UNIVERSITY OF GEORGIA
College of Pharmacy
International Biomedical Regulatory Sciences

International Biomedical Regulatory Sciences Certificate and Masters (MS) Degree Programs Student Handbook

Welcome to the International Biomedical Regulatory Sciences Graduate Program at the University of Georgia. This handbook is designed to guide you throughout your academic journey by outlining key program policies, requirements, and available resources. We encourage you to review it carefully and refer back to it as needed during your time in the program.

Program Website: https://rx.uga.edu/departments/academic/ibrs/

Updated: January 2026

Important Note: This Graduate Handbook does not replace or supersede the Graduate Bulletin found at https://grad.uga.edu/graduate-policies/.

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Preface

The purpose of the Student Handbook is to provide information concerning the procedures and policies of graduate education within the International Biomedical Regulatory Sciences (IBRS) Programs and the Graduate School of the University of Georgia (UGA). It supplements the Graduate School Bulletin, the UGA Graduate School website, and the IBRS Departmental webpages. All graduate students, including all certificate students and master's degrees students, are expected to carefully read the policy manual, retain it for future reference, and abide by it in the interest of making graduate study in the department a successful experience.

To help students quickly identify which policies, requirements, and procedures apply to their specific academic path, this handbook uses four standardized audience icons. Each icon appears beside sections that are relevant to that particular group of students. The following icons indicate which students should reference each section

Audience Icons and Their Meaning

Icon Label	Applies To	Purpose
 **Certificates & Master Students — All**	All graduate students in the program, including Certificate and MS students	Marks information that applies universally to every student, regardless of degree track.
 **Master of Science Students — All MS**	All MS students (both Project and Thesis)	Highlights requirements and policies that apply only to students enrolled in the MS degree.
 **Master Students — Project Path**	MS Project students in Regulatory Sciences or Clinical Trials	Identifies content specific to the Project track, including project expectations, milestones, and submission requirements.
 **Master Students — Thesis Path**	MS Thesis students in Regulatory Sciences	Indicates sections that apply exclusively to Thesis-track students, including research expectations, committee structure, and thesis submission guidelines.

Table 1: Audience Icons and Their Meaning

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Students in the master's programs—Regulatory Sciences and Clinical Trials Management, whether on the Project or Thesis path—are encouraged also to consult the MS Guide. This guide offers clear guidelines to reduce uncertainty in the master's research process and helps navigate the administrative requirements of the degree. It is available in eLC within the IBRS Documentation Library.

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International Biomedical Regulatory Sciences Student Handbook

1. Introduction

The International Biomedical Regulatory Sciences (IBRS) Program at the University of Georgia is dedicated to advancing education and professional development in biomedical regulatory sciences. The program prepares students to navigate the complex regulatory environments governing drugs, biologics, medical devices, and clinical research in the United States and globally.

The goals of the IBRS Program are to:

- Provide rigorous, practice-oriented education in biomedical regulatory sciences
- Support interdisciplinary training that integrates science, policy, ethics, and regulatory compliance
- Serve full-time students working toward another degree and working professionals through flexible, high-quality online programs
- Promote engagement with regulatory science research and real-world applications
- Contribute to the workforce development needs of industry, government, and academic institutions

1.1. Academic Unit Overview/Organization

The International Biomedical Regulatory Sciences Program is a graduate-level program within the University of Georgia's College of Pharmacy. The mission of the IBRS Program is to provide students with graduate-level distance education that develops competencies in biomedical regulatory and clinical sciences, so they become subject matter experts in the global healthcare regulations that govern the development, manufacturing, effectiveness, and safety of medicinal products.

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1.2. Faculty and Staff

Program Administrative Contacts

Grace Gowda, Ph.D., RAC Director and Associate Professor, International Biomedical Regulatory Sciences Program UGA College of Pharmacy Email: grace.gowda@uga.edu Office Phone: 678-985-6827	Johnna Hodges Assistant Director, International Biomedical Regulatory Sciences Program UGA College of Pharmacy Email: jhodges@uga.edu Office Phone: 678-985-6808	Beverly Minor Office Lead International Biomedical Regulatory Sciences Program UGA College of Pharmacy Email: beverlyminor@uga.edu, Office Phone: 678-985-6809

This Program reports to
Michael Bartlett, Ph.D.
Graduate Coordinator &
Associate Dean
UGA College of Pharmacy
Email: mgbart@uga.edu
Office Phone: 706-542-5390

Faculty and Staff

The IBRS Program is supported by a multidisciplinary team of faculty and staff with expertise across regulatory sciences, clinical trials, pharmaceutical sciences, medical device development, and related fields.

A current listing of IBRS faculty and staff, including titles, contact information, and links to faculty research profiles, is available through the College of Pharmacy and IBRS program websites. Students are encouraged to review faculty research interests to identify potential mentors and collaborators.

- IBRS Homepage: https://rx.uga.edu/departments/academic/ibrs/
- College of Pharmacy faculty directory: https://rx.uga.edu/faculty-staff/directory/

Who do I contact for questions or problems with...?

- General graduate program issues and concerns, waivers, extensions, grievances, and needed coordinator signatures:
    - Johnna Hodges, jhodges@uga.edu, 678-985-6808

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    - Beverly Minor, beverlyminor@uga.edu, 678-985-6809
- Courses, forms, deadlines, UGA and Graduate School requirements:
    - Johnna Hodges, jhodges@uga.edu, 678-985-6808
    - Beverly Minor, beverlyminor@uga.edu, 678-985-6809
- Access to networks:
    - UGA EITS Helpdesk: https://eits.uga.edu/, 706-542-3106
- Course questions:
    - Instructor or Course Support

1.3. Program Structure

Program Structure Within the College

The Interdisciplinary Biomedical Regulatory Sciences (IBRS) Program is housed within the University of Georgia College of Pharmacy. As part of the College, the program works in alignment with College and University policies and maintains close collaboration with College leadership, the Graduate School, and other academic units to support student advising, admissions, curriculum development, and program administration. This structure allows IBRS to deliver specialized regulatory science education while remaining fully integrated within the College's academic and administrative framework.

Program's Physical Address

The IBRS Program operates out of the UGA Gwinnett Campus in Lawrenceville, Georgia. The program's physical address is 2530 Sever Road, Suite 100, Lawrenceville, Georgia 30043. The department email address is regsciences@uga.edu and the phone number is 678-985-6809.

Description of Program Components/Options - IBRS Program Overview

The Interdisciplinary Biomedical Regulatory Sciences (IBRS) Program at the University of Georgia offers a range of graduate-level educational opportunities designed to prepare students for careers in regulatory sciences, clinical trials, and related fields.

The program offers two Master of Science degrees: the MS in Regulatory Sciences, which can be completed via a Project Path or a Thesis Path, and the MS in Clinical Trials Management, offered through a Project Path. Students pursuing a Doctor of Pharmacy (PharmD) degree also have the option to enroll in a dual PharmD/MS program, integrating graduate-level regulatory training with their professional studies.

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In addition, IBRS provides four graduate certificate programs for focused, specialized training: the Regulatory Sciences Certificate, the Clinical Trials Management Certificate, the Drug Safety and Pharmacovigilance Certificate, and the Chemistry, Manufacturing, and Controls Certificate. These programs are structured to offer both flexibility and rigor, combining practical experience with foundational knowledge to support professional growth in biomedical regulatory fields.

