APP. 1: Thesis and Project-based MS Options: A Comparison

The University of Georgia College of Pharmacy
Office of Regulatory Affairs & Clinical Design and Management
Requirements for Graduate Certificates, M.S. Non-Thesis Option, and M.S. Thesis Option

Characteristics/ Requirements	Graduate Certificate in BioPharma Regulatory Affairs	Graduate Certificate in Clinical Trials Design & Monitoring	M.S. in Regulatory Affairs Non-Thesis & Thesis Options
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 for 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)
			PHAR 6950 *Masters Seminar in Regulatory Affairs* and *Comp. Written Examination* (3 hrs)
Or			
MS Thesis (6 hrs min)			**PHAR 7000**, *Masters Research* (3 hrs min) and **PHRM 7300**, *Master's Thesis* (3 hrs min)

App. 3: UGA RA Program Course Listings

All available Regulatory Affairs Program Graduate Courses

Course ID	Course Title	Hours
PHAR 6010	Introduction to Pharmaceutical, Biotechnology, and Medical Devices Industries	4.0
PHAR 6020	Food & Drug Law	3.0
PHAR 6030	Current Good Manufacturing Practices	4.0
PHAR 6100	Quality Assurance and Quality Control	3.0
PHAR 6120	Process Control and Validation	3.0
PHAR 6130	FDA Applications and Submissions	4.0
PHAR 6200	Clinical Trials Design & Monitoring	4.0
PHAR 6210	Clinical Trials Project Management	3.0
PHAR 6310	Good Clinical Practices	3.0
PHAR 6320	Understanding the Role and Function of the FDA	3.0
PHAR 6800	Applied Project in Regulatory Affairs	3.0
PHAR 6900	Internship (Regulatory Affairs Internship)	3.0
PHAR 6950	Master's Seminar	3.0
PHRM 7000	Master's Research Course	3.0
PHAR 7100	Biostatistical Applications for Pharmaceutical and Biotechnology Industries	3.0
PHRM 7210-GCP	Special Topics in Pharmacy - Good Clinical Practices	3.0
PHRM 7230	Ethics in Research	3.0
PHRM 7300	Master's Thesis	3.0

Thesis Path required courses – Master's of Science Degree Total hours required: 38 credit hours min.

Course ID	Course Title	Hours
PHAR 6010	Introduction to Pharmaceutical, Biotechnology, and Medical Devices Industries	4.0
PHAR 6020	Food & Drug Law	3.0
PHAR 6030	Current Good Manufacturing Practices	4.0
PHAR 6100	Quality Assurance and Quality Control	3.0
PHAR 6120	Process Control and Validation	3.0
PHAR 6130	FDA Applications and Submissions	4.0
PHRM 7230	Ethics in Research	3.0
PHAR 7100	Biostatistical Applications for Pharmaceutical and Biotechnology Industries	3.0
PHRM 7300	Master's Thesis	3.0
	Total credit hours of required courses	30
	3-4 Elective courses at 3 to 4 credit hours each	9-12

Electives*

Course ID	Course Title	Hours
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
PHRM 7000	Master's Research Course	3.0
PHAR 6320	Understanding the Role and Function of the FDA	3.0

**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.*

Project Path required courses – Master's of Science Degree Total hours required: 39 credit hours min.

Course ID	Course Title	Hours
PHAR 6010	Introduction to Pharmaceutical, Biotechnology, and Medical Devices Industries	4.0
PHAR 6020	Food & Drug Law	3.0
PHAR 6030	Current Good Manufacturing Practices	4.0
PHAR 6100	Quality Assurance and Quality Control	3.0
PHAR 6120	Process Control and Validation	3.0
PHAR 6130	FDA Applications and Submissions	4.0
PHRM 7230	Ethics in Research	3.0
PHAR 7100	Biostatistical Applications for Pharmaceutical and Biotechnology Industries	3.0
PHAR 6800 AND/OR PHAR 6900	Applied Project in Regulatory Affairs Internship (Regulatory Affairs Internship)	3.0 3.0
PHRM 6950	Master's Seminar	3.0
	Total credit hours of required courses	33
	2 Elective courses at 3 to 4 credit hours each	6

Electives*

Course ID	Course Title	Hours
PHAR 6200	Clinical Trials Design & Monitoring	4.0
PHAR 6210	Clinical Trials Project Management	3.0
PHAR 6310	Good Clinical Practices	3.0
PHAR 6320	Understanding the Role and Function of the FDA	3.0
PHAR 6800	Applied Project in Regulatory Affairs	3.0
PHAR 6900	Internship (Regulatory Affairs Internship)	3.0

**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.*