University Council

February 27, 2026

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Dear Colleagues:

The attached proposal from the College of Pharmacy for an Online Graduate Certificate in Biopharmaceutical Regulations will be an agenda item for the March 6, 2026, Full University Curriculum Committee meeting.

Sincerely,

Susan Sanchez, Chair

cc: Provost Benjamin Ayers
Dr. Marisa Anne Pagnattaro

PROPOSAL FOR AN ONLINE CERTIFICATE PROGRAM

Date: 10/16/2025

College/School: College of Pharmacy

Department/Division: International Biomedical Regulatory Sciences

Certificate Title: Biopharmaceutical Regulations

CIP: 51200202

Level: Graduate

Campus: Online

Proposed Effective Date: Fall 2026

Program Abstract:

The International Biomedical Regulatory Sciences (IBRS) program's objective is to provide graduate-level online education designed to increase knowledge in the regulatory framework and to develop competencies in regulatory, clinical, and government processes that are critical in helping assure the development, manufacturing, and marketing of safe and effective medical products around the world. The assessments and evaluations during the courses and final project work enhance competencies such as critical thinking, problem solving, communication, and strategic thinking needed to be successful in the medical products industry.

Regulatory Affairs (RA) professionals are employed in industry, government and academia and provide a range of services related to the regulation, development, manufacturing and marketing of pharmaceuticals, medical devices, *in vitro* diagnostics, biologics, biotechnology, nutritional products, cosmetics, and veterinary products. There are many specialized areas within the regulatory sciences, and the proposed certificate will address one of the areas.

The College of Pharmacy proposes a Graduate Certificate in Biopharmaceutical Regulations to allow students to gain specialized knowledge and regulatory expertise for working in this area of the medical products industry. The biopharmaceutical industry is expected to continue its robust long-term growth, with some reports projecting 7% growth by 2032, far exceeding the average for all occupations. Developing and offering this graduate certificate will support the workforce development needs in this sector. The certificate curriculum will require a total of 18 credit hours and will cover an overview of regulatory requirements for medical products and bioethics for research and development of medical products, good clinical and manufacturing practices, and biopharmaceutical regulatory science. The students receiving the Graduate Certificate in Biopharmaceutical Regulations will be knowledgeable in the life cycle of medical products from development to post-marketing, which are essential skills for workforce preparedness for professionals in the field.

Roles and Responsibilities of a Biopharmaceutical/Biologics Regulatory Professional:

- Research applicable laws, guidelines, and standards (e.g., FDA, CFR, EMA, WHO, ICH) related to biopharmaceuticals and biologics.

- Communicate key regulatory insights to internal stakeholders for successful development of biopharmaceutical products including preparation of regulatory strategy and risk assessments. Support preparation of briefing documents for regulatory agency meetings.

- Liaise with teams in Quality Assurance, Clinical, Manufacturing, and Research and Development to ensure regulatory requirements are integrated into project plans.

- Support regulatory activities for marketed biologics or biopharmaceuticals (e.g., CMC updates, labeling changes, post-approval variations) and provide input in change control processes. Monitor and communicate changes in global regulatory requirements.

- Prepare, review, and compile regulatory submissions (e.g., INDs, BLAs, NDAs, CTAs, amendments, and annual reports) related to biopharmaceuticals and biologics including biosimilars. Track submission status, commitments, and approvals to ensure timely compliance.

1. Assessment

A needs assessment demonstrating a sufficient pool of qualified applicants.

The College of Pharmacy currently offers graduate-level certificate programs in International Biomedical Regulatory Sciences; Clinical Trials Design and Management; Drug Safety and Pharmacovigilance; and Chemistry Manufacturing and Controls, as well as a Master of Science (M.S.) degree in Pharmacy, with areas of emphasis in International Biomedical Regulatory Sciences and Clinical Trials Management. The graduate certificate programs provide a foundational core for individuals who wish to transition into entry-level regulatory affairs or clinical trial positions. These graduate education offerings are geared for both working professionals and traditional students using an online learning environment designed to allow individual flexibility yet provide a standard academic structure to advance student learning from one semester to the next.

