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UNIVERSITY OF GEORGIA
College of Pharmacy
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 serves as a guide to help students navigate their academic journey and make the most of their graduate experience. Please familiarize yourself with the program policies, requirements, and resources outlined below.

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

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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 information contained in 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.

Students in master's degree Programs, both Regulatory Sciences and Clinical Trials Management, Project and Thesis paths, are encouraged to also review the **MS Guide** document. The MS Guide document provides a set of guidelines intended to take out some of the uncertainty of the master's research process and assists with navigating through the administrative requirements of the MS degree. It is located within eLC and the IBRS Documentation Library.

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International Biomedical Regulatory Sciences Student Handbook

1. Introduction

The International Biomedical Regulatory Sciences (IBRS) Graduate Program at the University of Georgia offers a thorough education in the regulatory principles and practices governing medical products. This program equips students for careers in biomedical regulatory and clinical sciences, preparing them to become experts in applying global healthcare regulations to the development and manufacturing of safe and effective medical products. This Graduate Handbook does not replace or supersede the Graduate Bulletin found at https://grad.uga.edu/graduate-policies/.

This handbook serves as a guide to help students navigate their academic journey and make the most of their graduate experience. Please familiarize yourself with the program policies, requirements, and resources outlined below.

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2. Program Administrative Contacts

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

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

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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
  - 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

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3. Disability Statement

The University of Georgia' IBRS Program is committed to providing reasonable access and accommodations for people with disabilities upon request. If you have a disability and require reasonable accommodations, please reach out to the department. If you plan to request accommodations, please also consider registering with the Disability Resource Center.

Disability Resource Center, Division of Student Affairs
The University of Georgia, 114 Clark Howell Hall, Athens, GA 30602-3338
(706)542-8719 (voice); (706)542-7719 (fax); (706)542-8778 (tty).
email: drc@uga.edu and URL: https://drc.uga.edu/

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4. Academic Advising and Policies

4.1. Advisors

All Students: Ms. Hodges (jhodges@uga.edu) will serve as the primary student academic advisor for all Masters-level Students. Ms. Minor (beverlyminor@uga.edu) will serve as advisory for all Certificate Students. Each semester, the IBRS Office will reach out to students via email with a tentative schedule of courses for the upcoming semester. At that time, the students must identify the courses in which they wish to

enroll. It is imperative that each student respond to this email message, otherwise the student will not be cleared to enroll.

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4.2. Minimum Enrollment

All Students: All enrolled students pursuing graduate certificates or degrees at the University of Georgia must register for a minimum of 3 hours of credit during any semester in which they use University facilities and/or faculty/staff time. Students must also be registered for a minimum of three credit hours in the semester in which they graduate.

4.3. Continuous Enrollment Policy

MS Students only: All enrolled graduate 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) credits in at least two semesters per academic year (Fall, Spring, Summer) until the degree is attained or status as a degree-seeking graduate student is terminated. All students must be enrolled for at least three graduate credits in the semester in which degree requirements are completed.

4.4. 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 Student Advisor for additional information.

4.5. 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 six-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.

4.5.a. Extension of Time

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.

4.6. Appeals

UGA graduate students have the right to appeal certain academic decisions. The appeals process starts at the unit responsible for the decision (ex. grades will start with the instructor that taught the course. For most appeals, an unfavorable ruling at one level can be appealed to the successive level.

4.7. Financial Assistance

All Students: The IBRS Program does not offer financial assistance, teaching assistantships or other types of sponsorships. Students should consult the University's Office of Financial Aid at osfa.uga.edu/. Reminder, certificate students are not eligible for federal financial assistance.

4.8. 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://gradstatus.uga.edu/
- Log in to GradStatus using your UGA MyID and password. Go to Forms. Select Request for Change of Degree Objective (G136). Follow the directions.

