REGULATORY AFFAIRS
master's program

REGULATORY AFFAIRS
certificate program

CLINICAL TRIALS DESIGN
AND MANAGEMENT
certificate program

LEARN FROM
industry experts
Online Graduate Education Programs in BioPharma Regulatory Affairs & Clinical Trials

REGULATORY AFFAIRS
master’s program

REGULATORY AFFAIRS
certificate program

CLINICAL TRIALS DESIGN AND MANAGEMENT
certificate program

FOR WORKING PROFESSIONALS

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 implementation of scientifically valid clinical trials. With a concentration on the monitoring of clinical trials, the goal of this program is to prepare regulatory affairs professionals to meet the challenges and responsibilities of today’s pharmaceutical industry.

www.RA.Rx.UGA.edu
Online Graduate Education Programs in
BioPharma Regulatory Affairs
& Clinical Trials

www.RA.Rx.UGA.edu
FOR WORKING PROFESSIONALS

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 implementation of scientifically valid clinical study designs including monitoring of clinical trials and directing daily clinical trial operations. The interdisciplinary program encompasses core competency areas integral to the drug product development and medical device design validation required for federal regulatory clearance.

The Clinical Trials Certificate Program offers graduate credit courses leading to a UGA certificate and, if a student completes additional graduate courses, the certificate course work may be applied toward a Master's Degree in Pharmacy with an emphasis in Regulatory Affairs.
The Clinical Trials Design and Management Certificate Program is designed so that working professionals taking classes as part-time students can complete the Graduate Certificate Program in one academic year.

**17 total semester hours**

*Course topics include:*
- Intro to the Pharmaceutical, Biotechnology & Device Industries (4 hrs)
- Biostatistical Applications for Pharmaceutical & Biotechnology Industries (3 hrs)
- Ethical Issues in Research (3 hrs)
- Clinical Trials Design & Monitoring (4 hrs)
- Project Management in Clinical Trials (3 hrs)

**Sample part-time schedule:**

**Fall Semester**
- Intro to the Pharmaceutical, Biotechnology & Device Industries (4 hrs)
- Ethical Issues in Research (3 hrs)

**Spring Semester**
- Clinical Trials Design & Monitoring (4 hrs)
- Project Management in Clinical Trials (3 hrs)

**Summer Semester**
- Biostatistical Applications for Pharmaceutical & Biotechnology Industries (3 hrs)

Application, enrollment and other information is available at [www.RA.Rx.UGA.edu](http://www.RA.Rx.UGA.edu) or by emailing regaffairs@rx.uga.edu.
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 gain an understanding of the scientific and technical background of new products.

The program plan is ideal for working professionals and consists of 14 semester credit hours, delivered by Internet-based instruction, with occasional face-to-face sessions at the UGA Gwinnett Campus. The Regulatory Affairs Graduate Certificate coursework can be applied toward the UGA Master of Science degree program with an emphasis in Regulatory Affairs.

UGA’s educational program and degree option for Regulatory Affairs professionals covers:

- Pharmaceuticals • Biologics • Medical Devices
- Veterinary Products • Combination Products
CERTIFICATE PROGRAM PLAN

14 total semester hours

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

Sample part-time schedule:

Fall Semester
- Intro to Pharmaceutical, Biotechnology & Device Industries (4 hrs)
- Ethical Issues in Research (3 hrs)

Spring Semester
- Food & Drug Law (3 hrs)

Summer Semester
- Current Good Manufacturing Practices (3 hrs)

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
The University of Georgia Gwinnett Campus
2530 Sever Road
Lawrenceville, GA 30043-4005
(678) 985-6809

www.RA.Rx.UGA.edu
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.

www.RA.Rx.UGA.edu
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.
Graduate Programs in BioPharma Regulatory Affairs

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

The University of Georgia Gwinnett Campus
2530 Sever Road
Lawrenceville, GA 30043-4005
(678) 985-6809

www.RA.Rx.UGA.edu