General Program Information:

- **Online, Part-Time**: All programs are designed for working professionals and are offered only on a part-time basis.
- **No Assistantship or Visa Sponsorship**: We do not provide scholarships, assistantships, or visa sponsorship.
- **GPA Requirement**: Applicants should have a minimum undergraduate GPA of 3.0.
- **Tuition**: Please calculate tuition costs using the **Estimated Cost Calculator** on the UGA Bursar's Office website. Financial assistance is available through UGA's Office of Financial Aid: https://osfa.uga.edu/.

Graduate Programs:

Certificate: The IBRS Program offers the following graduate certificate options:

1. Regulatory Sciences Certificate – 14 credit hours: https://rx.uga.edu/academic-programs/certificates/regulatory-sciences-graduate-certificate-program/
2. Clinical Trials Design & Monitoring Certificate – 17 credit hours: https://rx.uga.edu/academic-programs/certificates/clinical-trials-certificate-program/
3. CMC Certificate Program – 14 credit hours: https://rx.uga.edu/academic-programs/certificates/chemistry-manufacturing-controls-graduate-certificate-program/
4. Drug Safety and Pharmacovigilance – 17 credit hours: https://rx.uga.edu/academic-programs/certificates/drug-safety-and-pharmacovigilance/

Master of Science Programs: In addition to the certificate options, the IBRS Program offers Master of Science degree Programs.

1. Master of Science in Regulatory Sciences – 39 credit hours, with both Project and Thesis path options.
   Learn more: https://rx.uga.edu/academic-programs/master-of-science/regulatory-sciences-masters-degree/
2. Master of Science in Clinical Trials Management – 33 credit hours, available as a Project path only.
   Learn more: https://rx.uga.edu/academic-programs/master-of-science/clinical-trials-management-masters/

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Application Requirements:

1. Submit your application through the Graduate School Admissions portal: https://grad.uga.edu/admissions/apply-now/.
    - Domestic application fee: $75; International: $100.
2. Select Online Campus and your intended program.
3. Upload a Résumé and Statement of Purpose.
4. Submit Unofficial Transcripts and later, Official Transcripts upon admission.
5. Letters of Recommendation:
    - MS: Three (3) letters
    - Certificates: Two (2) letters
6. Writing Sample (MS applicants only):
    - Maximum 5 pages on a regulatory sciences topic of your choice.
7. Interview (MS applicants only): Schedule an interview with the department prior to the application deadline.

Application Deadlines: *Only completed applications will be considered*.

- Domestic Applicants:
    - Fall: June 1 | Spring: November 1

- International Applicants:
    - Fall: April 15 | Spring: October 15
- No admissions for Summer semester

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2. Professional Standards of Behavior

Ethical and Professional Conduct

Students in the program are expected to conduct themselves professionally, demonstrating integrity, accountability, and respect for others and the campus environment. Professional standards align with University of Georgia policies and current disciplinary norms. Students must comply with university policies governing research and academic conduct, including Academic Honesty, Non-Discrimination and Anti-Harassment, Workplace Violence, and the Student Code of Conduct.
Source: https://conduct.uga.edu/code-of-conduct/

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Academic Performance Expectations

Students are also expected to maintain academic standards, including a minimum 3.0 GPA in all required coursework, and to fulfill program-related obligations such as attending required seminars, meetings, and presentations. Adherence to these standards is essential for satisfactory progress and maintaining good standing in the program.

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3. Disability Statement

The University of Georgia's IBRS Program is committed to providing reasonable accommodations and access for students with disabilities. If you have a disability and require accommodations, please contact the department and consider registering with UGA's Accessibility and Testing Center. If you plan to request accommodation, please also consider registering with the Accessibility and Testing Center at UGA.

Accessibility and Testing, Division of Student Affairs
The University of Georgia, 114 Clark Howell Hall, Athens, GA 30602-3338
Phone: (706)542-8719 (voice) | Fax: (706)542-7719 | TTY: (706)542-8778
Email: uga.access@uga.edu
Website: https://accessibility.uga.edu/

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4. Academic Advising and Registration Communication

4.1. Advisors

All Students: Ms. Johnna Hodges (jhodges@uga.edu) serves as the primary academic advisor for master's-level students in the IBRS Program. Ms. Beverly Minor (beverlyminor@uga.edu) serves as the academic advisor for all graduate certificate students.

Each semester, the IBRS Office will contact students by email with a tentative course schedule for the upcoming term. Students are required to review this information and indicate which courses they plan to enroll in. A timely response to this email is essential, as students who do not respond will not be cleared for registration. Students are therefore expected to monitor their email closely and respond promptly to all advising and registration communications from the IBRS Office.

Students who are enrolled in another degree program at UGA should note that their primary academic advisor for that program remains their home department advisor. The IBRS advisor provides guidance specifically related to IBRS courses, certificates, or graduate-level requirements within the IBRS Program.

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5. Enrollment Policies

5.1. Minimum Enrollment

All Students: All students pursuing graduate certificates or degrees at the University of Georgia are required to enroll in a minimum of three credit hours during any semester in which they use University facilities or receive faculty or staff support. In addition, students must be registered for at least three credit hours in the semester in which they plan to graduate.

5.2. Continuous Enrollment Policy ("Graduate Enrollment Policy")

Also known as Graduate Enrollment Policy
MS Students only: In accordance with the UGA Graduate School policy, all master's students must maintain continuous enrollment from matriculation until completion of all degree requirements. Continuous enrollment is defined as registering for a minimum of three (3) graduate or professional course credits in at least two semesters per academic year (Fall, Spring, Summer). This requirement includes enrollment in the semester in which degree requirements are complete. Enrollment continues until the degree is awarded or the student's status as a degree-seeking graduate student is formally terminated.
Source: https://grad.uga.edu/graduate-policies/

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6. Academic Policies and Program Administration

6.1. Leave of Absence

MS Students only: A leave of absence provides a mechanism for students experiencing unusual circumstances to be exempt temporarily from the continuous enrollment policy. A leave of absence requires approval of the Graduate Coordinator and the Dean of Graduate School. A leave of absence will be granted only for good cause such as serious health-related issues, significant family issues, and other major personal circumstances that interfere with the ability to undertake graduate study. Reach out to the IBRS Academic Advisor for additional information.
Source: https://grad.uga.edu/graduate-policies/

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6.2. Time Limits

MS Students only: Master's degree students must complete all degree requirements, including all coursework on their program of study, within eight years of matriculation. The eight-year limit begins with the semester the student matriculated into the program and ends with the last semester before the beginning of the eighth year. The IBRS Program has been given an eight-year window, compared to other MS Program because of its part-time nature.
Source: https://grad.uga.edu/graduate-policies/

MS Students only: The eight-year limit begins with the semester the student matriculated into the program and ends with the last semester before the beginning of the eighth year.

6.2.a. Extension of Time

MS Students only: A special request for an extension of time on the eight-year expiration of coursework may be made to the Dean of the Graduate School in the form of a petition. For this, the student will work with their academic advisor. This request must include specific reasons that the student did not complete requirements in the time allotted per the Graduate School policy. A petition of this type must include 1) a specific timeline for the completion of requirements; and 2) an approved program of study and a letter of support from both the program graduate coordinator and the Academic Advisor.