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4.9. Transfer Credits

All Students: Students may appeal to the IBRS Program Director to have transfer credits applied. No more than six (6) credit hours can be transferred. The student must be able to document that they have previously taken and are knowledgeable in the subjects contained in the course under appeal. Documentation must include a copy of the course syllabus and a grade of **B** or above.

4.10. Grades and GPAs

All Students: Grades and GPAs: A student must achieve a grade of B or better in each of their certificate courses to be awarded that certificate. A student will not be awarded a certificate if they receive a grade of B- or less in a given course. A student can repeat the course but must achieve a grade of B or better in order to obtain the certificate.

MS Students only: In line with the UGA Graduate School, to be eligible for admission to candidacy and graduation, a student must maintain an average of 3.0 (B) both on the graduate transcript and on all courses on the program of study. No grade below C (2.0) will be accepted as part of a program of study for a graduate degree.

4.11. Grade Appeals

Grade appeals: The appeal goes first to the unit responsible for the decision (for example, grades or departmental graduate program policies are appealed to the department; graduate school policies are appealed to the graduate school; university policies to the Educational Affairs Committee). 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 Academic Affairs Policy Manual is found at https://provost.uga.edu/policies/academic-affairs-policy-manual/.

4.12. 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, per university policy.

- Certificates: There is no "graduation" ceremony for certificate completions.
- 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/.
- Masters students are eligible to participate in graduation ceremonies.
- UGA does not have a summer commencement ceremony, but summer graduates are permitted to participate in the fall commencement event following degree completion. Students who have not completed degree requirements as determined by the Graduate School and by published deadlines will not be allowed to walk in the ceremony but may return to walk in a subsequent commencement event. There are no exceptions to this policy.
- To Pharm.D. students (Dual enrolled students): If you hold an undergraduate degree, IBRS certificates and the MS degree can be awarded at the time of completion of your graduate studies. If you do not hold an undergraduate degree, certificates and the MS degree will be awarded upon completing your Doctor of Pharmacy degree.

4.13. Dismissal

All Students: Students may be dismissed from the program at the end of any semester for insufficient progress towards graduation, failure to follow the student's Program of Study or other university or program guidelines, or low grades.

University of Georgia graduate students must maintain a grade point average of 3.0 or higher on all graduate courses taken. GPA below 3.0 are unacceptable for courses on the Program of

Study including all core courses.

In the first semester that the cumulative GPA falls below 3.0, students are placed on academic warning by the University of Georgia Graduate School and are required to meet with the graduate coordinator to develop a plan to improve their academic performance. If the cumulative GPA is below 3.0 for a second consecutive semester, the student is placed on academic probation. If the student receives a GPA below 3.0 in any semester while on probation, they are dismissed from the Graduate School.

IBRS graduate students may be dismissed from the program at the end of any semester if they have not made sufficient academic progress to warrant continuation of study, have not met their responsibilities, have not met their admittance stipulations, or have not maintained accepted standards of conduct. This would apply to students who spend two consecutive semesters with a cumulative GPA below 3.0; students who make a "U" or a grade below a "C" in a core course; or ethical violations. Failure to make acceptable progress in the thesis or project may be demonstrated by unsatisfactory grades in thesis research or project courses (PHAR 6950E, PHRM 7000, and PHRM 7300) or by more than one poor committee evaluation.

Ethical violations that warrant dismissal from the program include but are not limited to violation of ethical principles concerning falsification of data or records; plagiarism; and academic dishonesty – including incorporation of materials into papers, theses, presentations, etc. without appropriate attribution.

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5. Written Student Complaints

All Students: The University of Georgia is committed to excellence in a teaching/learning environment dedicated to serve a diverse and well-prepared student body, to promote high levels of student achievement, and to provide appropriate academic support services. In line with this commitment, the University addresses all written student complaints in a fair, professional, and timely manner and in accordance with established procedures (Academic Affairs Policy Manual 4.05-4, https://policy.uga.edu/policies/#/home). Written Student Complaints are not meant to circumvent or replace existing UGA policies and procedures designed to address issues brought forward by students (e.g., the UGA Hotline, the NDAH Policy, Graduate School Appeals Process, etc.). Currently, enrolled students can submit a written student complaint through the web-based system available at https://studentcomplaints.uga.edu/. As part of the submission process, the student is required to log in to verify student status and provide a summary of the complaint, along with identifying the university functional area connected to the complaint.