Currently, there are only graduate programs available for Regulatory Affairs Professionals. Most regulatory professionals start in one area within the medical products industry and then transition into regulatory affairs. According to the Regulatory Professional Society (RAPS), more than half of the regulatory professionals have an advanced degree such as a master's or Ph.D. that is not necessarily in regulatory sciences. With the growth of the discipline of regulatory sciences, many universities are offering graduate programs in regulatory affairs or allied fields such as quality assurance and clinical. The area of biopharmaceuticals and biologics, such as monoclonal antibodies, mRNA therapeutics, and cell and gene therapy, is anticipated to drive future growth in the medical products industry. Companies expanding in this area are looking for advanced education and credentialing of professionals in this area of biopharmaceuticals. There is also an expectation that there are opportunities for personalized medicine with the advancement of cell and gene therapy products. The faculty anticipate that the proposed graduate certificate along with other graduate certificates or master's degrees offered by the IBRS program will support the expected workforce need in advanced education and credentialing in area of biopharmaceuticals.

A needs assessment was conducted to demonstrate that there is sufficient pool of qualified applicants. The University of Georgia student population participated in the needs assessment

as many of the graduate certificate and master's degree prospective applications generally are from this pool of students who take courses or pursue graduate certificates to enrich their resumes.

To assess the interest of students in obtaining a Graduate Certificate in Biopharmaceutical Regulations as part of their educational program, an anonymous QuestionPro survey was sent to all graduate students within the College of Pharmacy, the College of Engineering, the College of Agricultural and Environmental Sciences, as well as the College of Veterinary Medicine. A total of 91 students completed the survey. The majority of the students who responded to the survey were either Pharm.D. or Ph.D. students, followed by graduate students in other programs.

Fig.1: Demographics of Participants in the Survey

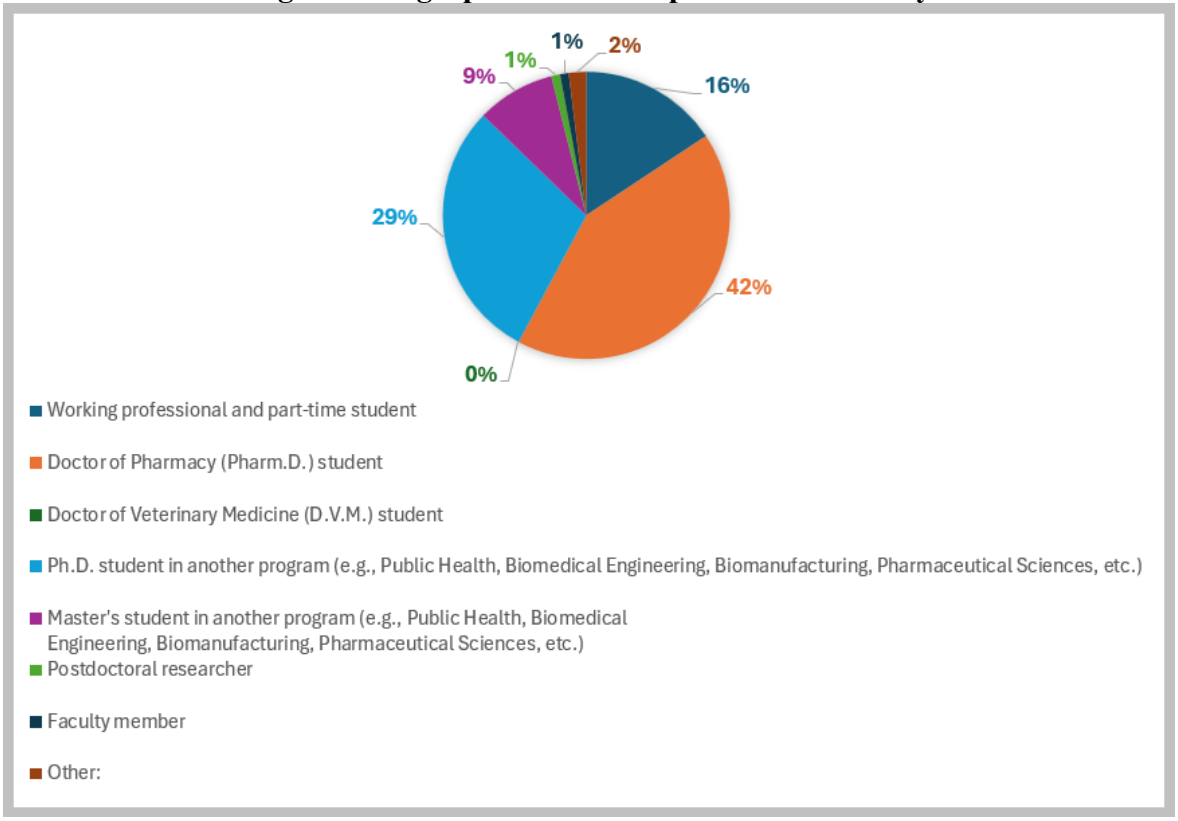
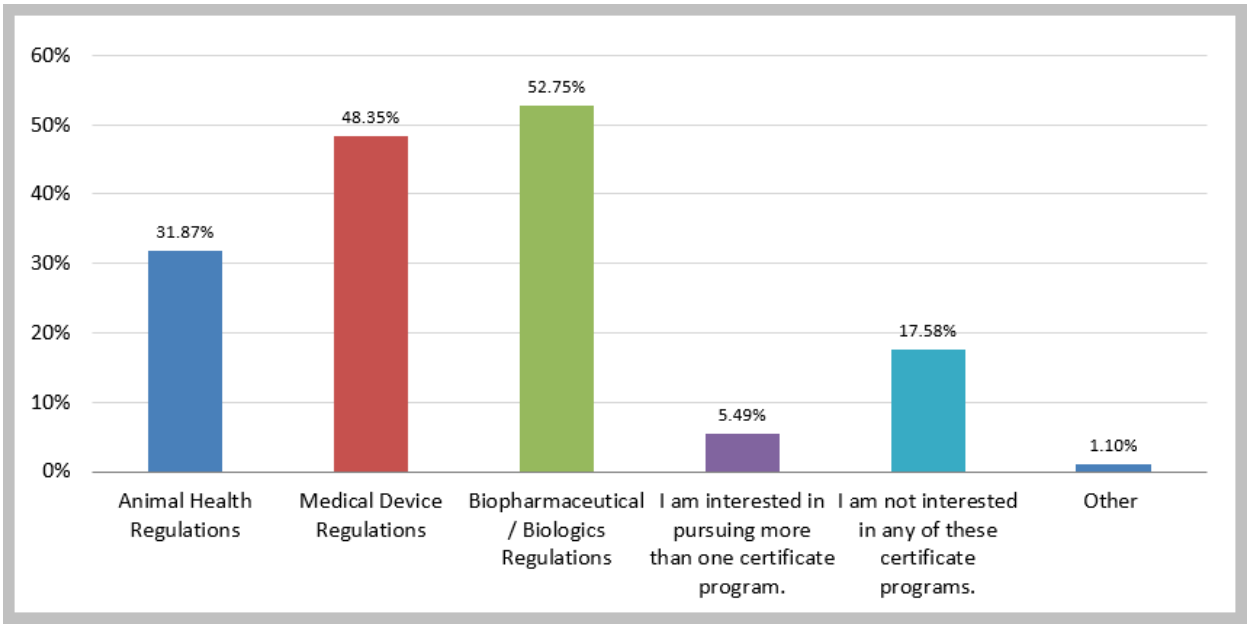