6.3. Appeals

This section provides a general overview of academic appeals. Grade-specific appeals are addressed in Section 6.8. UGA graduate students have the right to appeal certain academic decisions. The appeals process begins with the unit responsible for the decision (e.g., course grades start with the instructor). Unfavorable rulings at one level may be appealed to the next level.
Source: https://policy.uga.edu/policies#/programs/SkqcrwuO6

6.4. Financial Assistance and Funding

All Students: The IBRS Program does not offer financial assistance, teaching assistantships, or other forms of sponsorship. The IBRS Office does not administer or advise on financial aid matters and is not involved in decisions related to how students finance their studies. Students with questions about financial aid should contact the University of Georgia Office of Financial Aid at osfa.uga.edu/.

Please note: Students enrolled in graduate certificate programs are not eligible for federal financial assistance.

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6.5. Change of Degree Path

MS Students only: During your MS program, if you wish to switch from one-degree path to another within the IBRS Department, you may request this change following these guidelines:

- Changing from thesis to non-thesis, or the reverse, is at the discretion of the department.
- At the time of your request, no more than 20 semester hours of course credit should be completed.
- Ensure that none of your course work has expired.
- Discuss the change with your major professor. If you have not selected one, contact the Assistant Director for guidance.
- Draft a request email/letter to Dr. Gowda, Program Director, grace.gowda@uga.edu. In your letter to Dr. Gowda, address your desire to change and detail the reasons for this change. Include in your letter any discussions that you have had with your major professor on this proposed change.
- If your request is approved, you will need to submit your request to the UGA Graduate School at Navigate to https://grad.uga.edu/current-students/forms/. Go to Additional Forms and Change Degree Objective
- Log in using your UGA MyID and password. Follow the directions.

6.6. Transfer Credits

All Students: Students may submit a request to the IBRS Program Director for the application of transfer credit from accredited institutions. A maximum of six (6) credit hours may be approved for transfer. Approval is contingent upon a determination that the prior course content is comparable in scope, depth, and learning objectives to the IBRS course for which transfer credit is requested. To be considered, students must provide documentation demonstrating prior completion of the relevant coursework. Required documentation includes a copy of the course syllabus and evidence of a final grade of **B** or higher.

6.7 Use of Credit hours

Course and resident credit used to satisfy the requirements of one degree cannot be used to satisfy the requirements of another degree, unless the student is enrolled in an approved dual degree program that allows the use of double credit.
Source: https://policy.uga.edu/policies#/programs/Hk3_OPudp

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6.8. Grades and GPAs

All Students: To be awarded a certificate, a student must maintain a cumulative grade point average (GPA) of 3.0 or higher across all certificate and applicable master's-level coursework. Any course in which a student earns a grade of C– or lower must be repeated. Students who do not meet these academic requirements will not be eligible to receive the certificate and may jeopardize their academic standing with the UGA Graduate School.
Source: https://policy.uga.edu/policies#/programs/BkcJDP_OT

6.9. Grade Appeals

Grade appeals: The following outlines the departmental process for grade appeals, consistent with University of Georgia policy.

If the student does not agree with the assigned final grade, the student should first reach out to the instructor who assigned the grade and detail his/her concern. If the appeal is not resolved with the instructor, the student should appeal to the department head. The grade appeal process is outlined at: https://honesty.uga.edu/student-appeals/grade-appeals/

An unfavorable ruling at one level can be appealed to successive levels. For example, a department ruling can be appealed to the College in which the institutional unit is located; a college ruling can be appealed to the University Council Educational Affairs Committee; the Educational Affairs Committee ruling can be appealed to the President of the University; and the President's ruling can be appealed to the Board of Regents.

Specifically, University of Georgia students have the right to appeal academic decisions. The burden of proof for appeal rests with the student. The policies governing the process of appealing grades are covered in the Academic Affairs Policy Manual, General Academic Policy: Student Appeals (Section 4.05-01). All grade appeals must be initiated in writing to the instructor within one calendar year from the end of the term in which the grade was recorded. The process for appealing a grade in the Regulatory Sciences Department is as follows:

1. The student first appeals a grade to the instructor who assigned the grade. If the appeal is not resolved with the instructor, the student makes an appeal to the department as described below.

2. The student submits in writing to the Department Head a petition to change a grade. The petition should include:
   a) Documentation of a good faith effort to resolve the matter with the instructor. Include appropriate correspondence with the instructor.
   b) An explanation of the grade that the student believes should have been assigned and why that grade is more appropriate than the one that was

assigned.

c) The student should include why he/she feels the grade was assigned incorrectly. The information should include evidence for supporting that conclusion, including reference to the course syllabus, any other graded class assignments, or other materials that might pertain to your case. The appeal letter should address questions like - Were the criteria for the assignment explained clearly? Was the grading system that was used explained clearly? Were explanations provided for the low grade?

d) As explained in the Academic Affairs Manual: "A primary criterion for a successful grade appeal is the demonstration that the grade was the result of a factual error or that it was influenced by improper or unprofessional bias on the part of the instructor."

e) Grade appeals, or chances to redo assignments, are not granted simply because a student did not understand the directions. As graduate students, it is the student's responsibility to contact the instructor for clarification of assignment directions if needed.

3. The Department Head will appoint a three- or four-member faculty committee to collect evidence and to make a recommendation to the Department Head. This *ad hoc* committee may be composed of two or three faculty within the Regulatory Sciences Department and perhaps one additional faculty member outside the RS department, but within the College of Pharmacy. The committee process will include:
   a) A review of the student's petition and any other related evidence that the committee deems necessary to understand the situation.
   b) An opportunity for the student to meet with the committee.
   c) An opportunity for the faculty member to meet with the committee.

4. The committee makes a written recommendation to the Department Head.

5. The Department Head will communicate the departmental response to the student and the instructor.
   - If the Department Head does not decide to change the grade, the student may appeal, in the following order, to the UGA Graduate School, and the Educational Affairs Committee of the University Council.
   - If the Department Head decides to the change the grade, the instructor will be given the opportunity to sign the grade change form. If the instructor chooses not to sign the form, the Department Head will sign for the instructor and send the form to the Registrar's Office.

The full Student Appeals Process is located at https://honesty.uga.edu/Student-Appeals/Grade-Appeals/ and https://policy.uga.edu/policies#/programs/r1F-Ed4_T?q=grade%20appeals&&limit=20&skip=0&bc=true&bcCurrent=Student%20Academic%20Appeals%20Policy&bcItemType=programs

6.10. Academic Standards and Dismissal Policy

All Students: The IBRS Program is committed to maintaining high academic and professional standards. All students are expected to demonstrate consistent progress toward graduation, uphold ethical principles, and meet the academic requirements set by the University of Georgia and the program. The following outlines GPA expectations, academic standing procedures, and circumstances under which a student may be dismissed from the program.

GPA Requirements:

- All UGA graduate students must maintain a cumulative GPA of **3.0 or higher** on all graduate coursework.
- Courses on the Program of Study, including core courses, must meet this standard.

Academic Warning and Probation:

- If a student's cumulative GPA falls below 3.0 for **one semester**, they are placed on **academic warning** and must meet with the graduate coordinator to develop an improvement plan.
- If the GPA remains below 3.0 for **two consecutive semesters**, the student is placed on **academic probation**.
- A GPA below 3.0 during probation may result in **dismissal from the Graduate School**.

