



University Council

February 27, 2026

UNIVERSITY CURRICULUM COMMITTEE – 2025-2026

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Dear Colleagues:

The attached proposal from the College of Pharmacy for an Online Graduate Certificate in Medical Device and Technologies 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 PROGRAM

Date: 10/16/2025

College/School: College of Pharmacy

Department/Division: International Biomedical Regulatory Sciences

Program (Major and Degree): Medical Device and Technologies Regulations

CIP: 51200203

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 Medical Device and Technologies Regulations (MDTR) to allow students to gain specialized knowledge and regulatory expertise for working in this area of the medical industry. The medical device industry supports a wide range of medical products, from a simple syringe to a complex MRI/PET imaging machine. With the advancement of technology, new areas such as wearable devices and digital devices have propelled growth in the field. It is anticipated that additional evolution of these devices will happen once the artificial intelligence technology strengthens and becomes part of medical devices. Developing and offering the Graduate Certificate in Medical Device and Technologies Regulations will support the workforce development needs in this sector. The proposed certificate curriculum will require a total of 16 credit hours and will cover an overview of regulatory requirements for medical products, overview of bioethics for research and development of medical products, good clinical practices, medical device development, and global medical devices. These courses are essential for workforce preparedness for an MDTR professional.

Roles and Responsibilities of a Medical Device Regulatory Professional include:

- Research, interpret and apply applicable laws, guidelines, and standards (e.g., U.S. FDA

21 CFR Parts 820 (Quality System Regulation), 807 (510(k)), and 814 (PMA); EU MDR 2017/745 and IVDR 2017/746; and ISO 13485, ISO 14971, IEC 62304, etc. Support regulatory intelligence activities—tracking evolving standards, guidance, and legislation.

- Develop and implement regulatory strategies for new medical devices, software, or technologies to ensure timely market access (e.g., FDA, EMA, MHRA, Health Canada).
- Assess regulatory pathways and classifications (e.g., Class I–III, 510(k), De Novo, PMA, CE marking). Provide regulatory input during product design and development, ensuring regulatory requirements are integrated from the start (Design Controls, Risk Management, Usability).
- Review design documentation, labeling, and advertising materials for compliance. Ensure clinical evaluation and performance testing plans meet regulatory expectations. Support changes and lifecycle management (design changes, labeling updates, new indications).
- Prepare, compile, and submit regulatory applications, such as FDA 510(k), De Novo, PMA, IDE; EU Technical Documentation for CE marking; International submissions (e.g., TGA, PMDA, NMPA, Health Canada). Track submission progress and maintain up-to-date regulatory documentation.
- Liaise with regulatory agencies to address questions, deficiencies, or inspection findings. Monitor and report adverse events and recalls (vigilance, MDR, field safety corrective actions). Maintain regulatory compliance through post-market surveillance and periodic reporting (e.g., PMCF, PMSR, PSUR). Ensure ongoing compliance with Quality Management Systems (QMS) and audit readiness.
- Serve as the primary contact with regulatory authorities and notified bodies. Represent the company in regulatory meetings, inspections, and audits.
- Become knowledgeable in areas listed below, but not limited to:
 - Digital Health & Software as a Medical Device (SaMD): compliance with FDA’s Digital Health policies, IMDRF SaMD frameworks, and cybersecurity requirements.
 - Combination Products: navigate dual jurisdiction (drug-device, biologic-device) regulatory pathways.
 - Artificial Intelligence and Machine Learning (AI/ML): monitor adaptive algorithm regulatory guidance.
 - Global Harmonization: Leverage IMDRF, ICH, and MDSAP frameworks for multi-country approvals.

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 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. Growth in the medical device industry is expected, especially in the area of medical technology, with innovation in digital technologies (e.g., wearables), combination of drug-device technologies (e.g., insulin pumps), and use of artificial intelligence and machine learning (e.g., diagnostic imaging). With the growth of the medical device and technology industry, there will be an increased need for regulatory professionals, and companies are increasingly looking for sophisticated talent with the expectation for advanced education and credentialing. The faculty anticipate that the proposed graduate certificate, together with other graduate certificates and the master's degree offered by the IBRS program, will support the expected workforce need in advance education and credentialing in the area of medical device and technology industry.

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 Medical Device and Technologies Regulations as part of their educational program, an anonymous QuestionPro survey was sent to all 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. 91 students took 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