The complaint is then routed to the proper functional area and the designated contact assigned the given complaint reviews the complaint and determines a course of action.

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6. Compliance Policies

6.1. Academic Honesty

All Students: Students in the IBRS graduate program are held to the highest ethical standards. There is absolutely no place in the graduate program for academic or scientific dishonesty, including all forms of plagiarism and data falsification. Academic dishonesty is grounds for dismissal from the program. See the UGA policy on academic honesty at https://honesty.uga.edu/. Each student must become familiar with these standards and regulations and is responsible for maintaining and adhering to the strictest standards of academic and scientific integrity and honesty. All academic work must meet the standards contained in "A Culture of Honesty." Each student is responsible to inform themselves about those standards before performing any academic work. A Culture of Honesty is the University of Georgia's policy and procedures for handling cases of suspected dishonesty and can be found online 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 "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."

6.2. Responsible Conduct in Research

See 7.8 of this document.

All Students, but mostly MS Students: Students conducting research must adhere to the highest standards of Responsible Conduct of Research, in addition to the University's academic integrity policies. Before starting any research for PHAR 6800, PHAR 6900, PHAR 6950, PHAR 7000, or PHAR 7300, you must identify a major professor and submit your protocol to the Institutional Review Board (IRB) for approval or exemption. Ensure that you and your major professor are trained in Biomedical Research through the CITI Training Module, accessible via the UGA Pep portal.

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6.3. UGA Non-Discrimination and Anti-Harassment Policy

UGA Non-Discrimination & Anti-Harassment Policy:
https://eoo.uga.edu/civil_rights_NDAH/ndah-policy/

6.4. Workplace Violence

UGA Workplace Violence Policy is found at:
https://safeandsecure.uga.edu/workplace-violence/.

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7. IBRS Academic Programs of Study

7.1. 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.)
PHAR 6030E: Current Good Manufacturing Practices (4 hrs.)

PHRM 7230E: Ethics in Research (3 hrs.)

To be awarded this certificate, a student must receive a grade of B or better in EACH course.

7.2. 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 receive a grade of B or better in EACH course.

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

The DR 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 receive a grade of B or better in EACH course.

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

The CMC Certificate Learning Outcomes

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 receive a grade of B or better in EACH course.

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7.5. Master of Science Degree – Regulatory Sciences (38 to 39 Credit Hours)

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

Master of Science (Thesis or Project Path) 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.

Curriculum and Program Requirements

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

Course Name (Core Courses)	Credit Hours	Semester Offered*

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PHAR 6010E	Introduction to Pharmaceutical, Biotechnology, and Medical Devices Industries: A Regulatory Overview	4	Fall, Spring
PHAR 6020E	Food and Drug Law	3	Varies
PHAR 6030E	Current Good Manufacturing Practices (cGMPs)	4	Varies
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 Name (Core Courses)		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	

B. Additional required courses for MS Thesis student

- for **MS Thesis Student only**:

Course Name (Elective Courses)		Credit Hours	Semester Offered
PHRM 7300	Masters Research	3	As needed

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C. An additional **12 to 15 credit hours of electives** is required for both Thesis and Project students. Appropriate electives include:

	Elective Courses	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, Spring
PHAR 6160E	Chemistry, Manufacturing, and Controls	4	Fall, Spring
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, Summer
PHAR 6340E	European Pharmaceutical and Biologics Regulatory Affairs	3	Spring
PHAR 6360E	Latin American Pharmaceutical and Biologics Regulatory Sciences	3	Summer
PHAR 6380E	Global Medical Device Regulatory Submissions	3	Fall, Summer
PHAR 6800E	Applied Project in Regulatory Affairs	3	As needed
PHRM 7210	Special Topics in Pharmacy	3	As needed
PHRM 7000 (Thesis students only)	Masters 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 + 12 electives = 39 credit hours minimum