IBRS Program-Specific Standards:

Students may be dismissed at the end of any semester for:

1. Insufficient academic progress toward graduation.
2. Failure to follow the Program of Study, university, or program policies.
3. Low grades, including:
    - Two consecutive semesters with a cumulative GPA below 3.0
    - A "U" or grade below a "C" in a core course
4. Unsatisfactory progress in thesis or project work (PHAR 6950E, PHRM 7000, PHRM 7300), demonstrated by poor grades or multiple negative committee evaluations.
5. Ethical violations, including but not limited to:
    - Falsification of data or records
    - Plagiarism
    - Academic dishonesty, such as using materials in papers, theses, or presentations without proper attribution

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Note: Students are expected to maintain acceptable academic performance and adhere to ethical and professional standards throughout their enrollment in the program.

6.11. Written Student Complaints

All Students: Written student complaints are addressed in a fair, professional, and timely manner, in accordance with University procedures. Complaints do not replace existing policies or procedures (e.g., UGA Hotline, NDAH Policy, Graduate School Appeals). Students can submit complaints via https://studentcomplaints.uga.edu/, logging in to verify student status and provide details. Complaints are routed to the appropriate functional area for review and action.

6.12. UGA Non-Discrimination and Anti-Harassment Policy

UGA Non-Discrimination & Anti-Harassment Policy: All students must comply with the UGA Non-Discrimination and Anti-Harassment Policy. This policy prohibits discrimination, harassment, and retaliation on the basis of protected characteristics. Students should familiarize themselves with the full policy at: https://eoo.uga.edu/civil_rights_NDAH/ndah-policy.

6.13. Workplace Violence

UGA Workplace Violence Policy: All students must comply with the UGA Workplace Violence Policy. This policy outlines expectations and procedures for preventing and reporting workplace or campus violence. The full policy is available at https://safeandsecure.uga.edu/workplace-violence/.

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7. Academic Integrity and Research Ethics

7.1. Academic Honesty

All Students: Students in the IBRS graduate program are expected to uphold the highest ethical standards. Academic or scientific dishonesty—including plagiarism, data falsification, or submitting the same work for credit without permission, is strictly prohibited and may result in dismissal. Students are responsible for familiarizing themselves with UGA's Academic Honesty policy ("A Culture of Honesty") available at https://honesty.uga.edu/.

UGA Student Honor Code states "*I will be academically honest in all of my academic work and will not tolerate academic dishonesty of others*."

Prohibited conduct includes, but is not limited to, "submitting for academic advancement an item of academic work that has been submitted (even when submitted previously by that student) for credit in another course, unless done pursuant to authorization from the instructor supervising the work or containing fair attribution to the original work."

7.1.a. Use of Artificial Intelligence in Coursework

Students may not use artificial intelligence (AI) tools to generate written work, discussion posts, or other assignments without obtaining prior approval *in writing* from the course instructor. Any use of AI without explicit permission is considered a violation of academic honesty and may result in disciplinary action. Students are responsible for understanding and following instructor guidance regarding AI-assisted work.

7.2. Responsible Conduct in Research

All Students: Students conducting research for PHAR 6800 (Applied Project), PHAR 6950 (Master Seminar), PHAR 7000, or PHAR 7300 must adhere to the highest standards of Responsible Conduct in Research (RCR), in addition to UGA's academic integrity policies.

Reminders:

- Do not begin any research (other than a literature review) for PHAR 6800 or PHAR 6950 without IRB approval or exemption.
- Communicate early with your major professor to ensure their CITI training is up to date.

Requirements before beginning research:

1. Identify a Major Professor
    - Must be a Regulatory Sciences faculty member.
    - Will serve as Principal Investigator (PI) for your IRB application.
2. IRB Approval or Exemption
    - No research (beyond literature review) may begin until IRB approval or exemption is obtained.
3. Training
    - Both the student and the Major Professor must have up-to-date CITI Biomedical Research training.
    - Access via the UGA Pep portal: https://hr.uga.edu/pep/ (search "Bio-medical Research" to locate the course).

Additional Guidance:

- Confirm with your Major Professor that their training is current to avoid delays.
- If the PI's training has expired, project submission to the IRB cannot proceed until the requirement is met.

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- Complete the required modules in manageable sections to accommodate your schedule.

Summary:
Students are responsible for ensuring that both they and their Major Professor meet training and IRB requirements before beginning research. Compliance with these policies is essential to maintain ethical standards, program integrity, and timely progress toward degree completion.

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8. IBRS Academic Programs of Study

This section describes the academic programs offered through the Institute for Biomedical and Regulatory Sciences (IBRS), including graduate certificate programs and Master of Science degree programs. Each program description outlines the program learning outcomes, required coursework, total credit hours, and academic requirements for completion.

8.1. Regulatory Sciences Certificate (14 Credit Hours)

The RS Certificate Learning Outcomes

The Regulatory Sciences Graduate Certificate Program provides a foundational core for students who wish to round out their experiences in regulatory affairs or transition into entry-level regulatory affairs positions. This specialized education is crucial to professionals to gain and maintain an understanding of the scientific and technical background of new or existing healthcare products.

At the close of the RS Certificate Program, the learners will be able to outline the product development process of the Food and Drug Administration (FDA); locate information necessary to perform in the role of the regulatory affairs professional; and distinguish between the subjective and interpretive aspects of the FDA regulations. The learners will also be able to categorize the complex interaction between regulatory and development processes; explain how the FDA enforces the laws and regulations; and interpret FDA laws and regulations. Students will be able to write methods and procedures complying with FDA's Good Manufacturing Practices regulations; gain an awareness of conflicts of interest and scientific integrity; and be able to identify the principles used in the ethical conduct of research.

The courses in the RS Certificate Program (14 credit hours) are:

PHAR 6010E: Intro to Pharmaceutical, Biotechnology & Device Industries (4 hrs.)
PHAR 6020E: Food and Drug Law (3 hrs.)

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PHAR 6030E: Current Good Manufacturing Practices (4 hrs.)
PHRM 7230E: Ethics in Research (3 hrs.)

To be awarded this certificate, a student must maintain an overall GPA of 3.0 or better.

8.2. Clinical Trials Design and Monitoring Certificate (17 Credit Hours)

The CT Certificate Learning Outcomes

The Clinical Trials Design & Management Certificate Program provides a foundation for preparing candidates to lead and manage the development and contribute to implementing scientifically valid clinical study designs including monitoring clinical trials and directing daily clinical trial operations. The interdisciplinary program encompasses critical core competency areas including biostatistics, federal regulations, bioethics and project management as integral parts of drug product development and medical device design validation required for federal and global regulatory market clearance and initial commercialization.

At the close of the Clinical Trials Certificate Program, the learners will be able to outline the product development process required under regulations enforced by the Food and Drug Administration (FDA). The student will gain an awareness of conflicts of interest and scientific integrity; and be able to identify the principles used in the ethical conduct of research. The student will be able to identify the roles and responsibilities of investigators, sponsors, and subjects of clinical research; be able to compare and contrast the regulations and Good Clinical Practices (GCP) governing clinical research; and describe the various objectives of a good clinical study design. The student will be able to demonstrate knowledge of regulations, policies, protocols and/or procedures needed to control, maintain, and audit records for regulatory compliance of clinical trials; and interact with statisticians regarding the design, data analysis plan, and implementation of preclinical and clinical studies for drugs, biologics, medical devices and combination products.

The courses in the CT Certificate Program (17 credit hours) are:

PHAR 6010E: Intro to the Pharmaceutical, Biotechnology & Device Industries (4 hrs.)
PHAR 7100E: Biostatistical Applications for Pharmaceutical & Biotechnology Industries (3 hrs.)
PHRM 7230E: Ethical Issues in Research (3 hrs.)
PHAR 6200E: Clinical Trials Design & Monitoring (4 hrs.)
PHAR 6210E: Project Management in Clinical Trials (3 hrs.)