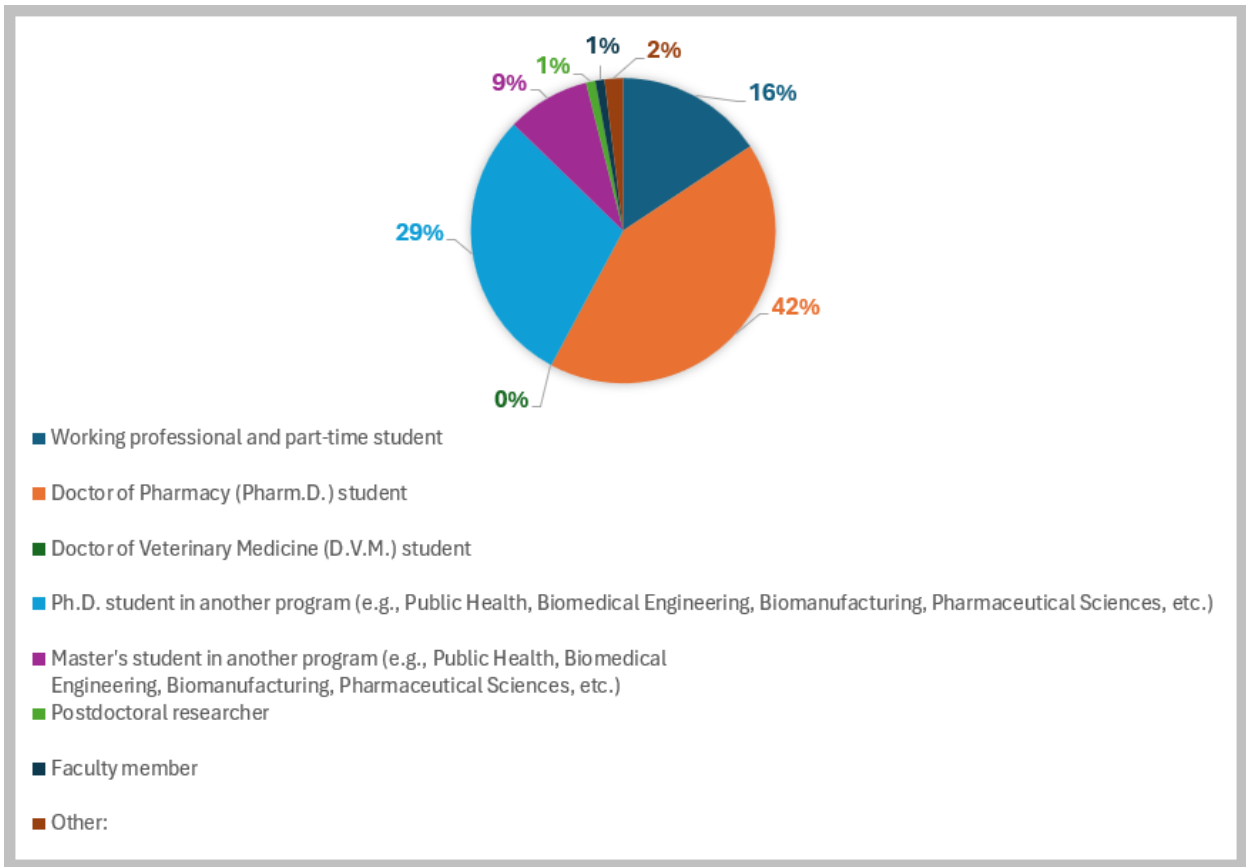
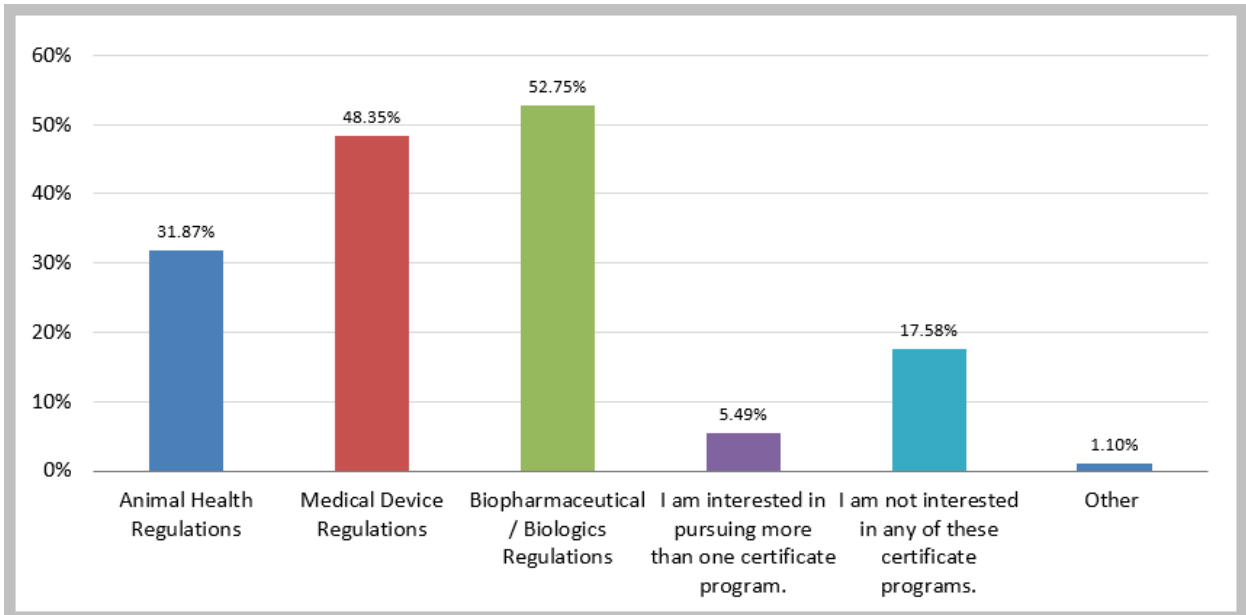


Fig. 2: Student Feedback on Interest to Obtain a Medical Device Regulations Graduate Certificate



Overall, approximately 48% of the students that participated in the survey were interested in obtaining the proposed certificate. The percentage increases to approximately 53% if those students interested in obtaining more than one graduate 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 Medical Device and Technologies 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 Medical Device and Technologies Regulations are designed to prepare students for the work in the highly regulated medical product industry in the specialized area of medical devices and technologies. Specifically, upon completion of this certificate program, students will be able to:

1. Apply regulatory principles for pharmaceuticals, biotechnology and medical device

industries.

