UNIVERSITY OF GEORGIA
College of Pharmacy
International Biomedical Regulatory Sciences

Certificate and Masters (MS) Degree Programs Student Handbook

This program was formally known as the University of Georgia's BioPharma Regulatory Affairs Program. The name was officially changed to International Biomedical Regulatory Sciences effective January 1, 2018.

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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 website. All graduate students including Certificate students and master's degree 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 Thesis and Project paths, are encouraged to also review the **MS Guide** document. This 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 at rs.rx.uga.edu/pdfs/Guide_for_MS.pdf.

International Biomedical Regulatory Sciences Student Handbook

Program Administrative Contacts

Grace Gowda, Ph.D., RAC Associate Professor and Director, International Biomedical Regulatory Sciences Program UGA College of Pharmacy Email: grace.gowda@uga.edu Office Phone: 678-985-6827	Michael Bartlett, Ph.D. Graduate Coordinator & Associate Dean UGA College of Pharmacy Email: mgbart@uga.edu Office Phone: 706-542-5390	Johnna Hodges Assistant Director, International Biomedical Regulatory Sciences Program UGA College of Pharmacy Email: jhodges@uga.edu Office Phone: 678-985-6808

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

- General graduate program issues and concerns, waivers, extensions, grievances, assignments, and coordinator signatures:
  - Johnna Hodges, jhodges@uga.edu, 678-985-6808
- Courses, forms, deadlines, UGA and Graduate School requirements:
  - Johnna Hodges, jhodges@uga.edu, 678-985-6808
- Access to networks:
  - UGA EITS Helpdesk: https://eits.uga.edu/, 706-542-3106

Disability Statement

The University of Georgia Regulatory Sciences 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: pbertot@uga.edu and URL: http://drc.uga.edu/

UGA Gwinnett Campus Representative is Laura Crawley, Ph.D., 678-985-6805,
email: lcrawley@uga.edu

IBRS Certificate & MS Graduate Admission Policies

Admission Criteria

Graduate students are admitted to the IBRS department Certificate and MS programs based on the Admission Committee's assessment of their ability to succeed in these graduate programs, and the commitment of an IBRS faculty member to serve as their major professor and faculty advisor. Key factors considered are: prior experience; evidence of work ethic and commitment to biomedical regulatory sciences; evidence of appropriate educational background; grade point average; English language exam scores (*for international applicants*); references; statement of purpose; program interview (*MS program only*); and other requirements of the Graduate School.

MS Students only: Students in the *MS Program* must identify a major professor/faculty advisor at approximately 18 to 20 credit hours into the program and the major professor must agree to accept the student as an advisee at that time. For details on thesis or project planning, please consult the UGA Regulatory Sciences Master's Student Guide Document (rs.rx.uga.edu/pdfs/Guide_for_MS.pdf).

Financial Assistance

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/.

Change of Degree Path

MS Students only: During your MS program, if you wish to switch from one-degree path to another, 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 17-20 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 letter to Dr. Bartlett, Graduate Coordinator, mgbart@uga.edu and Dr. Gowda, Program Director, grace.gowda@uga.edu. In your letter to Drs. Bartlett and 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 reapply to the UGA Graduate School for the approved degree code.
- Many of the same department and UGA Graduate School policies apply to both MS options. Review the department's MS Guide for details on the planning of your thesis or project as well as the graduation details.

Biomedical 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.

Clinical Trials Design and Monitoring (17 Credit Hours)

The CT Certificate Learning Outcomes

Geared toward a wide range of professionals, the Clinical Trials Design & Management Certificate Program provides a foundation for preparing candidates to lead and to 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 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.

Master of Science Degree (38 to 39 Credit Hours)

in Pharmacy with an emphasis in Regulatory Sciences

Master of Science (Thesis or Project Path) Learning Outcomes

Masters Students only: The Master of Science in Pharmacy with an emphasis in 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 MS Students**. Each of the following course **credits is required**:

Course Name (Core Courses)		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	Varies

PHAR 6030E*	Current Good Manufacturing Practices (cGMPs)	4	Varies
PHRM 7230E*	Ethical Issues in Research	3	Fall / Spring
PHAR 6100E*	Quality Control and Quality Assurance	3	Spring
PHAR 6120E*	Process Control and Validation	3	Fall
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	Summer
PHAR 6950E (Project student) PHRM 7300 (Thesis student)	Masters Seminar in Regulatory Affairs, or master's Thesis	3	As needed
Total		30	

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

B. Additional required course:

- 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

B. Additional elective course if needed:

- for **MS Thesis Student only**:

Course Name (Elective Courses)		Credit Hours	Semester Offered
PHRM 7000	Masters Research	1-6	As needed

C. An additional **6 credit hours of electives** are required for both Thesis and Project students. Appropriate electives include:

Elective Courses		Credit Hours	Semester Offered*
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	Varies
PHAR 6320E*	Understanding the Role and Function of the US Food and Drug Administration	3	Fall
PHAR 6340E*	European Pharmaceutical and Biologics Regulatory Affairs	3	As needed
PHAR 6360E*	Latin American Pharmaceutical and Biologics Regulatory Sciences	3	As needed
PHAR 6380E*	Global Medical Device Regulatory Submissions	3	As needed
PHAR 6800E	Applied Project in Regulatory Affairs	3	As needed
PHRM 7210E*	Special Topics in Pharmacy	3	Varies
PHRM 7000 (Thesis student)	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: 33 core courses + 6 electives = 39 credit hours minimum

MS Thesis Student: 32 core courses + 6 electives = 38 credit hours minimum

Advisement and Committees

All Students: Ms. Hodges will serve as student academic advisor for all students for course enrollment. Each semester, she will reach out to students via email with a tentative schedule of courses for the upcoming semester. At that time, the students will 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.