To be awarded this certificate, a student must maintain an overall GPA of 3.0 or better.

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8.3. Drug Safety and Pharmacovigilance Certificate (17 Credit Hours)

The DS PV Certificate Learning Outcomes

The Drug Safety and Pharmacovigilance Certificate Program provides a foundation for preparing candidates to lead and manage all aspects related to drug safety as members of a product development project team. Students will learn all aspects of managing Pharmacovigilance as members of a commercial product stewardship team. Students will learn how to liaise with regulatory authorities to communicate and negotiate study protocols and label language related to safety. They will learn how to support management in due diligence and strategic business activities. They will learn how to work with IRBs and data monitoring boards. There is a special focus on FDA's adverse event reporting systems and signal detection approaches for safety.

The learning objectives of the Drug Safety and Pharmacovigilance graduate certificate is to prepare the student for working in the highly regulated medical industry in the specialized area of Drug Safety or Pharmacovigilance. Upon Completion of the certificate program, students will be able to: Be knowledgeable in laws, regulations, and guidelines related to drug safety and pharmacovigilance principles; Outline the product development process for medical products; Locate information necessary in their role as drug safety and pharmacovigilance professionals; Describe the pre-approval and approval requirements for the safety of new products, including the maintenance of those products after marketing through pharmacovigilance systems; Familiar with the complex interaction between regulatory requirements and development processes for new products; Apply established principles of the submission process that regulatory authorities use to evaluate new medical product applications; Familiar with safety signal monitoring and detection technologies

The courses in the DS Certificate Program (17 credit hours) are:

PHAR 6010E: Intro to the Pharmaceutical, Biotechnology & Device Industries (4 hrs.)
PHAR 7100E: Biostatistical Applications for Pharmaceutical & Biotechnology Industries (3 hrs.)
PHRM 7230E: Ethical Issues in Research (3 hrs.)
PHAR 6140E: Overview of Drug Safety Throughout Medical Product Lifecycle (4 hrs.)
PHAR 6310E: Good Clinical Practice Regulations (3 hrs.)

To be awarded this certificate, a student must maintain an overall GPA of 3.0 or better.

8.4. Chemistry, Manufacturing, and Controls Certificate (14 Credit Hours)

The CMC Certificate Learning Outcomes

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The Chemistry, Manufacturing, and Controls Graduate Certificate Program provides a foundation for preparing candidates to lead and manage the development and contribute to the implementation of scientifically valid clinical study designs including monitoring of clinical trials and directing daily clinical trial operations. The interdisciplinary program encompasses critical core competency areas including biostatistics, federal regulations, bioethics, and project management as integral parts of drug product development and medical device design validation required for federal regulatory market clearance and initial commercialization.

At the close of the CMC – Chemistry, Manufacturing, and Controls Certificate Program, the learners will be able to outline the laws, regulations, and guidelines related to drug approval requirements. Learners will be able to apply both Good manufacturing practices (GMP) and quality by design (Qbd) principles. They will be able to outline the product development process for medical products. Learners will be able to locate information necessary to their role as CMC professionals. Learners will be able to describe the pre-approval and approval CMC requirements for new products, including the maintenance of those products after marketing. They will become familiar with the complex interaction between regulatory requirements and development processes for new products. They will be able to describe the key aspects of the manufacturing process as it relates to regulatory review and inspection policies. Finally, they will be able to apply established principles of submission process that regulatory authorities use to evaluate new medical product applications.

The courses in the CMC Certificate Program (14 credit hours) are:

PHAR 6030E: Current Good Manufacturing Practices (4 hrs.)
PHAR 6100E: Quality Control and Quality Assurance (3 hrs.)
PHAR 6120E: Process Control and Validation (3 hrs.)
PHAR 6160E: Chemistry, Manufacturing, and Controls (4 hrs.)

To be awarded this certificate, a student must maintain an overall GPA of 3.0 or better.

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8.5. Master of Science Degree – Regulatory Sciences

in Pharmacy with an emphasis in **Regulatory Sciences**

Master of Science (Project Path 33 credit hours or Thesis 38 credit hours) Learning Outcomes

Master's Students only: The Master of Science in Pharmacy with an emphasis in the Regulatory Sciences Program assures a strong professional background needed to succeed in administrative positions and specialized areas required of this hands-on profession. This program is for individuals with a clear objective to cultivate a career in regulatory affairs and those with an industry background desiring advanced education in regulatory sciences and management. The Master of Science for Regulatory Sciences Program covers regulatory requirements for Pharmaceutical, Biologic, Medical Device, Animal Health, International Regulations, and Combination Products.

At the close of the Master of Science Program, the learner will be able to:

- Outline the product development process of the Food and Drug Administration (FDA);
- Describe the pre-approval and approval process for new and existing products, including the planning and implementation of clinical studies.
- Categorize the complex interaction between regulatory and development processes.
- Explain food, drug and cosmetic-related laws, regulations and guidelines.
- Identify device and drug GMP and state and federal requirements.
- Identify the principles used in the ethical conduct of research.
- Determine ways to integrate quality systems approaches into manufacturing processes that meet FDA regulatory review and inspection policies.
- Apply established principles of process control and validation.
- Apply established principles of processes and regulations that FDA uses in regulating new medical products marketing applications.
- Analyze and interpret statistical issues related to government approval of new pharmaceuticals, biologicals, or medical devices.
- Analyze in-depth a major critical issue in biomedical regulatory affairs; and
- Compile, evaluate, and debate the issue with fellow classmates and faculty.

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Curriculum and Program Requirements

A. **For all Regulatory Sciences MS Students**. Each of the following course **credits is required**:

Course ID (Core courses)	Course Title	Credit Hours	Semester offered*
PHAR 6010E	Introduction to Pharmaceutical, Biotechnology, and Medical Devices Industries: A Regulatory Overview	4	Fall, Spring
PHAR 6020E	Food and Drug Law	3	Spring, Summer
PHAR 6030E	Current Good Manufacturing Practices (cGMPs)	4	Fall, Spring, Summer
PHRM 7230E	Ethical Issues in Research	3	Fall, Spring, Summer
PHAR 6130E	U.S. Marketing Applications for New Drugs, Biologics, Medical Devices, and Animal Health Products	4	Spring
PHAR 7100E	Biostatistical Applications for the Pharmaceutical and Biotechnology Industries	3	Fall, Spring
Total		21	

**Must have a minimum of five students for a class to be offered.*

B. Additional required course for MS Project students:

- for **MS Project Student only**:

Course ID (Core courses)	Course Title	Credit Hours	Semester offered*
PHAR 6800E, Or PHAR 6900E	Applied Project in Regulatory Affairs Or Internship in Biomedical Regulatory Affairs	3	As needed
PHAR 6950E (Project student)	Masters Seminar in Regulatory Affairs, or master's Thesis	3	As needed
Total		6	

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B. Additional required courses for MS Thesis student

- for **MS Thesis Student only**:

Course ID (Core)	Course Title	Credit Hours	Semester Offered
PHRM 7300	Masters Research	3	As needed

C. An additional **6 to 14 credit hours of elective course work** is required for both Thesis and Project students. Appropriate electives include:

