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 Animal Health 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: 10/17/2025

College/School: College of Pharmacy

Department/Division: International Biomedical Regulatory Sciences

Certificate Title: Animal Health Regulations

CIP: 51200200

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, including the 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 major areas in the field.

The College of Pharmacy proposes a Graduate Certificate in Animal Health Regulations (AHR) to allow students to gain specialized knowledge and regulatory expertise for working in this specialized area of the medical products industry. The certificate curriculum will require a total of 18 credit hours and will cover an overview of regulatory requirements for medical products, overview of bioethics for research, good clinical practices, current good manufacturing practices, and animal health regulations. These courses are essential for workforce preparedness for an AHR professional.

Roles and Responsibilities of an Animal Health Regulations Professional include:

- Interpreting and applying U.S. and global regulatory requirements for the development, approval, and maintenance of animal health products, including drugs, biologics,

pesticides, diagnostics, and medical devices.

- Developing and executing regulatory strategies that ensure compliance with FDA (CVM), USDA (APHIS/CVB), or EPA (OPP) requirements throughout the product lifecycle-from concept to post-approval.

- Assessing and managing regulatory overlaps and gray areas between agencies, such as biopharmaceuticals regulated by both FDA and USDA or products falling under both drug and pesticide definitions.

- Preparing, submitting, and managing regulatory filings such as Investigational New Animal Drug (INAD) files, New Animal Drug Applications (NADAs), product license applications, and pesticide registrations, including associated user fee and electronic submission processes.

- Addressing data requirements, responding to regulatory inquiries, and facilitating timely approvals and continued compliance.

- Monitoring and maintaining product compliance after approval, including renewals, labeling updates, manufacturing changes, and adverse event reporting in alignment with pharmacovigilance requirements.

- Evaluating and ensuring accuracy of labeling, advertising, and promotional claims, confirming they are consistent with approved product indications and regulatory standards.

- Internationally, interpreting jurisdictional and international regulatory differences, including VICH guidelines and country-specific requirements, to support global product registration and harmonization efforts.

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 sciences or allied fields such as quality assurance and clinical. However, all the graduate programs in regulatory sciences are geared towards human health, with the exception of the Graduate Certificate in Animal Health offered by Kansas State University. The IBRS graduate program at UGA currently offers an elective course in Animal Health Regulations. The animal health market was valued at $13 billion in 2025 (as per U.S. Animal Health Market Report), with many companies looking for sophisticated talent with a growing expectation for advanced education and credentialing. With the proximity of College of Veterinary Medicine, the faculty anticipate that the graduate certificates and master's degree offered by the IBRS program will support the expected need in advance education and credentialing workforce needs of the animal health industry.

A needs assessment was conducted to demonstrate that there is a 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 Animal Health Regulations as part of their educational program, an anonymous QuestionPro survey was sent to graduate students within the College of Pharmacy, the College of Engineering, the College of Agriculture and Environmental Sciences, and 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