Thesis and Project Committees

Masters Students only: At the midpoint of the student's program, i.e. about 18-20 credit hours, each student will form a Thesis or Project Advisory 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. The Advisory Committees consist of the major professor as chairman plus two additional faculty

members. Details on thesis or project planning, please consult the UGA Regulatory Sciences Master's Student Guide Document (rs.rx.uga.edu/pdfs/Guide_for_MS.pdf).

Committee Role

Masters Students only: Student progress in the program will be evaluated by the Advisory Committee. 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 and the thesis or project prospectus.

The Final Program of Study is an official document listing the courses for a degree program which is to be filled out on the official form by the student and Major Professor and approved by the Thesis Advisory Committee and the UGA Graduate School. Please consult the UGA Regulatory Sciences Master's Student Guide Document (rs.rx.uga.edu/pdfs/Guide_for_MS.pdf)

Deadline: The final Program of Study must be submitted prior to scheduling the thesis defense or project presentation.

Project or Thesis Research, Writing, and Defense

Masters Students only: Please consult the UGA Regulatory Sciences Master's Student Guide Document (rs.rx.uga.edu/pdfs/Guide_for_MS.pdf) for extensive review of the thesis or project details.

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.

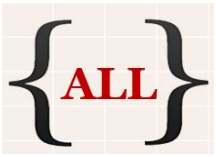
- Forms: http://grad.uga.edu/index.php/current-students/forms/
- Deadlines: http://grad.uga.edu/index.php/current-students/important-dates-deadlines/

More detail on this process if included in the UGA Regulatory Sciences Master's Student Guide Document (ra.rx.uga.edu/pdfs/Guide_for_MS.pdf).

Transfer Credits

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.

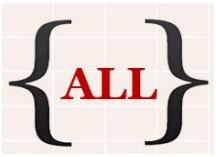
Grades and GPAs



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.

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.

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, Student Appeals Process is located at http://www.uga.edu/provost/polpro.htm.

Academic Performance and Dismissal

University of Georgia graduate students must maintain a grade point average of 3.0 or higher on all graduate courses taken. Grades below 3.0 are not acceptable for courses on the Program of Study, which includes all required 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 teacher- student relationships; falsification of data or records; plagiarism; and academic dishonesty – including incorporation of materials into papers, theses, presentations, etc. without appropriate attribution.

Academic Honesty

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 www.uga.edu/honesty/. 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 www.uga.edu/honesty/. 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."

Additional Policies and Helpful Information

Graduate School Bulletin

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 www.uga.edu/gradschool/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.

ATHENA: Schedule of Classes and Online Registration

Registration instructions for each semester including the list of course offerings, class dates and drop/add policies will be emailed to you by the Program's Assistant Director. They are also available on ATHENA, the online access to student information system.

Responsible Conduct in Research

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.

Email Responsibility

The University relies on electronic communication, motivated by its convenience, speed, cost-effectiveness, and environmental advantages. Because of its general acceptance, use, and availability, the University considers email to be one of the official means of communication. We send official correspondence to **UGA email addresses only.** Therefore, it is expected, particularly of distance learning students, that emails will be read by students in a timely fashion. Students should check their email frequently and consistently, with the recognition that **certain communications may be time-critical.** Failure to check one's email is not an excuse for missed assignments or activities. If you chose to forward your UGA email to an outside address, understand that the University is not responsible for the handling of email by outside vendors, nor are students who use outside accounts absolved from responsibility for messages not received or read. If you opt to forward your messages to another email address, it is your responsibility to read all messages even if they get diverted to your junk mail or trash folders.

Moreover, each of your UGA email addresses are added to class-specific listservs so we can distribute information more effectively. Use of these listservs helps the department to disseminate class-specific information. If you forward your messages to another email system, make sure your email system allows for messages from the domains **@uga.edu**, **@rx.uga.edu** and **@usg.edu**.

Enrollment Policies

Graduate students must register for a minimum of 3 hours of credit during any semester in which they use University facilities and/or staff time. All enrolled students pursuing graduate degrees at the University of Georgia 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), including the 3 hours of Graduate credit that is required for registration during the semester in which degree requirements are complete, until the degree is attained or status as a degree-seeking graduate student is terminated. Failure to maintain continuous enrollment will require that the student reapply to the Graduate School and pay an additional reenrollment fee. Please see grad.uga.edu/index.php/current-students/policies-procedures/academics/enrollment-policy/.

Leave of Absence

A leave of absence provides a mechanism for students experiencing unusual circumstance to be exempt temporarily from the continuous enrollment policy. A leave of absence requires approval of the Graduate Program Coordinator and the Dean of Graduate School. A leave of absence will be granted only for good cause such as serious medical and health-related issues, major financial and employment issues; pregnancy, childbirth, child care, elder care, and other significant family issues; and other major personal circumstances that interfere with the ability

to undertake graduate study. For questions, about the Leave of Absence process, please contact the Assistant Director of the RS Program.

For questions about UGA Graduate School or Departmental policy or other information contained within this document, please contact the Assistant Director of the IBRS Program.