Course ID	Course Title	Credit hours	Semester Offered*
PHAR 6100E	Quality Control and Quality Assurance	3	Spring
PHAR 6120E	Process Control and Validation	3	Fall
PHAR 6140E	Overview of Drug Safety Throughout Medical Product Lifecycle	3	Fall
PHAR 6150E	Medical Device Development	3	Fall
PHAR 6160E	Chemistry, Manufacturing, and Controls	4	Fall
PHAR 6170E	Biopharmaceutical Regulatory Science	4	Fall
PHAR 6180E	Animal Health Regulatory	4	Spring
PHAR 6200E	Clinical Trials Design and Management	4	Spring
PHAR 6210E	Project Management in Clinical Trials	3	Summer
PHAR 6310E	Good Clinical Practice Regulations for Drugs, Biologic Products, and Medical Devices	3	Fall
PHAR 6340E	European Pharmaceutical and Biologics Regulatory Affairs	3	Summer
PHAR 6360E	Latin American Pharmaceutical and Biologics Regulatory Sciences	3	Summer
PHAR 6380E	Global Medical Device Regulatory Submissions	3	Spring
PHAR 6800E	Applied Project in Regulatory Affairs	3	As needed
PHRM 7210	Special Topics in Pharmacy	3	As needed
PHRM 7000 (Thesis students only)	Master's Research	1-6	As needed

**Must have a minimum of five students for the class to be offered.*

Total course credits

MS Project Student: 27 core courses + 6 electives = 33 credit hours minimum
MS Thesis Student: 24 core courses + 14 electives = 38 credit hours minimum

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8.6. Master of Science Degree – Clinical Trials Management (33 Credit Hours)

in Pharmacy with an emphasis in **Clinical Trials Management**

Master of Science (Project Path only) Learning Outcomes

Master's Students only: The Master of Science (M.S.) in Pharmacy with an Area of Emphasis in Clinical Trials Management is designed to enhance students' foundational skills in regulatory requirements, essential in the safe and effective development, registration, and maintenance of medical products. In addition, students will learn skills and develop competencies in scientific, clinical, technical, and practical aspects of medical product development as well as how the different functions within the medical industry work to succeed in the regulated environment. Students completing the Area of Emphasis in Clinical Trials Management will have career opportunities in clinical research, clinical operations, clinical monitoring, or regulatory affairs, or as faculty in a regulatory sciences or clinical trials program.

At the close of the Master of Science Program, the learner will be able to:

- Lead and manage the development and monitoring of clinical trials and directing daily clinical trial operations.
- Describe the laws, regulations, and guidelines related to clinical trials (e.g., diverse study population) and registration of medical products.
- Outline the product development process of the Food and Drug Administration (FDA);
- Identify the principles used in the ethical conduct of research.
- Analyze and interpret statistical issues related to government approval of new pharmaceutical, biologics, or medical devices.
- Describe the pre-approval and approval process for new products, including the maintenance of those products after marketing.
- Outline principles of Good Clinical Practice and Good Manufacturing Process.
- Explain drug safety and pharmacovigilance requirements for medical products.
- Categorize the complex interaction between regulatory sciences and product development processes.
- PROJECT: Research and analyze in-depth a major critical issue in the clinical/regulatory area

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Curriculum and Program Requirements

A. **For all Clinical Trials Management MS Students**. Each of the following course **credits is required**:

Course ID (Core)	Course Title	Credit Hours	Semester Offered*
PHAR 6010E	Introduction to Pharmaceutical, Biotechnology, and Medical Devices Industries: A Regulatory Overview	4	Fall, Spring
PHRM 7230E	Ethical Issues in Research	3	Fall, Spring, Summer
PHAR 6030E	Current Good Manufacturing Practices (cGMPs)	4	Fall, Spring, Summer
PHAR 6140E	Overview of Drug Safety Throughout the Medical Product Life Cycle	4	Fall
PHAR 6200E	Clinical Trials Design and Monitoring	4	Spring
PHAR 6210E	Project Management in Clinical Trials	3	Summer
PHAR 6310E	Good Clinical Practices	3	Fall
PHAR 7100E	Biostatistical Applications for the Pharmaceutical and Biotechnology Industries	3	Fall, Spring
PHAR 6950E	Master's Seminar in Regulatory Affairs	3	As needed
Total		31	

**Must have a minimum of five students for a class to be offered.*

B. Elective courses:

C. 1 course or 3 elective hours is required for this program. Appropriate electives include:

Course ID (Electives)	Course Title	Credit hours	Semester Offered*
PHAR 6020E	Food and Drug Law	3	Spring, Summer
PHAR 6800	Applied Project (recommended)	3	As needed
PHAR 6130E	U.S. Marketing Applications for New Drugs, Biologics, and Medical Devices	4	Spring
PHAR 6340E	European Pharmaceutical and Biologics Regulatory Affairs	3	Summer

**Must have a minimum of five students for the class to be offered.*

Total course credits

MS Project Student: 31 core courses + 3 electives = 33 credit hours minimum

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9. Program Milestones and Degree Completion

9.1. Selection of Major Professor / Project or Thesis Advisor

MS Students: Selection of Major Professor/Project or Thesis Advisor
It is very important that new students become acquainted with the faculty, particularly in their area of interest, as soon as possible. All faculty are willing to talk with new students about their career interests and possible research topics.

Each student is responsible for identifying a graduate faculty member willing to serve as their Major Professor. No faculty member is required to serve as a Major Professor for any student. The Major Professor will provide guidance on your applied or capstone project and typically serves as the primary mentor throughout PHAR 6800 and PHAR 6950E. Faculty outside the Regulatory Sciences Program may serve on committees but cannot act as Major Professors.

Tips for selecting a Major Professor:

- Reach out to faculty whose expertise aligns with your interests.
- Discuss potential projects and confirm willingness to serve as your Major Professor.
- Your Major Professor will support development of your project proposal and final capstone project, ensuring alignment with regulatory science principles.

The terms **"major professor," "major advisor," and "committee chair"** are used interchangeably and all refer to the same role. The **major professor** is the committee member who serves as the student's primary project advisor and general mentor for their project. The major professor **must be a Regulatory Sciences faculty member**, as they are responsible for advising on the regulatory aspects of the project. Faculty outside of the Regulatory Sciences Program may serve on the committee but **cannot** serve as the major professor.

Common duties of a major professor include:

- Helping the student define their project topic.
- Assisting the student with IRB training and serving as the Primary Investigator for IRB purposes.
- Helping the student select and set up their advisory committee.
- Working with the student and committee to ensure all project requirements are met.
- Providing specific guidance on designing and carrying out the project.

Students should become acquainted with faculty, particularly in their area of interest, as soon as possible. During the first semester, students are encouraged to meet with multiple faculty members to identify a major professor and form an advisory committee.

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9.2. MS Program of Study Form (required)

Master's Students: Early in the PHAR 6800, 6950E or 7300, students must complete a **Program of Study (PoS) form**, a required Graduate School form outlining coursework and research for degree completion.

- Complete the PoS form during enrollment in **PHAR 6800** (Applied Project) or **PHAR 6950E** (Master Seminar).
- Include all required and elective courses, as well as research milestones.
- Submit the form to the UGA Graduate School by the **second full week of the semester** in which degree requirements will be completed.
- Form and deadlines are available at: UGA Graduate School Forms and Important Dates.

The PoS serves as a roadmap for your academic progress and ensures alignment with Graduate

[https://grad.uga.edu/current-students/important-dates-deadlines/].

