 7000 Masters Research (3 sem hrs)
PHRM 7300 Masters Thesis (3 sem hrs)

6. Consistency with Principles of Good Practice

All distance-learning activities offered by the College of Pharmacy are in accord with the Principles of Good Practice as outlined at The Advanced Learning Technologies website: http://alt.usg.edu/research/goodpractice.html.These principles encourage a high level of student-faculty contact, cooperation among students, active listening, prompt feedback, emphasis on task, assessment integrity, communication of high expectations, and respect for diverse talents and ways of learning (Chickering & Gamson, 1987). The department will assess all online courses through surveys and questionnaires and faculty and student interviews.

The program provides an appropriate balance of foundation, core, research, and elective courses and through the sequential scheduling of courses students are better able to plan their program of study. The learning structure provides opportunities for growth and development, faculty support, and the rigor of the program is comparable to traditional programs.

7. Fiscal Implications of the Program

The program plans to enroll its first master's level student cohorts in May 2006. The information below shows the projected costs in its first year (FY05):

Proposed Budget for Regulatory Affairs Graduate Program (P = Projected)

FY	05-06 (P)	06-07 (P)	07-08 (P)
INCOME			
Unrestricted funds from previous yr [p]	14,450	7,592	233
Tuition return [p]	21,902	39,241	50,193
Program fees [p]	54,000	91,800	129,000
Grant support [p]	95,000	50,000	25,000
Industry support [p]	5,000	5,000	5,000
Total Income	**183,352**	**193,633**	**209,426**
EXPENSE			
Personnel			
Faculty	122,000	115,000	118,000
Staff	30,000	22,000	23,000
Benefits	18,200	14,000	14,600
Extra Compensation	4,500	4,500	6,500
Honorarium	4,500	9,000	9,000
Total Personnel	**179,200**	**164,500**	**171,100**
Operating			
Supplies	14,770	20,000	22,000
Software	5,000	2,000	2,000
Teaching Resources	8,000	5,000	2,500
Recruiting/Marketing	3,000	1,000	2,000
Postage	1,000	1,000	1,200
Telephone/Fax	1,000	1,000	1,200
Total Operating	**32,770**	**23,000**	**28,900**
Total Expenses	**213,970**	**180,760**	**193,400**
GRAND TOTAL	**14,450**	**7,592**	**233**

a. What is the funding stream for this type of delivery as well as upgrades and replacements?
The funding stream for the program will be derived from tuition returns, which augment the base budget. Initially, the College of Pharmacy received an ICAPP grant to support the development of regulatory affairs graduate certificate to help fill a vital workforce need for specialized professionals in Georgia biomedical companies. The projected budget illustrates the necessity of a substantial program fee and tuition return in order to meet our goal of breaking even in year three (see tuition and fee rate below).

b. What are the line costs for delivering this program?
The majority of courses in the program are taught as part of normal instructional assignments by UGA faculty. Consultant faculty from industry may require extra compensation.

c. Will tuition adjustments be requested?
Regular in-state graduate student tuition will be assessed (currently $182/semester hr) along with an additional program fee (currently set @ $1,350 per student per semester), which will be returned to the College to cover the costs of this self-supporting program.

At present, the primary audience is Georgia residents who will pay in-state tuition. Future enrollment projections include attracting a regional audience and then a national and international

audience. Nationally, there are a limited number of programs in regulatory science; therefore, our program has generated significant attention from bioindustry leaders in Georgia, the Southeast and elsewhere. Additionally, our program helps the Board of Regents' achieve its goal of developing curricula that matches the economic development needs of the state. Because of these dynamic factors, we remain optimistic that our program will continue to attract grant and industry support that will help offset the start-up costs of the program, while we grow in enrollment and credit hour production.

Tuition and Fee Schedule - Comparison with other National Programs

Tuition and Fees Schedule	1hr	3hr	6hr	9hr
Current Grad In-State Tuition Rate (182/hr)	182	546	1,092	1,638
Technology Fee	75	75	75	75
Program fee per semester	1,350	1,350	1,350	1,350
Total per semester	1,607	1,971	2,517	3,063

Graduate Programs in Regulatory Affairs for Comparison

Institution	1 course/semester (3 semester hr)	2 courses/semester (6 semester hr)
Johns Hopkins	2,075	4,150
UGA	**1,971**	
San Diego State	1,910	3,820
Temple University	1,872	3,744
Northeastern	1,323	2,646
UGA		**2,517**
California State	708	1,416

d. What are the external sources of funding and support for the program?

Initially, the College of Pharmacy received an ICAPP grant to support the development of regulatory affairs curricula to help fill a vital workforce need for specialized professionals in Georgia biomedical companies. Upon conclusion of this grant, the program will plan to be self-supporting. The fee structure of $1350 per semester and $182 per credit hour will allow the program to be self sustaining without the need of external funding sources.

e. Will there be any operating budget request for this program that would exceed normal operating budget guidelines?

There will be no operating budget requests for this program that would exceed normal operating budget guidelines. The University already provides site licenses for WebCT, networks to host the hardware and software, and support services through the Office of Instructional Support and Development as well as MSD (Manage Software Distribution). Faculty members already have access to laptop to be able to teach in the program anywhere and anytime. In addition, MSD provides software at reasonable prices so faculty members can to stay current with the latest software developments.

f. Please demonstrate the cost and benefit of developing this program for a distance education format.

By creating this program in a distance learning environment, we are attracting prospective students to the University who might not otherwise consider an advanced or graduate degree in Regulatory

Affairs. This program will serve an audience of professionals who because of distance would have to travel to the UGA for an on-campus certificate or master's degree. Furthermore, the demands of their work and personal lives could prevent them from attending an on-campus program. Thus, this program will serve an entirely new audience and truly extends the boundaries of the campus to anywhere in the world.

8. Assessment

Assessment and evaluation will focus on the course/program, instructors, students, and technology. Instructional results will be assessed throughout the courses as well as through summative evaluations at the completion of each course. This will allow the instructor to know how well the goals were achieved as well as the learning outcomes. Students will demonstrate knowledge acquisition through the completion of quizzes, papers, projects, and activities that relate to the instruction. Additionally, level of achievement will be compared to traditional classroom achievement to ensure that the same high standards are maintained in the distance education delivery system.

As part of an ongoing evaluation the department will address the following areas:

- Student participation online and the quantity and quality of this participation
- The quantity and frequency of interaction between students and between the instructor and the students
- Student satisfaction and comfort level with the learning environment
- Institutional resources available to students, such as technical support, library usage, and the bookstore services
- Evidence of the development of critical thinking skills and knowledge acquisition reflected in student assignments, communications, and projects
- Student retention and satisfaction
- Faculty satisfaction

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