

REGULATORY AFFAIRS

master's program

FOR WORKING PROFESSIONALS

The rapidly expanding pharmaceutical and biomedical industries necessitate a greater number of Regulatory Affairs professionals to manage the FDA approval process of new products and maintain regulatory compliance. Specialized and convenient education is crucial for busy professionals to apply complex principles in an ever-changing regulatory environment. 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 management.

UGA's *Master's of Science for Regulatory Affairs Program* covers regulatory requirements for Pharmaceutical, Biologic, Medical Device, Animal Health, and Combination Products.



The University of Georgia
Gwinnett Campus

www.RA.Rx.UGA.edu

UGA
BioPharma
Regulatory Affairs
Graduate Education Programs

MASTER'S PROGRAM PLAN

38 total semester hours

Course topics include the 14 semester hours in the RA Certificate

Program:

- Intro to Pharmaceutical, Biotechnology & Device Industries (4 hrs)
- Food & Drug Law (3 hrs)
- Current Good Manufacturing Practices (4 hrs)
- Ethics in Research (3 hrs)

Additional core courses:

- Quality Control & Quality Assurance (3 hrs)
- Process Control & Validation (3 hrs)
- Biostatistics (3 hrs)
- Master's Thesis or Major Project

Advanced electives are:

- Regulatory Affairs • Quality Control & Quality Assurance • Internship
- Clinical Trials Management • FDA Applications & Submissions
- Developing Leadership Skills • Drug Development • Veterinary Products

Sample part-time schedule:

Fall Semester

- PHAR 6100: Quality Assurance & Quality Control
- PHAR 6200: Clinical Trials Design & Monitoring

Spring Semester

- PHAR 6800: Applied Project
- PHAR 6130 : FDA Submissions

Summer Semester

- PHAR 7100: Biostatistics
- PHAR 6120: Process Validation

Application, enrollment and other information is available at www.RA.Rx.UGA.edu or by emailing regaffairs@rx.uga.edu.

Office of Regulatory Affairs & Clinical Trials
Graduate Education Programs
College of Pharmacy

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