9.3. Responsible Conduct in Research / IRB Requirements

MS Students: Students conducting research must adhere to the highest standards of Responsible Conduct of Research and University academic integrity policies.

Before beginning any research for PHAR 6800, PHAR 6900, PHAR 6950, PHAR 7000, or PHAR 7300:

1. Identify a Major Professor.
2. Submit a research protocol to the Institutional Review Board (IRB) for approval or exemption.
3. Complete required training through the CITI Training Module via the UGA Pep portal (https://hr.uga.edu/pep/).

Key reminders:

- Do not start research until IRB approval/exemption is granted.
- Ensure both student and Major Professor have current CITI training in Biomedical Research.
- Projects involving patients or identifiable personal data may trigger extensive IRB oversight, so consider alternatives that do not require IRB continuous review.

9.4. Applied Project, Internship, and Capstone Project classes

Master's Students only: Information on the independent study courses (PHAR 6800, 6900E, 6950E).

The IBRS Master's programs include three core independent courses—PHAR 6800 (Applied Project), PHAR 6900 (Internship), and PHAR 6950E (Master Seminar)—that

are critical to program completion. Each course is 3 credit hours and requires active engagement with a Major Professor or faculty committee. These courses are independent in nature, meaning they are tailored to the individual student's project or internship. Students must initiate communication with faculty to confirm project topics, deliverables, and expectations.

Requirements:

- Students must take either PHAR 6800 or PHAR 6900, but not both.
- PHAR 6800 is strongly recommended as it provides a head start on the capstone project and is often more practical for working professionals or students concurrently enrolled in other programs.
- PHAR 6950E must be taken in the semester the student intends to graduate.

For PHAR 6800 and PHAR 6950, your major professor will serve as your primary project advisor and general mentor, guiding the development of your applied or capstone project. The major professor must be a Regulatory Sciences faculty member, and faculty outside the program cannot serve in this role. This faculty member will help you define your project, complete IRB training if applicable, select your advisory committee, and ensure all project requirements are met.

PHAR 6800 – Applied Project (Recommended)

- Independent study course designed to explore and develop a capstone project idea.
- Students work closely with a Major Professor (Regulatory Sciences faculty only) to propose a project that aligns with career objectives and program requirements.
- The project may involve drafting a regulatory analysis, performing an assessment, or developing an applied study related to biomedical regulatory issues in pharmaceuticals, medical devices, or biologics.
- Students may also expand on previous work or projects from their professional practice within the last two years.
- Grading: Traditional letter grade (A, A-, B+, etc.).
- Purpose: Prepares students for PHAR 6950E by refining research questions, project scope, and deliverables.
- Faculty Role: Major Professor provides guidance on project design, regulatory relevance, and deliverables.

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Students should use this PHAR 6800 course as a precursor to the PHAR 6950E, Masters Seminar, course. Use this course to explore your Final Project idea for the PHAR 6950E class. Find a project of interest that is related to regulatory sciences or clinical trials. Explore that topic in this course.

PHAR 6900 – Internship

- Offers practical application of regulatory science skills through part- or full-time internships with biomedical industries or agencies.
- Requires a Major Professor for supervision and an approved Memorandum of Understanding with the internship site.
- Students are required to secure their own internship and get it approved through the IBRS Program.
- Focus: Application of regulatory principles, research activities, and a major project that addresses the educational needs of the student.
- Evaluation: Graded Satisfactory/Unsatisfactory (S/U) based on completion of assignments, performance, and final project presentation. Evaluation involves input from the preceptor, faculty, and self-assessment by the student.

PHAR 6950E – Master Seminar / Capstone Project

- Taken in the student's final semester to demonstrate mastery of knowledge and skills.
- Involves completing and presenting a comprehensive project that integrates program learning and applies it to real-world regulatory challenges.
- Structure:
    - Three-member faculty committee (including Major Professor) oversees the project.
    - Graded S/U; may be retaken, if necessary, but incomplete grades are not permitted. The student will have to pay tuition again.
    - Students will coordinate the date and time of the Capstone Presentation and then request a web-conference link.
- Project Expectations:
    - Prepare a formal write-up for committee review (submit to committee at least two weeks prior to presentation).
    - Deliver a professional 20–30-minute presentation via Zoom.
    - Students must schedule their Project Presentation to allow a minimum of two weeks for committee review of the Project Write-up.
    - Presentations must be scheduled no later than the deadline noted at https://grad.uga.edu/index.php/current-students/important-dates-deadlines/ for Final date for receipt of the following by the Graduate School: Final Defense Approval Form & ETD Submission Approval Form
    - Avoid using patient-identifiable data to prevent IRB delays.

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Timeframe: With the project write-up, the faculty committee must have at least two weeks to review the student's Major Project Write-up prior to the student's project presentation. Go to: https://grad.uga.edu/current-students/important-dates-deadlines/

1. Select the appropriate semester under "Important Dates by Semester."
2. Locate the final deadline for completing all requirements (Capstone notification deadline).
3. Record the deadline and calculate:
    - Student presentation scheduling deadline: 1-week (5) days before the Graduate School deadline.

Key Notes:

- Students are responsible for initiating communication with Major Professors to define project scope and deliverables.
- PHAR 6800 is recommended for students who want a head start on their capstone project; PHAR 6900 is best suited for those seeking professional internship experience.
- PHAR 6950E serves as the culminating experience that confirms mastery of regulatory science knowledge and skills.

9.5. Project and Thesis Committees

Master's Students only: The *advisory committee along with the major professor share responsibilities to monitor graduate student progress and guide the student toward timely completion of their degree program. The advisory committee is charged with guiding the design of capstone project or thesis, reading and approving the final write-up or thesis and approving the final oral examination (defense).*

At the midpoint of the student's program, after a student has chosen a major professor, the student will work with the major professor (chair) to identify two additional faculty members to serve on the student's committee.

9.5.1. Committee's Role

- Responsibilities include monitoring student progress, guiding capstone/thesis research, approving the Program of Study, and evaluating the final presentation or defense.
- If multiple committee members or the Major Professor provide an "Unsatisfactory" evaluation, a **remediation plan** must be developed, which may include additional coursework or more frequent meetings.

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9.6. Project or Thesis Research, Writing, and Defense

Master's Students only: Students are responsible for coordinating the research, write-up, and defense/presentation with their committee. The student must notify the IBRS Office of the scheduled date and time so a web-conference link can be created.

Work closely with your committee and give them **at least two weeks** to review your project write-up before presenting.

Expectations:

- Work closely with the committee and allow at least **two weeks** for review of the project write-up.
- Schedule and conduct a professional Zoom presentation (20–30 minutes) summarizing your project.
- Dress professionally and ensure the presentation aligns with the written project.
- Faculty committee meets privately after the presentation to decide on approval.
- Notify the IBRS Office of the presentation date; the Office will create the Zoom link.
- Final approval triggers completion verification for the Graduate School.

- Due to the complexity and depth of the capstone project, students often find that it extends beyond a single semester. This course demands critical thinking, advanced research, and project management skills. Students are expected to work closely with faculty advisors to ensure their project meets the rigorous academic standards of the program and contributes meaningfully to the field.

- This course is graded as an S/U and can be taken a second time, if necessary, without impacting your GPA. Because of the rigor, it is advised to register for this course the term you know you will complete the program. Remember, *incomplete* grades are **not** an option for this class. The student needs to ensure that they continue to make progress toward the completion of their project in order to receive an S (satisfactory) grade.

