

MASTER OF SCIENCE IN HEALTH SCIENCES IN THE FIELD OF REGULATORY AFFAIRS

The regulation of clinical research is in itself a dynamic and emergent field. It brings together the science in which products—drugs, devices, biologics, and vaccines—and treatment protocols are developed for improved global health care. Both the master’s degree and graduate certificate programs prepare scientists and regulatory professionals to manage the key elements of the clinical research regulatory process. The rigorous curriculum focuses on regulatory strategy, regulatory guidance, legal and ethical issues, processes for product development, and the business and political components of regulation in clinical research, all while reinforcing the science behind the methods.

Students graduate from the program having mastered the fine line between regulatory leadership and guidance. They manage partnerships with sponsors and emerging pressures to further take into account global health, outcomes research, and healthcare cost containment. Contemporary regulatory affairs leadership requires a foundation in data analysis and research. This program has been designed to meet all of these objectives. The distance education format provides a contemporary option for self-directed professionals who work in the field with industry or who may be just entering the field with one of the health and human services agencies charged with providing oversight and guidance to industry. Our course work has been developed in partnership with colleagues in industry and public regulatory agencies. The curriculum is taught by faculty members who bring both the perspectives of the sponsor and those of public health agencies.

As a result, the program provides each graduate with a robust academic education, while giving the student access to key leaders and practitioners in regulatory affairs. This program has been strategically designed to generate leaders who will meet the needs of the emerging trends in regulatory affairs.

Visit the program website (<https://smhs.gwu.edu/regulatory-affairs/>) for additional program information.

ADMISSIONS

Admission Fall – July 15

Deadlines:

Spring – November 1

Summer – April 15

The application and all supporting documentation (fees, statement of purpose, letters of recommendation, transcripts) must be received by the deadline in order for the application to be reviewed.

Standardized Not required

Test Scores:

Recommend: Two (2) recommendations must be submitted with your application. Generic recommendations provided by career or placement offices will be accepted only if they provide all essential information requested on the GW recommendation form. Recommendations will not be accepted from friends or family members.

Prior Academic Records: Transcripts required from all colleges and universities attended, whether or not credit was earned, the program was completed, or the credit appears as transfer credit on another transcript. Transcripts must be forwarded in their original sealed envelopes.

If academic records are in a language other than English, a certified English language translation must be provided in addition to the original transcripts; translations alone will not be accepted.

Official transcripts from institutions outside the U.S. must be accompanied by an official transcript evaluation from an accredited independent evaluating agency. Please be sure you request a detailed evaluation that includes all course titles, credit hours, grades, U.S. degree equivalency, grade-point averages (GPA), and date of degree conferral. Please see the list of acceptable foreign credential evaluation services (<https://www.naces.org/members>).

Statement of Purpose: In an essay of 250 to 500 words, describe your reasons for undertaking study in the Health Sciences at The George Washington University. You should state your academic objectives, career plans, and related qualifications, including collegiate, professional, and community activities, as well as any other substantial accomplishments not already mentioned on the application form.

Additional Requirements: Relevant clinical research experience or health science experience.

International Applicants: Please review International Applicant Information carefully for details on required documents and English language requirements.

PLEASE NOTE that the Health Sciences programs require the following minimum English language test scores for admission:

- Academic IETLS: an overall band score of 7.0 with no individual band score below 6.0; or

- TOEFL: 600 on paper-based or 100 on Internet-based;

- PTE Academic: 68

Supporting documents not submitted online should be mailed to:

George Washington University
ATTN: Transcript Processing Center
8300 Norman Center Dr
Suite 400
Bloomington, MN 55437

Alternatively, official electronic transcripts can be sent to transcripts@hsprograms.gwu.edu.

Contact for questions:

hsphora@gwu.edu
 202-994-0384 (phone)
 202-994-0870 (fax)
 Hours: 9 am to 5 pm, Monday through Friday

REQUIREMENTS

The following requirements must be fulfilled: 36 credits, including 33 credits in required courses and one 3-credit elective course.

Code	Title	Credits
Required		
Regulatory affairs courses		
RAFF 6201	Introduction to Global Regulatory Affairs	3
RAFF 6202	Regulatory Drug Biologics	3
RAFF 6203	Regulatory Strategy in the Development of Devices and Diagnostics	3
RAFF 6204	Clinical Research for Regulatory Affairs	3
RAFF 6205	Regulatory Affairs Compliance	3
RAFF 6275	Leadership in Regulatory Affairs	3
Graduate research courses		
HSCI 6263	Biostatistics Translational Research	3
HSCI 6264	Epidemiology Translational Research	3
Strategic leadership courses		
HSCI 6223	Topics in Health Care Leadership	3
HSCI 6240	Issues and Trends in the Health Care System	3
HSCI 6241	The Health Care Enterprise	3
Elective		
One course selected from the following:		
CML 6274	Health Economics and Finance	3
CRA 6203	Partnerships with Human Subjects	3
CRA 6208	International Clinical Research	3
CRA 6209	Quality and Risk Management	3
CRA 6210	Medical Writing/Clinical Research	3

HCQ 6201	Building a Quality Culture	3
RAFF 6206	International Regulatory Affairs	3
RAFF 6207	Advertising and Promotion of Regulated Medical Products	3