Differences between the Non-Thesis (Project) and Thesis Options for the M.S. in Pharmacy with an emphasis in BioPharma Regulatory Affairs Offered by the University of Georgia College of Pharmacy

Background:

Regulatory Affairs (RA) professionals are employed in industry, government and academia and provide a range of services related to the regulation, development, manufacturing and marketing of pharmaceuticals, medical devices, *in vitro* diagnostics, biologics, biotechnology, nutritional products, cosmetics, and veterinary products. RA professionals come from diverse backgrounds and usually have experience in other science-based careers before transitioning into a career within regulatory affairs. Often, they have worked in the fields of medicine, law, nursing, pharmacy, engineering, clinical laboratory science, research or healthcare manufacturing. According to the Regulatory Professional Society (RAPS), more than half the RA professionals have an advanced degree, most often in a scientific or technical field.

The University of Georgia (UGA) College of Pharmacy offers the Master's of Science (M.S.) degree in Pharmacy, with an emphasis in Regulatory Affairs. The degree provides a strong professional foundation needed to succeed in administrative positions and in specialized areas that require tactical and strategic skill sets. These graduate education offerings are geared for working professionals and as such are primarily planned to be taken on a part-time basis. Classes are designed to allow individual flexibility, yet provide a standard academic structure to advance student learning from one semester to the next. The graduate certificate and the M.S. program require separate application processes and admission criteria.

Pathways for the Master's Degree (Thesis and Non-Thesis)

There are two pathways for the UGA M.S. degree in Regulatory Affairs. (1) The non-thesis pathway (or Project pathway) requires at least 39 semester hours, which includes an applied project or internship and a comprehensive examination. And, (2) the thesis pathway requires at least 39 semester hours, which includes the development and oral defense of a research-based thesis. Time to complete the thesis program frequently takes longer to complete than the non-thesis option. This is because it requires independent research, with close scrutiny of research methodology and assessment of results. In addition, writing a thesis is time-consuming and must conform to stringent research guidelines.

<u>Non-thesis Pathway</u>

The non-thesis pathway is intended to develop professionals with a strong applied background in biomedical product development; risk assessment and management; and, monitoring and communicating change in the regulatory environment. The non-thesis pathway will engage the students in real-world application, practice development and experiential learning needed for career success. These practical aspects of the job are highly desired by employers and the non-thesis pathway is particularly suitable for students who do not plan to pursue research intensive positions or complete a Ph.D.

Thesis Pathway

The thesis pathway requires the completion of a research-based thesis. The value of choosing the thesis pathway includes the development of specialized skills and knowledge that maybe more attractive to certain employers. A thesis may be especially valuable for work requiring research in cutting-edge development companies. Completing a master's thesis demonstrates research competencies, involves direct research experience, and strengthens ones potential application to Ph.D. programs. While completing a master's thesis, the student learns how to research published literature in a targeted field, how to write for a scholarly audience, and how to present ones work in writing and in public forum. In addition, the student will learn more about a select topic than one would learn in a classroom.

All Masters Students:

All students enrolled in the master's program, whether thesis or non-thesis, must complete the 30 semester hours graduate core curriculum (see Program of Study - Appendix 1). In addition, relevant thesis (research) or non-thesis (application-based) requirements must be met and are summarized below. *Note: A chart that compares course requirements for the Graduate Certificate, the M.S. with Thesis, and the M.S. with Non-Thesis Pathway is included as Appendix 2.*

After completing at least 17 hours of core coursework, each student must declare either the thesis or non-thesis option. This decision will be made in concert with the student's advisor and in discussion with program faculty.

Non-thesis Option (Project MS)

Students pursuing the non-thesis pathway must complete and receive committee approval of a focused area of study/exploration, consisting of at least 9 additional semester hours beyond the 30 hour core curriculum. The concentration of courses and experiential learning is intended to better prepare the student for the job market and includes:

- 3 hrs of additional elective(s) or other appropriate courses related to the student's career objective (e.g., pharmaceutical, device, biological, FDA operations, international regulations, animal health).
- 3 hrs of an applied project and/or internship related to the student's career objective.
  - PHAR 6800 (Applied Project in Regulatory Affairs) and/or
  - PHAR 6900 (Internship in Biomedical Regulatory Affairs)
- 3 hrs of *Masters Seminar in Regulatory Affairs*, an in-depth topical exploration in regulatory science that complements the applied project and/or internship (co-requisite w/PHAR 6800 or 6900 & described below).
- Pass a comprehensive written examination, administered by the student's graduate advisory committee.

Non-Thesis Committee: Students who declare the non-thesis pathway will select an appropriate major professor, who is associated with the area of concentration for which the student is inclined to pursue. The major professor will serve as advisor to supervise the final program of study, and help select a

three person non-thesis Advisory Committee. At least two of the committee members, including the major professor, must hold a UGA College of Pharmacy faculty appointment and be an instructor in the program of study. The third committee member may be an appropriate outside expert in regulatory science. The Advisory Committee, in consultation with the student is charged with approving the student's Program of Study, determining the culminating applied project and/or experiential education component based on the needs of the student, coordinating the student's seminar, and administering and evaluating the final examination over the Program of Study.

Comprehensive Examination: A written comprehensive examination, administered during the student's last semester tests the student on three topical areas of regulatory affairs, determined by the student's advisory committee. This examination is designed to provide students with an opportunity to display a comprehensive understanding of the discipline of Regulatory Affairs. Students must be able to effectively integrate course work from their program of study into their responses to the questions. The comprehensive examination may not be taken prior to the last semester of course work. Students will apply to take the examination in advance, normally during the first two weeks of the semester/term in which they desire to take the examination. Each exam will be graded by at least two program faculty, and the student's answers will be assigned one of three grades: pass with distinction, pass, or fail. Students failing the comprehensive examination on the first attempt may retake it a second time. If a student fails the examination a second time, the student's committee shall decide if remediation of coursework is applicable and/or feasible, or if the student should be dismissed from the program.