9.7. Graduation / Completion

All Students: Awarding the MS Degree and/or completed Certificates

- Graduate students must register for a minimum of 3 hours in the semester in which the degree or the certificate requirements are completed, according to university policy.

- For Master students, Applications for graduation must be submitted in Athena by the UGA Graduate School's deadline, www.grad.uga.edu/index.php/current-students/important-dates-deadlines/.
- Master's students may participate in UGA commencement ceremonies (no summer ceremony; summer graduates can attend fall commencement).
- Certificates: There is no "graduation" ceremony for certificate completions.

Dual-enrolled Pharm.D. students:

- If you hold an undergraduate degree, IBRS certificates and the MS degree can be awarded upon completion of graduate studies.
- If there is no undergraduate degree, certificates and MS degree are awarded upon completion of the Pharm.D.

9.8. Forms and Deadlines required for graduation

1) Your **Program of Study form**: A Program of Study outlines the courses required to complete your degree, including core courses within your major, concentration, minor, and as listed in the catalog. These courses are identified through a degree evaluation tool accessible via the student portal. You will complete this using *GradStatus* (https://gradstatus.uga.edu) by submitting form G138. Please note, do not fill out the Graduate School's Advisory Committee form, as that is only required for MS Thesis students.

2) **Apply to Graduate** using Athena: You will also want to make sure you **apply for graduation.** You can apply to graduate no sooner than one semester before your actual graduation. https://athena.uga.edu.

3) New: **Major Professor/Faculty Supervisor Selection:** All graduate students must now use the Enrolled Student Progress Portal [https://gradapply.uga.edu/portal/my_progress] (under the "AdvCmte" tab) to identify / propose their Major Professor.

Submit forms one semester before intended graduation and verify deadlines. Deadlines are found at http://grad.uga.edu/index.php/current-students/important-dates-deadlines/. Consider submitting these forms about one semester before you plan to graduate.

9.9 MS Thesis Path (Regulatory Sciences – Limited Enrollment)

The MS Thesis path in Regulatory Sciences is available on a limited basis and is intended for students pursuing original, hypothesis-driven research. This option **requires 38 credit hours** and differs from the Project path in both scope and timeline.

Students pursuing the Thesis path must:

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- Conduct original research under the supervision of a Regulatory Sciences faculty member
- Comply with all Graduate School thesis requirements, including committee formation, research approval, thesis formatting, and a formal thesis defense.

Due to the depth and rigor of thesis research, students should begin planning at least six months in advance of anticipated completion. Early identification of a Major Professor and research topic is required.

Enrollment in the MS Thesis path requires advance approval from the IBRS Program and a faculty member willing to serve as Major Professor. This option is not available for Clinical Trials Management students.

10.0. Additional Policies and Helpful Information

10.1. Graduate School Bulletin

All Students: All graduate programs at the University of Georgia are administered through and governed by the UGA Graduate School. Details of programs, policies, requirements, and procedures for graduate studies are described and annually updated in the Bulletin found at https://grad.uga.edu/graduate-bulletin/. Students are responsible for familiarizing themselves with the Bulletin and for meeting all program requirements and deadlines.

10.2. ATHENA: Schedule of Classes and Online Registration

All Students: Registration instructions for each semester including the list of course offerings, class dates and drop/add policies will be emailed to the students. They are also available on ATHENA, the online access to student information system: https://athena.uga.edu.

10.3. Email Responsibility

All Students: The University relies on electronic communication for its convenience, speed, cost-effectiveness, and environmental benefits. Given its widespread acceptance and accessibility, the University considers email to be an official means of communication. Official correspondence will be sent only to UGA email addresses. Therefore, it is essential, especially for distance learning students, to

regularly check their UGA email. Students should frequently and consistently monitor their inboxes, recognizing that certain communications may be time-sensitive. Missing an email is **not** an excuse for failing to complete assignments or activities on time.

If the student chooses to forward his/her UGA email to an external address, be aware that the University is not responsible for how outside vendors handle UGA emails. Forwarding UGA email does not exempt the student from the responsibility of reading all messages, even those that may end up in spam or trash folders. Additionally, emails regarding sensitive information, such as registration or grades, sent from non-UGA accounts (e.g., name@gmail.com) will go unanswered, as sharing student information with non-UGA accounts is prohibited.

We will only communicate only with the registered student, so please refrain from asking spouses, parents, or others to contact the IBRS Office on behalf of the student.

Furthermore, UGA email addresses are automatically added to class-specific listservs to facilitate efficient distribution of course-related information. If the student forwards his/her UGA email to another email system, ensure that this system allows messages from the **@uga.edu** domain.

10.4. UGA Campus Resources

All Students: The University of Georgia offers a comprehensive range of resources to support students' academic success. Here are some key resources available:

Athena: The online portal to the student information system that allows students to access course schedules, register for courses, view student records, check holds, and access financial aid information (https://athena.uga.edu).

Bursar's Office: Responsible for tuition and fees, payment plans, deadlines, taxes, and other student account services (https://busfin.uga.edu/).

Counseling & Psychiatric Services (CAPS): Provides mental health support and services to help students achieve their academic and personal goals (https://caps.uga.edu/) or call 706- 542-2273 for more information.

Accessibility & Testing: Offers accommodations and services for graduate students with disabilities (https://accessibility.uga.edu/, 706.542.8719).

Graduate School: Coordinates graduate programs across all schools and colleges, providing resources for continuing students (https://www.grad.uga.edu). Contacts are:

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- gradinfo@uga.edu – For currently enrolled students including questions about transfer credits, academic probation, programs of study, changing graduation date, etc.
- gradadm@uga.edu – For applicants and newly admitted students including questions on verification of lawful presence, application status, etc.

Information Technology: UGA's central IT department is the Enterprise Information Technology Services (EITS). They manage key technology systems and services on campus, including UGAMail, Athena, and eLearning Commons (eLC). If you need assistance, contact the EITS Help Desk at helpdesk@uga.edu or call 706-542-3106. The EITS Help Desk's website, https://www.eits.uga.edu/, provides detailed instructions on resetting your UGA MyID password and configuring your UGAMail account for your phone. It also offers answers to other frequently asked questions. For the UGA Student Technology Guide and New Student Tech Checklist, select https://eits.uga.edu/newtocampus/ on the EITS website.

Office of the Registrar: Provides various academic services, including student transcripts, certification letters, graduation clearance, course scheduling, and more. See https://www.reg.uga.edu for more information.

University Health Center: Offers primary, specialty, and mental health care services to full-Ime UGA students and their eligible partners (https://healthcenter.uga.edu/).

University Libraries: Provides a wide array of electronic and print resources, with librarians available to assist students (https://www.libs.uga.edu/).

Writing Center: Assists students with the writing process, idea elaboration, and editing their work (https://www.english.uga.edu/jill-and-marvin-willis-center-writing), click on the "Booking an appointment" link.

Graduate School Commencement: Graduation details: UGA Graduate School has a commencement website for details on Graduation from the University: https://commencement.uga.edu/. Caps, gowns, and hoods may be purchased at the University of Georgia Bookstore. Contact the bookstore at 706-542-3171 for purchasing information. Regarding hood and tassels and the appropriate colors, https://www.academicapparel.com/caps/regalia_colors.html Science Gold for MS.

Questions about the IBRS program: regsciences@uga.edu

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