MS Thesis Student: 24 core courses + 15 electives = 38 credit hours minimum

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

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

Master of Science (Project Path) 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

Curriculum and Program Requirements

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

Course Name (Core Courses)	Credit Hours	Semester Offered*

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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	Varies
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 7100E	Biostatistical Applications for the Pharmaceutical and Biotechnology Industries	3	Fall, Spring
PHAR 6950E	Master's Seminar in Regulatory Affairs	3	As needed
Total		27	

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

B. Additional elective courses:

C. 1 course or 3 elective hours is required for this program.

Appropriate electives include:

Elective Courses		Credit Hours	Semester Offered*
PHAR 6020E	Food and Drug Law	3	Varies
PHAR 6130E	U.S. Marketing Applications for New Drugs, Biologics, and Medical Devices	4	Spring
PHAR 6340E	European Pharmaceutical and Biologics Regulatory Affairs	3	Spring

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

Total course credits

MS Project Student: 27 core courses + 3 electives = 33 credit hours minimum

7.7. Applied Project, Internship, and Capstone Project classes

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

Students need either PHAR 6800, Applied Project, or PHAR 6900E, RS Internship. These courses are 3 credit hours each. PHAR 6800 or PHAR 6900 – one class or the other, but not both. PHAR 6950E is the course taken the semester the student wished to graduate. It is 3 credit hours.

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PHAR 6800, PHAR 6900, and PHAR 6950 are all *independent* in nature. This means that the course is created specifically for the student in the UGA system. Because it is independent in nature, it is incumbent upon the student to initiate communication with the instructor and/or committee to confirm a topic and identify the deliverables of the course(s). When you sign up for these courses, you should plan on reaching out to your major professor to arrange a meeting.

PHAR 6800: Most students who are working and/or taking classes in other programs often opt to enroll in PHAR 6800 rather than PHAR 6900. 6900 is the internship course. Internships are not very practical for working professionals or students in other degree programs like the Pharm.D.

This PHAR 6800 course is an independent study. For PHAR 6800, you need to work with a major professor. This person will oversee your applied project. You should reach out to a faculty member with whom you are interested in working. Email this person and ask if he/she would be willing to serve as your Major Professor for the PHAR 6800 course. Generally, you will use this person as your major professor for your MS Project too, but it is not absolutely necessary to do that. Once you've identified the instructor you will work with, let me know so that I can create a course for you with the PHAR 6800 course in mind. The PHAR 6800 is graded as a traditionally graded course – A, A-, B+, B, B-, etc.

The advisor/major professor for the PHAR 6800 course must be a Regulatory Sciences faculty member so that they can advise you on the regulatory nature of your project. Faculty outside of the Regulatory Sciences Program cannot serve as the major professor.

This PHAR 6800 course represents a functional study or drafting of the proposal on a topic that is related to the student's career objectives and their final project. Each student will propose a project on a biomedical (pharma, medical device, or biologics) regulatory issue, service, assessment, or application to write up and present according to the guidelines below. The project should be a "real world" application of a specific body of knowledge to address an area in need of study, development, or evaluation. In order to provide possible credit for past knowledge and experience, students also have the option to formally write-up a previous project of significant rigor conducted in the last two years or expand/develop further a project that the student is currently working on at his or her practice site.

It is strongly advised that students avoid capstone projects involving patients or patient-identifiable personal data. Such projects will trigger heightened scrutiny by UGA's Institutional Review Board Office, leading to additional periodic reporting requirements, the necessity for secure data storage, and other details that could significantly prolong and delay student projects. Instead, students are encouraged to select projects that do not involve patient data and can be submitted to the IRB office without requiring IRB involvement or scrutiny or qualifying for exemption.

