GEORGETOWN UNIVERSITY

School of Continuing Studies



Guide Healthcare Research in a Complex Scientific and Regulatory Landscape

In the ever-changing and complex landscape of regulations and policy guiding research, there is a growing demand for professionals who can find innovative, ethical, and compliant solutions to healthcare needs. Georgetown University's Master of Professional Studies in Regulatory Affairs is shaping the next generation of these sought-after professionals.

Featuring a blend of science, ethics, policy, and business, the program examines the full scope of the medical product development lifecycle across national, international, and emerging markets. Students develop the competencies needed to guide regulatory processes through the entire product lifecycle—from pre-clinical research, to clinical trials involving humans, product approval by the U.S. Food and Drug Administration and other regulatory bodies, and post-marketing activities such as safety monitoring. Program graduates will be prepared for regulatory affairs leadership roles in a variety of organizational settings.

PROGRAM FEATURES

Specialized Curriculum. The program prepares students with the technical knowledge and analytical skills needed to pursue a wide range of careers in the regulatory space.

Comprehensive Approach. Students develop a deeper understanding of the product lifecycle, as well as the strategies needed to seamlessly manage the considerations and complexities across all stages.

Flexible Format. The program's flexible curriculum enables students to take classes online, on campus, or through a combination of both; students also have the options to enroll in the program on either a part-time or full-time basis.

Industry Expertise. Students engage with industry leaders and scholars through a combination of classroom learning and hands-on experience in the field.

Unparalleled Opportunities. Capitalizing on Georgetown's location in the heart of Washington, D.C., the program provides unique opportunities for students to engage with some of the nation's leading regulatory affairs experts, organizations, and institutions.

CAREERS

Georgetown's program prepares students with a strategic and practical toolset that places them in high demand in the growing field of regulatory affairs. Graduates will be able to pursue a broad range of positions within business, government, and nonprofit organizations, including:

- · Global Clinical Affairs Manager
- · Regulatory Affairs Specialist
- · Regulatory Analyst
- Regulatory Affairs Research Associate
- Regulatory Risk Management Specialist
- Manager of Clinical Development
- Human Research Protection Program Manager/Director
- Institutional Review Board Manager



CURRICULUM

To earn the master's in Regulatory Affairs degree, students must successfully complete 36 credits (12 courses)

CORE COURSES

(6 Credits)

- Ethics of Regulatory and Clinical Affairs
- Capstone

FOUNDATION COURSES

(18 Credits)

- The Regulation of Pharmaceuticals
- The Regulation of Medical Devices
- The Regulation of Biologics
- Food, Drug, and Cosmetic Act and Laws
- Principles of Good Manufacturing Practice
- Regulations of Human Experimentation and Good Clinical Practice

SAMPLE ELECTIVE COURSES

(3-15 Credits)

- Regulatory Labeling and Promotional Principles of Medical Products
- Regulatory Submissions Practicum
- Strategic Planning and Project Management in Regulatory and Clinical Affairs
- Major International Markets in Regulatory Affairs
- Introduction to Drug Safety and Pharmacovigilance
- Institutional Human Research Protection Program (HRPP) Management

EARN YOUR
MASTER'S DEGREE IN
Regulatory
Affairs

APPLICATION DEADLINES

Visit our admissions page for more information about application deadlines and applying online.

TUITION

Educational expenses are assessed each semester based on the number of credits for which you are registered. Visit our website for current tuition rates.

FOR APPLICATION
INFORMATION AND TO APPLY, VISIT:
scs.georgetown.edu/mastersregaffairs