2. Evaluate ethical considerations from research through the development of medical device/technology products, and interpret regulatory standards for safety, efficacy and quality.
3. Outline and evaluate the key stages of medical device development from concept through market launch.
4. Develop strategies for achieving successful clinical trial applications and marketing approvals.
5. Summarize the phases of a Quality Management System (QMS) and analyze how QMS principles are applied to ensure compliance with regulatory standards. (e.g., ISO 13485, ISO 14971) throughout the development lifecycle.
6. Define the risk-based classification of medical devices and explain how the risk classification determines study and submission requirements.
7. Develop and document design solutions to meet technical and regulatory requirements including design inputs, outputs, and supporting documentation; evaluating material and component choices; integrating human factors and usability studies, biocompatibility evaluations, risk management, and overall product safety.
8. Prepare and submit regulatory filings in US, EU, and international markets by developing intended use and indications for use statements, identifying submission requirements, and creating an integrated launch plan linking regulatory, manufacturing, and marketing milestones.
9. Analyze the global harmonization process for marketing medical devices worldwide including the roles of IMDRF, ICH, and MDSAP
10. Define post-market compliance requirements for making changes to the device, labels etc., and reporting requirements for safety.
11. Strategize, prepare and respond to regulatory authority questions (applications, submissions, and 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 Medical Device and Technologies 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, 7, 10, 11]

- **PHAR 6150E, Medical Device Development (3 hours):** This course explores medical device development from a Quality Management System (QMS) perspective, covering concept initiation through design validation and transfer. Students learn about design development and planning, fundamental requirements and standards, testing, clinical investigations, and regulatory requirements, focusing on documenting design inputs/outputs, and QMS elements throughout the development lifecycle. [Learning objectives – 3, 5, 6, 7, 8, 9]
- **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, 10, 11]
- **PHAR 6380E, Global Medical Device Regulatory Submissions - The Marketing Application Process (3 hours):** Overview of the regulatory process for marketing medical devices among countries on a global basis, including a review of major regulations and agencies in the various countries that are responsible for overseeing the marketing of medical devices. [Learning objectives – 3, 5, 6, 7, 8, 9]
- **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, 10, 11]

Total = 16 hours

Curriculum Map (Primary / Supporting Alignment)

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

Learning Outcomes	PHAR 6010E	PHAR 6150E	PHAR 6310E	PHAR 6380E	PHRM 7230E
1. Apply regulatory principles for pharmaceuticals, biotechnology and medical device industries	P	S			
2. Evaluate ethical considerations and interpret safety, efficacy and quality standards			S		P
3. Outline and evaluate key stages of medical device development from concept through market launch		P		P	

4. Develop strategies for successful clinical trial applications and marketing approvals		S	P	S	
5. Summarize QMS phases and analyze application of ISO 13485, ISO 14971, etc.		P		P	
6. Define risk-based classification of medical devices and determine study/submission requirements	S	P		P	
7. Develop and document design solutions meeting technical and regulatory requirements	S	P		P	
8. Prepare and submit regulatory filings (US, EU, international) and develop integrated launch plans		P		P	
9. Analyze global harmonization (IMDRF, ICH, MDSAP)		S		P	
10. Define post-market compliance and safety reporting requirements	S		P		S
11. Strategize and respond to regulatory authority questions, submissions, and inspections	S		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.

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.

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
- Demonstrate interest or experience in medical devices, regulatory sciences, or related fields

Application Process

- Applications submitted through the university's graduate admissions system
- Required materials include 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 program 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 Medical Device and Technologies Regulations will consist of 16 credit hours, structured to provide foundational and applied knowledge in medical devices regulatory sciences.

Course Delivery

- Courses delivered in online format; part-time format
- Organized in 15/16 weeks for Fall and Spring 11-week format for Summer semester
- 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 five semesters if student takes one class at a time.
- May be completed over three 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 Medical Device and Technologies Certificate will have clearly defined student learning outcomes related to:

- Regulatory frameworks governing medical device products
- Preclinical and clinical development requirements
- Compliance and post-market surveillance considerations
- International regulatory comparisons (as 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 medical devices, IBRS will periodically seek feedback from:

- Industry professionals in the medical device industry
- 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 three to five 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 medical device regulatory sciences within this scope and format.

This certificate is differentiated by:

- Its regulatory science focus
- 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 engineering, 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 Medical Device and Technologies 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