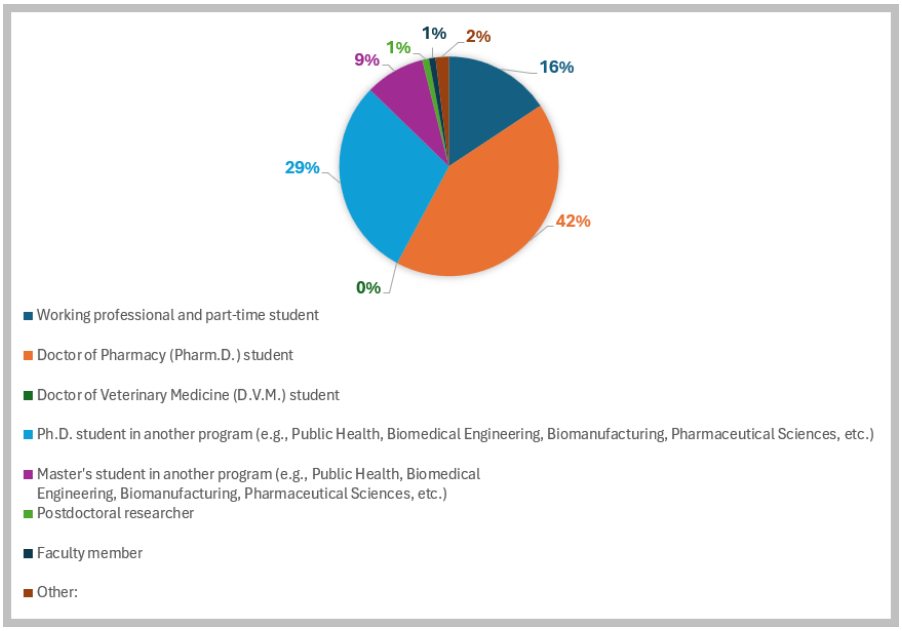
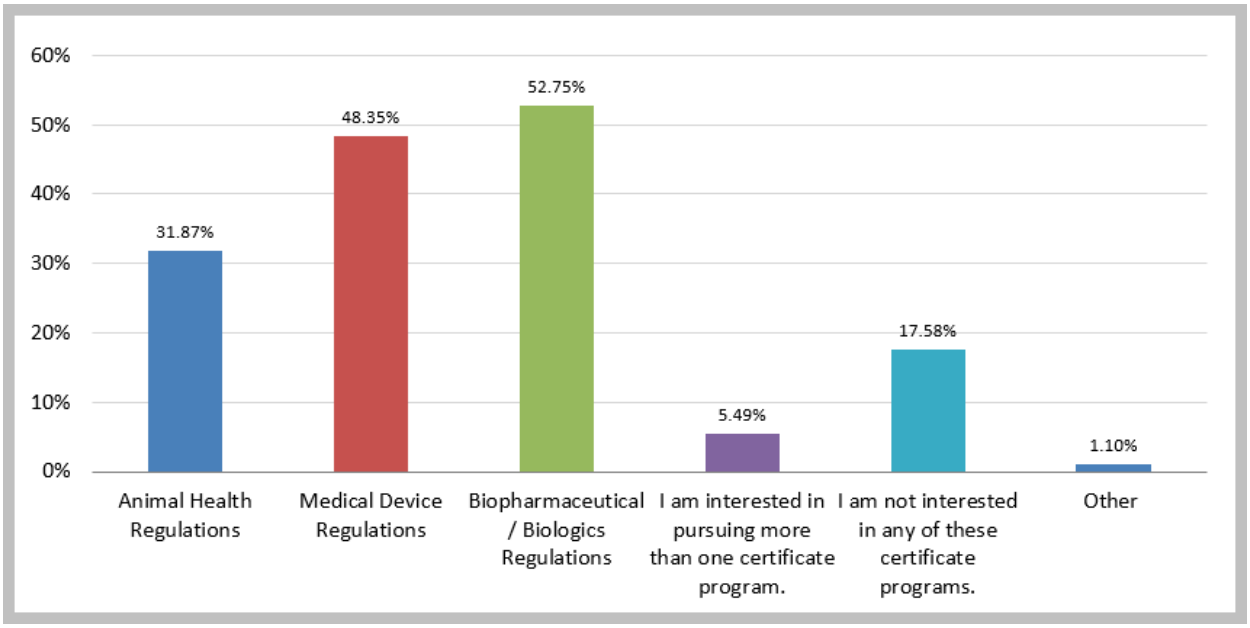


Fig. 2: Student Feedback on Interest to Obtain an Animal Health Graduate Certificate



Overall, approximately 32% of the students that participated in the survey were interested in obtaining the proposed certificate. The percentage increases to approximately 37% if students interested in obtaining more than one certificate program are added. This assessment clearly supports the fact that there is a sufficient pool of qualified students with interest in obtaining the proposed Graduate Certificate in Animal Health 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 Animal Health Regulations are designed to prepare students for work in the highly regulated medical product industry in the specialized area of animal health regulations. Specifically, upon completion of this certificate program, students will be able to:

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

2. Evaluate ethical considerations throughout biopharmaceutical development and interpret the regulatory standards for safety, efficacy and quality.

3. Describe the animal health industry paradigm and differentiate among the regulatory frameworks of the FDA, USDA, and EPA.

4. Summarize the manufacturing and clinical standards for development and registration of animal health products based on the applicable regulatory authority (FDA, EPA, or USDA).

5. Outline the global development process and identify safety, efficacy, and quality requirements for animal drugs, animal biologics, animal pesticides, and medical devices.

6. Explain and interpret the VICH requirements of veterinary products and analyze the key regulatory differences between the US and other markets that may need to be

considered when developing animal health products.

7. Compare and contrast the FDA's Center for Veterinary Medicine (CVM), USDA's Animal and Plant Health Inspection Service (APHIS) - Center for Veterinary Biologics (CVB), and EPA's Office of Pesticide Programs (OPP) in the following areas:

a. Describe organizational structure and laws/regulations applicable

b. Differentiate the regulatory and study requirements for product registration, the approval process, and the maintenance of products on the market once approved.

c. Summarize the electronic submission process

8. Explain the principles of Pharmacovigilance and analyze differences in the pharmacovigilance requirements for FDA, USDA, and EPA including signal detection and adverse event trending and reporting requirements.