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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: This course will offer students opportunities to apply knowledge and skills of regulatory science through participation in a part- or full-time internship with a biomedical related industry or agency. Internship is arranged by individual, faculty, and participating institution by mutual consent and must be covered by an approved Memorandum of Understanding. Focus of the internship includes Research and application of regulatory issues in biomedical industries or governmental agencies. The site will have a major project that addresses the educational needs of the student.

This PHAR 6900 course is an independent study. For PHAR 6900, you need to work with a major professor. This person will oversee your internship. This course is graded as a S/U (Satisfactory/Unsatisfactory); based on completion of assignments, evaluation of performance and final project. Evaluation of the Internship will be a joint effort between the assigned preceptor, IBRS faculty, and through student self-assessment that details success toward the learning objective, experiences, tasks, and the project performed at the site. The student will make a final presentation to an appropriate audience highlighting his or her contribution towards the assigned internship project.

PHAR 6950E: This is the course a student must register for the term they wish to graduate. A final project in a master's degree program is a culminating academic endeavor that allows students to demonstrate their knowledge, skills, and mastery of the subject matter in their field of study. A capstone project is a comprehensive project that integrates knowledge and skills acquired throughout the program. It typically involves solving a real-world problem or completing a substantial project that reflects the practical application of the knowledge gained during the master's program.

The purpose of the final project is to demonstrate a deep understanding of the subject matter, critical thinking abilities, research skills, and the ability to apply knowledge to real-world situations. It is assessed by faculty members or a committee, and successful completion of the final project is a requirement for obtaining a master's degree. PHAR 6950E – the Master's Seminar Course - 3 credit hours is the course where you will develop and present this capstone project. This is the course you need to register for the term you wish to graduate. This course is graded as an S/U and can be taken multiple times without impacting your GPA. (3 Credit Hours). This course will be created for the student during the final term of the program. Students can retake the course if the student is unable to complete the project. However,

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.

It is strongly advised that students avoid capstone projects involving patients or patient-identifiable personal data. Such projects will trigger heightened scrutiny by UGA's Institutional Review Board Office, leading to additional periodic reporting requirements, the necessity for secure data storage, and other details that could significantly prolong and delay student projects. Instead, students are encouraged to select projects that do not involve patient data and can be submitted to the IRB office without requiring IRB involvement or scrutiny or qualifying for exemption.

For this course/project, a faculty committee of three members is required. This course is a 3-credit hour course. The advisor/major professor for the PHAR 6950 course must be a Regulatory Sciences faculty member so that they can advise the student on the regulatory nature of the selected project. Faculty outside of the Regulatory Sciences Program cannot serve as the major professor.

Timeframe: With the project write-up, the faculty committee should have at least two weeks to review the student's Major Project Write-up prior to the student's project presentation. For example, if classes for the Spring semester ends on May 1. This means the student will need everything done by May 1st including the project presentation and the write-up. Working backward, the student should have the write-up done and submitted to the faculty committee by April 15th and the project presentation done by April 30/May 1st.

7.8. Responsible Conduct in Research

All Students, mostly MS Students: In addition to the basic University principles and policies governing academic integrity, students engaged in scientific research have a special obligation to adhere to the highest standards of Responsible Conduct of Research. UGA's Institutional Review Board, https://research.uga.edu/hrpp/, is responsible for maintaining research integrity at the University. Before undertaking any research for PHAR 6800, PHAR 6900, PHAR 6950, PHAR 7000 or PHAR 7300, it is imperative that the student identify a major professor, and the student submit the student protocol to the IRB Office for approval or exemption. Do not proceed with any research activities until this criterion is addressed.

Ensure that the student are properly trained in the rules of Biomedical Research. To access the CITI Training Module, log into the UGA Pep portal at https://hr.uga.edu/pep/. Search for "Bio-medical Research" with the hyphen to locate the training more efficiently. Launch the course, which will redirect the student to the CITI - Collaborative Institutional Training Initiative portal

and the Bio-medical Research course. Complete the necessary modules. The student may choose to do a few modules at a time to manage their schedule effectively.

