

Brochure

The University of Georgia's International Biomedical Regulatory Sciences Program Brochure is broken down into three parts:

- I. Part One: The Master's Program
- II. Part Two: The Regulatory Sciences Certificate Program
- III. Part Three: The Clinical Trials Design & Monitoring Certificate Program.



REGULATORY SCIENCES

master's program

A CAREER IN REGULATORY SCIENCES

The rapidly expanding 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 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 sciences and those with an industry background desiring advanced education in regulatory management.

UGA's Master of Science for Regulatory Sciences Program covers regulatory requirements for Pharmaceutical, Biologics, Medical Devices, Veterinary Products, and Combination Products.



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International Biomedical
Regulatory Sciences
College of Pharmacy

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MASTER'S PROGRAM

The Regulatory Sciences Master's Program is designed so that students can take classes part-time in an online environment.

38 total semester hours

Course topics include the 14 semester hours in the RS certificate

Program:

- Intro to the 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)
- Biostatistical Applications for the Pharmaceutical and Biotechnology Industries (3 hrs)
- FDA Applications & Submissions (4 hrs)
- Master's Thesis or Project (3 hrs)

Advanced electives are:

- Applied Project or Internship • Clinical Trials Design and Monitoring • Clinical Trials Project Management • Understanding the Role and Function of the United States Food and Drug Administration • Good Clinical Practice Regulations for Drugs, Biologic Products, and Medical Devices • European Pharmaceutical and Biologics Regulatory Sciences • Latin American Pharmaceutical and Biologics Regulatory Sciences • Global Medical Device Regulatory Submissions - The Marketing Application Process

Sample part-time schedule:

Fall Semester

- Quality Assurance & Quality Control (3 hrs)
- Clinical Trials Design and Monitoring (4 hrs)

Spring Semester

- Applied Project (3 hrs)
- FDA Applications & Submissions (4 hrs)

Summer Semester

- Biostatistical Applications for the Pharmaceutical and Biotechnology Industries (3 hrs)
- Clinical Trials Project Management

Application, enrollment and other information is available at **RS.Rx.UGA.edu** or by emailing regsciences@uga.edu.

International Biomedical Regulatory Sciences
A Unit of the College of Pharmacy

The University of Georgia Gwinnett Campus
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**UNIVERSITY OF
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REGULATORY SCIENCES

certificate program

A CAREER IN REGULATORY SCIENCES

The rapidly expanding 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 professionals to gain an understanding of the scientific and technical background of new products.

This program plan is ideal For Working Professionals and consists of 14 semester credit hours, delivered by internet-based instruction with occasional live sessions. The Regulatory Sciences Graduate Certificate coursework can be applied toward the UGA Master of Science degree program with an emphasis in Regulatory Sciences.

UGA's educational program and degree option for Regulatory Sciences professionals covers:

- *Pharmaceutical* • *Biologics* • *Medical Devices*
- *Veterinary Products* • *Combination Products*



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CERTIFICATE PROGRAM

The Regulatory Sciences Certificate Program is designed so that students can take classes part-time can complete the Graduate Certificate Program in one academic year (including summer semester).

14 total semester hours

Course topics include:

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

- Current Good Manufacturing Practices (4 hrs)

Summer Semester

- Food and Drug Law (3 hrs)

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CLINICAL TRIALS DESIGN AND MANAGEMENT

certificate program

A CAREER IN CLINICAL TRIALS MANAGEMENT

Geared toward a wide range of professionals, the **Clinical Trials Design & Management Certificate Program** provides a foundation for preparing candidates to lead and 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 graduate certificate and, if a student completes additional graduate courses, the certificate course work may be applied toward a Master of Science Degree in Pharmacy with an emphasis in Regulatory Sciences.



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College of Pharmacy
Clinical Trials Design & Management

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CT CERTIFICATE PROGRAM

The Clinical Trials Design & Management Certificate Program is designed so students can take classes part-time and complete the Graduate Certificate Program in one academic year (including summer semester).

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)

Summer Semester

- Biostatistical Applications for Pharmaceutical & Biotechnology Industries (3 hrs)
- Project Management in Clinical Trials (3 hrs)

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