9. Delineate and assess the jurisdictional overlaps between FDA and USDA for biopharmaceuticals, and between FDA and EPA for products and chemicals classified as both drugs and pesticides.

10. Interpret and explain the basis for labeling and product claim approval requirements and evaluate their role in regulated product advertisement and promotion.

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 Animal Health 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, 5, 6, 7, 8, 9, 10]
- **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 – 4, 5, 6, 7]
- **PHAR 6180E, Animal Health Regulatory (4 hours):** Foundational knowledge in animal health regulations for drugs, biologics, and medical devices. Animal Health Regulatory will cover the life cycle of animal health products from discovery through

development, registration, and commercialization of the products including product stewardship and management of products. [Learning objectives – 3, 4, 5, 6, 7, 8, 9, 10]

- **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 – 4, 7, 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, 5, 8]

Total = 18 hours

Curriculum Map (Primary / Supporting Alignment)

Legend: P = Primary emphasis / direct assessment; S = Supporting contribution

Learning Outcomes	**PHAR 6010E**	**PHAR 6030E**	**PHAR 6180E**	**PHAR 6310E**	**PHRM 7230E**
1. Apply regulatory principles governing pharma, biotech & device industries	P	S	P	S	
2. Evaluate ethical considerations & interpret safety/efficacy/quality standards	S		S		P
3. Describe animal health industry paradigm & differentiate FDA/USDA/EPA frameworks	S		P		
4. Summarize manufacturing & clinical standards for development/registration	S	P	P	S	
5. Outline global development process & identify safety/efficacy/quality requirements	S	S	P		S
6. Explain VICH requirements & analyze U.S. vs global differences	S	S	P		
7. Compare FDA CVM, USDA APHIS-CVB & EPA OPP (structure, approval, e-submissions)	S	S	P	S	
8. Explain pharmacovigilance principles & analyze agency differences	S		P	S	S

9. Assess jurisdictional overlaps (FDA/USDA; FDA/EPA)	S		P		
10. Interpret labeling & product claim approval requirements	S		P		

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.

The certificate will be administered within the College of Pharmacy's International Biomedical Regulatory Sciences program. The courses will be instructed by faculty who already teach the courses listed above for other programs currently offered by IBRS and supported by the same course coordinators. The certificate can be completed at the learner's pace, so there is not a time limit, except within the graduate school's timeline requirements of eight years before courses begin to expire.

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
- Demonstrate interest or experience in animal health, regulatory science, veterinary products, or related fields

Application Process

- Applications submitted through the university's graduate admissions system
- Required materials: official transcripts, statement of purpose, and CV (if applicable)
- Applications 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 published on websites
- Admission decisions communicated within a defined review period (e.g., 2 weeks after deadline)

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

B. Program Structure, Course Schedule, and Duration

Credit Hours

The Graduate Certificate in Animal Health Regulations will consist of 18 credit hours, structured to provide foundational and applied knowledge in animal health regulatory sciences.

Course Delivery

- Courses delivered in online format; part-time
- Organized in 15/16 weeks for Fall and Spring 11 weeks for Summer semesters
- Designed to accommodate working professionals or students enrolled full-time in other 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 5 semesters if student takes one class at a time.

- May be completed over 3 semesters if student takes two classes at a time 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 certificate, 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 Animal Health Certificate will have clearly defined student learning outcomes related to:

- Regulatory frameworks governing animal health products
- Preclinical and clinical development requirements
- Compliance and post-market surveillance considerations
- International regulatory comparisons (where applicable)

Assessment methods will include:

- Course-embedded assessments
- Capstone or applied project evaluations
- Indirect measures (student feedback, alumni surveys as available)

Assessment data will be reviewed annually, and documented action plans developed when necessary.

3). External and Industry Input
Given the applied nature of animal health regulatory sciences, IBRS will periodically seek feedback from:

- Industry professionals in animal health
- Regulatory professionals
- Alumni (as the program matures)

This ensures the curriculum remains aligned with current regulatory expectations and workforce needs.

4). Periodic Comprehensive Review
A comprehensive curriculum review will occur every 3–5 years to:

- Evaluate program outcomes
- Assess market demand
- 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 animal health regulatory sciences within this scope and format.

This certificate is differentiated by:

- Its regulatory science focus (rather than clinical veterinary practice)
- Its integration within the IBRS regulatory framework
- Its suitability for working professionals in industry, government, or academia
- Its alignment with global regulatory considerations

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

E. Sustainability and Long-Term Viability

The IBRS program will ensure sustainability through:

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

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