Fig. 2: Student Feedback on Interest to Obtain a Biopharmaceutical/Biologics Regulations Graduate Certificate



Overall, approximately 53% of the students that participated in the survey were interested in obtaining the proposed certificate. The percentage increases to approximately 57% if those students interested in obtaining more than one certificate program are added. This assessment clearly supports that there is a sufficient pool of qualified students with interest in obtaining the proposed Graduate Certificate in Biopharmaceutical Regulations, which could complement their current academic aspirations, such as Pharm.D., Ph.D., or master's degrees in other disciplines.

2. Admission Requirements

All requirements for admission to an Online Academic Degree Program will be the same as those for the same degree at an authorized unit.

All requirements for admission to an online academic degree program will be the same as those for the other graduate certificates currently offered by IBRS, as outlined below:

Admission Criteria:

- A bachelor's degree (or higher) is required. Preference will be given if applicant's degree is in life sciences, healthcare or engineering.
- The minimum undergraduate GPA standard for admission to the Graduate School at the University of Georgia for applicants who do not have a prior graduate degree is 3.0.
- Preference will be given if an applicant is employed in the pharmaceutical, medical device, biotechnology industries or related field.
- Applicants MUST apply to the UGA Graduate School

- Applicants are encouraged to include in their application materials a letter of support.

- Applicants must include a statement of purpose, no more than 3-pages, that addresses why they wish to enroll in this program.

- TOEFL scores are required for international applicants.

- 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 and Adobe Reader.

Note: Some of these requirements may be waived for students who want to pursue a graduate certificate while currently enrolled in another UGA graduate or terminal degree program using the Fast-Track application process.