Thesis Option

The thesis pathway consists of a minimum of 6 additional semester hours beyond the 30 hr core curriculum. The concentration of courses and research is intended to better prepare the student for specific jobs or a competitive Ph.D. program of study or equivalent. Students pursuing this pathway must complete a thesis that is focused in an area of research and guided and approved by a thesis - directed committee.

- 3 hrs of additional elective(s) or other appropriate courses related to the student's career objective (e.g., pharmaceutical, device, biological, FDA operations, international regulations, animal health).
- 6 hrs of thesis work
  PHRM 7000; *at least* 3 hours (Master Research)
  PHRM 7300; *at least* 3 hours (Master Thesis)
- Pass an oral examination and thesis defense administered by the student's graduate advisory committee.

Thesis Committee: Students who declare the thesis pathway will select an appropriate major professor, who can guide the student in research-based work related to an area of study that the student is inclined to pursue. The major professor will serve as the student's advisor to oversee the final program of study, and help the student select a three-person Thesis Advisory Committee. This committee approves the research proposal, supervises the progress of the thesis, and acts as the examining committee at the oral examination of the thesis (see below). At least two of the committee members, including the major professor must hold UGA Graduate School appointment. A third

committee member may be an appropriate outside expert in regulatory science, but his or her appointment must be approved by the Graduate School.

Oral Examination: Prior to the oral defense, the written thesis paper should be complete and virtually flawless. During the thesis defense, the master candidate is expected to present and defend thesis work in front of the student's thesis committee and other audience members, and in a cohesive manner. Students are asked a number of questions during and after the presentation, and must be armed with the knowledge and skills necessary to answer questions about the background, research design, and findings confidently. The thesis defense is an opportunity to take the stage and demonstrate growth and progress experienced as a graduate student. It allows the candidate to showcase research abilities and complete the degree requirements.

Appendices: 1. Course Requirement Comparisons for Graduate Certificate, the M.S. with Thesis Pathway, and the proposed M.S. with Non-Thesis Pathway
2. List of Program Electives

Appendix One: Course Requirement Comparisons for Graduate Certificate, the M.S. with Thesis Pathway, and the M.S. with Non-Thesis Pathway

Characteristics/ Requirements	Graduate Certificate in BioPharma Regulatory Affairs	Graduate Certificate in Clinical Trials Design & Monitoring	M.S. in Regulatory Affairs Non-Thesis & Thesis Pathways
Semester Hours	14 hrs	17 hrs	39 hrs min
Certificate/MS Core (14-17 hrs)	PHAR 6010 *Pharma, Biotech & Device Industries* (4 hrs)	PHAR 6010 *Pharma, Biotech & Device Industries* (4 hrs)	PHAR 6010 *Pharma, Biotech & Device Industries* (4 hrs)
	PHAR 6020 *Food & Drug Law* (3 hrs)	PHAR 7100 *Biostats Apps in BioPharma Industries* (3 hrs)	PHAR 6020 *Food & Drug Law* (3 hrs)
	PHAR 6030 *Current GMPs* (4 hrs)	PHRM 7230 *Ethical Issues in Research* (3 hrs)	PHAR 6030 *Current GMPs* (4 hrs)
	PHRM 7230 *Ethical Issues in Research* (3 hrs)	PHAR 6200 *Clinical Trials Design & Monitoring* (4 hrs)	PHRM 7230 *Ethical Issues in Research* (3 hrs)
		PHAR 6210 *Project Management in Clinical Trials* (3 hrs)	
MS Additional Core (13 hrs)			PHAR 6100 *QC & QA* (3 hrs)
			PHAR 6120 *Process Control & Validation* (3 hrs)
			PHAR 6130 *FDA Apps: Drugs, Biologics, Devices & Animal Products* (4 hrs)
			PHAR 7100 *Biostats Apps for Pharma & Biotech Industries* (3 hrs)
			PHRM 7230 *Ethical Issues in Research* (3 hrs)
MS Electives (6 hrs)			*Current approved electives or others by POD* (6 hrs min)
MS Non-Thesis (6 hrs)			PHAR 6800 *Applied Project in Regulatory Affairs* (3 hrs) and/or PHAR 6900 *Internship in Biomedical Regulatory Affairs* (3 hrs)
or			PHAR 6950 *Masters Seminar in Regulatory Affairs* and *Comp. Written Examination* (3 hrs)
MS Thesis (6 hrs min)			PHRM 7000, *Masters Research* (3 hrs min) and PHRM 7300, *Master's Thesis* (3 hrs min)

Appendix Two: List of Program Electives [1, 2]

Course ID	Course Title	Hrs.
PHAR 6200	Clinical Trials Design & Monitoring	4.0
PHAR 6210	Clinical Trials Project Management	3.0
PHAR 6310	Good Clinical Practices	3.0
PHAR 6800	Applied Project in Regulatory Affairs	3.0
PHAR 6900	Internship (Regulatory Affairs Internship)	3.0
PHAR 6320	Understanding the Role and Function of the FDA	3.0
	Critical Issues in Regulatory Sciences	3.0
	Comparative Global Regulations	3.0
	Good Laboratory Practices	3.0

[1] *If there is a UGA graduate-level course outside the department that the student wishes to take, such as Health Care Marketing or Health Communication, the student will need to contact the department for prior approval. The student should take into consideration that courses outside of the Regulatory Affairs Department are NOT necessarily distance learning courses.*

[2] Electives are subject to change