Note: Please be aware that the student's major professor will act as the Principal Investigator (PI) for the student's project's IRB application. It is crucial to confirm whether the student's major professor has completed the Bio-Medical Research module and the CITI module or ensure that their training is up to date. Should the major professor not have received the necessary training or if their training has expired, it will result in delays in processing the student's project submissions through UGA's IRB Office. In the event that the PI has not completed this essential training, or if it has expired, any project submission to the IRB portal cannot proceed until this training requirement is met. Such delays could potentially impact the student's progress on the project.

7.9. MS Program of Study Form (required)

Master's Students only: The MS Program of Study (PS) form is applicable to all MS students. This Graduate School form is found at https://grad.uga.edu/current-students/forms/. This form outlines the courses and research for students in accordance with the student's degree requirements. Students must complete a Program of Study form during their enrollment in either PHAR 6800 or PHAR 6950E. The Program of Study serves as a comprehensive record of the coursework undertaken for the graduate degree, encompassing both required and elective courses. The Program of Study is integral to the graduate program, serving as a foundational document that delineates all completed, in-progress, and planned coursework or credits necessary for degree fulfillment.

This form must be submitted to the UGA Graduate School by the specified deadline, as outlined in the UGA Graduate School Important Dates and Deadline [https://grad.uga.edu/current-students/important-dates-deadlines/]. The Program of Study form must be submitted to the Graduate School by Friday of the second full week of classes of the semester in which degree requirements are completed.

7.10. Project and Thesis Committees

Master's Students only: At the midpoint of the student's program, i.e. about 14-17 credit hours, each MS student will form a Project Advisory Committee or Thesis Committee. This committee will assess student progress through the program, approve the program of study and research prospectus, and conduct the thesis defense or project presentation. This Committee

consist of the major professor as chairperson plus two additional faculty members. Details on thesis or project planning, please consult the UGA Regulatory Sciences Master's Student Guide Document. Committee Chairs should be chosen from the IBRS Program only. Do not attempt to use a committee chair with someone outside of the IBRS department.

Committee Role

Master's Students only: Student progress in the program will be evaluated by the Advisory Committee. The purpose of a faculty committee for a Master's degree project is multifaceted and serves several key roles in the academic and professional development of the student. The faculty committee plays a crucial role in supporting the student's academic journey, ensuring the integrity and excellence of the research, and preparing the student for future professional or academic endeavors. Their primary purposes include guidance and mentorship, quality assurance, and evaluation and assessment

If more than one committee member or the major professor gives the student an "Unsatisfactory" evaluation, the student and major professor must develop a remediation plan to improve performance. For example, the remediation plan may include additional coursework and/or more frequent committee meetings. In addition to general assessment of the student's progress in thesis research or project development, the specific goal of the committee meeting is to approve the preliminary Program of Study.

7.11. Project or Thesis Research, Writing, and Defense

Master's Students only: It is the student's responsibility to coordinate thesis defense or project presentation with committee members. The student must notify the IBRS Assistant Director of the scheduled date, time and location for the thesis defense or project presentation at least two weeks in advance. It is the student's responsibility to apply for graduation, perform thesis format checks, and submit all required paperwork with the UGA Graduate School by the posted deadlines.

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8.0. Additional Policies and Helpful Information

8.1. 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 should become familiar with the current regulations, policies and schedules contained in this publication, and are responsible for meeting all requirements and deadlines for his or her degree program.

8.2. 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.

8.3. 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.

8.4. 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. See
https://www.uhs.uga.edu/caps/welcome
or call 706- 542-2273 for more information.

Disability Resource Center: Offers accommodations and services for graduate students with disabilities
(https://www.drc.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:

- 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.

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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://www.uhs.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/wriIng-center). To schedule an appointment, visit https://www.uga.mywconline.com and click on the "Appointments" link.