3. Program Content

The basic curriculum of the program will be equivalent to the authorized unit's approved program. The criteria for electives or substitutions for specific requirements will be equivalent online.

The learning objectives of the Graduate Certificate in Biopharmaceutical Regulations are designed to prepare students for work in the highly regulated medical products industry in the specialized area of Biopharmaceuticals and Biologics. Specifically, upon completion of this certificate program, students should be able to:

1. Apply regulatory principles governing pharmaceuticals, biotechnology and medical device industries.

2. Evaluate ethical consideration throughout the research and development of biopharmaceuticals, and interpret regulatory standards for safety, efficacy and quality.

3. Describe the unique characteristics and regulatory challenges associated with biopharmaceuticals/biologics including monoclonal antibodies, vaccines, biosimilars, oligonucleotides, cell and gene therapy products.

4. Explain the regulatory framework and submission requirements of biopharmaceuticals and biologics.

5. Develop strategies for successful clinical trial applications and marketing approvals.

6. Apply principles of post-market compliance, pharmacovigilance, and risk management requirements, including REMS.

7. Discuss emerging trends in advanced therapies, such as cell and gene therapies and vaccines.

8. Formulate effective strategies to prepare for and respond to regulatory authority questions, submissions, inspections, and meetings.

The certificate will be assessed as per the established goals and criteria for quality by the

College of Pharmacy. These include determination of the effectiveness by measuring the success of students earning the certificate and may include longitudinal review of graduates and their employment status.

Below is the outline of the curriculum for the Graduate Certificate in Biopharmaceutical Regulations.

- **PHAR 6010E, Pharmaceutical, Biotechnology, and Device Industries (4 hours):** 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. [Learning objectives – 1, 6, 8]

- **PHAR 6030E, Current Good Manufacturing Practices (4 hours)**: 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. [Learning objectives – 2, 3, 4, 8]

- **PHAR 6170E, Biopharmaceutical Regulatory Science (4):** Foundational knowledge and regulatory framework governing biologics, including monoclonal antibodies, vaccines, cell and gene therapies. Participants will gain a solid understanding of regulatory requirements, submission processes, and compliance considerations to support biologics development including biosimilars, commercialization of the products and life-cycle management including product stewardship. [Learning objectives – 3, 4,7, 8]

- **PHAR 6310E, Good Clinical Practice Regulations for Drugs, Biologic Products, and Medical Devices (3 hours):** 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. [Learning objectives – 5, 8]

- **PHRM 7230E, Ethical Issues in Research (3 hours):** Ethics of research in animals and human subjects, fraud, scientific misconduct, and conflicts of interest. [Learning objectives – 2, 8]

Total = 18 hours

Learning Outcomes	PHAR 6010E	PHAR 6030E	PHAR 6170E	PHAR 6310E	PHRM 7230E
1. Apply regulatory principles governing pharmaceuticals, biotechnology and medical device industries	P	S	S		
2. Evaluate ethical considerations and interpret regulatory standards for safety, efficacy and quality		P	S		P
3. Describe unique characteristics and regulatory challenges of biologics (mAbs, vaccines, biosimilars,		S	P		

Learning Outcomes	PHAR 6010E	PHAR 6030E	PHAR 6170E	PHAR 6310E	PHRM 7230E
oligonucleotides, cell and gene therapies)					
4. Explain regulatory framework and submission requirements for biopharmaceuticals and biologics		P	P		
5. Develop strategies for successful clinical trial applications and marketing approvals			S	P	
6. Apply principles of post-market compliance, pharmacovigilance, risk management, including REMS	P	S	S		
7. Discuss emerging trends in advanced therapies such as cell and gene therapies and vaccines			P		
8. Formulate strategies to prepare for and respond to regulatory authority questions, submissions, inspections, and meetings	P	S	P	P	S

4. Student Support Services

Each proposal must describe how students will have access to appropriate learning and student support services to ensure full participation in the learning experience. Services to be considered include academic advising or an advisory committee, technology support, financial aid advising, career planning, and disability services. Any special accommodations made for distance education students must be described.

Each student will have access to all the learning and student support services available to ensure full participation in the learning experience. Services include academic advising, technology support, career planning, and disability services.

In general, students will be advised during their enrollment in the IBRS Program. The advisor will be available for meetings with the students. Students currently enrolled in another graduate or terminal degree program will also be advised by their regular advisor.

5. Resident Requirements

Residence requirements will be identical to those established for the authorized degree program with residence at the approved location serving to meet that requirement.

Residence requirements will be identical to those established for other certificate programs within IBRS. The program is open to both degree-seeking and non-degree students. Applicants must meet the minimum Graduate School standards and non-degree students are required to apply through the Graduate School application process. All enrolled students will be subject to UGA's residency requirements.

6. Program Management

Each proposal must contain a specified plan for program maintenance and program quality. This plan will provide contact persons at cooperating units, a detailed timetable, and complete plans for application and matriculation of

students. In addition, specific plans should be provided concerning the schedule of courses, the duration of the program, program review, and possible duplication with other programs in the immediate area.

Program Management
The Graduate Certificate in Biopharmaceutical Regulations will be administered within the College of Pharmacy's International Biomedical Regulatory Sciences (IBRS) program. Courses will be taught by faculty who currently deliver these approved offerings within existing IBRS programs and are supported by established course coordinators.

The certificate may be completed at the learner's pace. There is no fixed time-to-completion requirement beyond the Graduate School's policy that coursework must be completed within eight years before credits begin to expire.

All courses included in the certificate are existing, approved IBRS offerings. The certificate utilizes established instructional, administrative, and assessment infrastructure currently in place within the program.

Program Leadership Structure
- **Program Director (IBRS):** Responsible for academic integrity, curriculum oversight, faculty coordination, strategic direction, and external engagement.
- **Assistant Director (IBRS):** Responsible for operational management of the certificate program, including admissions coordination, student advising oversight, course scheduling, compliance tracking, and liaison activities with cooperating units and university offices.

A. Application and Matriculation Plan
Admissions Requirements
Applicants must:
- Hold a bachelor's degree from an accredited institution (or be enrolled in an approved professional program)
- Meet minimum GPA requirements established by the Graduate School of 3.0.
- Demonstrate interest or experience in biopharmaceuticals, biologics, regulatory sciences, or related fields

Application Process
- Applications will be submitted through the university's graduate admissions system.
- Required materials include official transcripts, a statement of purpose, and a CV (if applicable).
- Applications will be reviewed by an IBRS Admissions Committee under the oversight of the Program Director.
- The Assistant Director will coordinate application tracking, communications with applicants, and onboarding logistics.

Admission Cycle
- Two entry cycles: Fall and Spring semesters
- Application deadlines will be published on program websites.
- Admission decisions will be communicated within a defined review period (e.g., two weeks after the application deadline).

Upon admission, students will receive orientation materials outlining program expectations, sequencing recommendations, and completion requirements.

B. Program Structure, Course Schedule, and Duration

Credit Hours

The certificate consists of 18 credit hours structured to provide foundational and applied knowledge in biopharmaceutical and biologics regulatory sciences.

Course Delivery

- Courses are delivered in an online, part-time format.
- Courses follow standard academic terms:
  - 15/16-week formats in Fall and Spring semesters
  - 11-week format in Summer semester
- The structure is designed to accommodate working professionals and students enrolled full-time in other academic programs.

Course Rotation

Courses will be offered on a predictable rotation to ensure timely progression. A two-year projected schedule will be maintained and updated annually by the Assistant Director in consultation with the Program Director and participating faculty.

Program Duration

- Designed for completion in approximately five semesters if a student takes one course at a time.
- May be completed in approximately three semesters if a student takes two courses per semester during Fall and Spring semesters.

C. Program Quality Assurance and Continuous Improvement

Courses within the certificate remain subject to established IBRS curriculum review and institutional assessment processes. In addition, IBRS will conduct an annual structured review of the certificate as a distinct academic offering, including evaluation of enrollment patterns, student progression, completion outcomes, and program coherence.

1. Annual Program Review

Each year, IBRS leadership will review:

- Enrollment trends
- Retention and completion rates
- Student course evaluations
- Faculty feedback
- Budget performance

The Assistant Director will compile annual performance data for review by the Program Director and Advisory Committee. Findings will be documented and used to guide program improvements.

2. Learning Outcomes Assessment

The certificate will have clearly defined student learning outcomes related to:

- Regulatory frameworks governing biopharmaceuticals and biologic products
- Preclinical and clinical development requirements for biologics
- Manufacturing compliance, quality systems, and current Good Manufacturing Practices
- Ethical considerations in research and development
- Post-market compliance, pharmacovigilance, and risk management requirements
- International regulatory comparisons and global submission strategies

Assessment methods will include:

- Course-embedded assessments
- Applied regulatory strategy projects
- Indirect measures (student feedback and alumni surveys as available)

Assessment data will be reviewed annually, and documented action plans will be

developed when necessary.

3. External and Industry Input

Given the specialized and rapidly evolving nature of biopharmaceutical and biologics regulation, IBRS will periodically seek feedback from:

- Industry professionals in biopharmaceutical and biotechnology sectors
- Regulatory affairs professionals
- Alumni (as the program matures)

This engagement ensures the curriculum remains aligned with evolving regulatory expectations, scientific advances, and workforce needs in biologics and advanced therapies.

4. Periodic Comprehensive Review

A comprehensive curriculum review will occur every three to five years to:

- Evaluate program outcomes
- Assess market demand in the biopharmaceutical and biotechnology sectors
- Review the competitive landscape
- Identify needed curricular revisions

D. Avoidance of Duplication

A review of institutional offerings indicates that no existing certificate program provides a focused curriculum specifically in biopharmaceutical and biologics regulatory sciences within this scope and delivery format.

This certificate is differentiated by:

- Its focused emphasis on biologics and advanced therapies
- Its integration within the IBRS regulatory science framework
- Its suitability for working professionals in industry, government, or academia
- Its alignment with global regulatory considerations for biologics and biotechnology products

The program complements existing pharmaceutical, biomedical, and regulatory science programs without duplicating their content or mission.

E. Sustainability and Long-Term Viability

The IBRS program will ensure sustainability of the certificate through:

- Defined enrollment targets
- Strategic outreach to biopharmaceutical, biotechnology, and regulatory professionals
- Predictable course scheduling
- Faculty workload planning

Enrollment trends, assessment data, and financial performance will be monitored annually by the Program Director and Assistant Director. If enrollment falls below established viability thresholds for multiple consecutive years, the program will undergo formal review for restructuring or possible sunset consideration.

7. Library and Laboratory Resources

The proposal must include a review of existing library and laboratory resources (or other specialized resources) at the host location. If deficiencies exist, the proposal must include a plan, including timetable and budget, for alleviating the deficiencies.

The students will be provided with learning resources within the course including textbooks, if appropriate, and will also include accessing regulatory authority websites such as FDA or

EMA, published papers and presentations to supplement their learnings.

8. Budget

The budget must provide a realistic estimate of the costs of developing and implementing a quality program. Consequently, each program budget must contain detailed estimates—specified separately for authorized and cooperating units—concerning faculty and staff positions, library, laboratory, and other specialized facility resource requirements, travel and other significant operating expenses. If the support for the program is the result of an internal reallocation of resources, explicit details should be included in the proposal. The budget must reflect the start-up costs of the program, projected costs for completion of the first cycle of students, and additional costs associated with any future cycles of students.

No additional fiscal investment is needed to create this graduate certificate program. The certificate is anticipated to enroll approximately 10 students. All academic courses identified in the program of study for the proposed certificate are currently being offered as required or elective courses in the current M.S. program in regulatory sciences. The faculty anticipate a gradual increase in student enrollment. If enrollment increases, additional faculty or staff resources may be necessary for the administration of the program and timely graduation of the students. At that time, a fiscal evaluation will be conducted to determine future resource requirements. The faculty anticipate the additional resources will be supported by students' tuition and fees. The certificate program will utilize the same E-rate for tuition used for the department's M.S. program and 4 other graduate certificate programs. This rate is $738 per credit hour.

This certificate leverages existing IBRS instructional capacity and infrastructure, requiring no new institutional investment. Any additional enrollment will generate incremental tuition revenue within the existing IBRS budget structure.

9. Program Costs Assessed to Students

Any costs beyond those normally associated with the program on campus must be spelled out and justified.

Standard graduate student costs will be utilized for the program.

10. E-Rate

If an e-rate will be charged, an approved e-rate form must be submitted through the Office of Online Learning.

The standard e-rate utilized for current IBRS courses will be charged.

Documentation of Approval and Notification

Proposal: Online Graduate Certificate in Biopharmaceutical Regulations

College: College of Pharmacy

Department: International Biomedical Regulatory Sciences

Proposed Effective Term: Fall 2026

School/College:

- College of Pharmacy Associate Dean, Dr. Michael Bartlett, 2/5/2026
- Graduate School Associate Dean, Dr. Anne Shaffer, 3/5/2026