

# MASTER OF SCIENCE IN HEALTH SCIENCES IN THE FIELD OF REGULATORY AFFAIRS AND CLINICAL RESEARCH LEADERSHIP

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. Program graduates develop knowledge and skills in regulatory strategy and clinical conduct to guide the development of new therapeutics.

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 core courses will provide our students with the foundation to support new product development based on the conduct and regulation of clinical trials including registration by health authorities and strategies to manage product updates and post-approval commitments. 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 and clinical research. 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://healthsciencesprograms.gwu.edu/programs/mshs-regulatory-affairs-and-clinical-research-leadership/>) for additional information.

## ADMISSIONS

Admissions Deadlines:	Fall - July 20
	Spring - December 1
	Summer - March 20
	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 Test Scores:	Not required
Recommendations required:	Two (2) letters of recommendation. Recommendations should be from an academic instructor who can strongly attest to your academic ability and/or someone who has served in a supervisory capacity for you and can strongly attest to your work ethic. Recommendations from family and friends are not accepted.
Prior Academic Records:	Official transcripts are required from all colleges and universities attended (including via dual enrollment), whether or not credit was earned, the program was completed, or the credit appears as transfer credit on another transcript. Official transcripts must be forwarded in their original sealed envelopes or sent electronically directly from the institution.
	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. For a list of acceptable foreign credential evaluation services, please follow this link: <a href="https://www.naces.org/members">https://www.naces.org/members</a> ( <a href="https://www.naces.org/members/">https://www.naces.org/members/</a> )

**Statement of Purpose:** In an essay of approximately 250-500 words, describe your interest in undertaking study at The George Washington University. What are some of your academic objectives or career goals? Please highlight any of your related qualifications and achievements-- including academic, community, professional, or extra-curricular activities relevant to your program of interest. Include any substantial accomplishments not already mentioned within the application.

**Degree and GPA Requirements:** Bachelor's degree from a regionally accredited institution  
Cumulative GPA of 3.0 or above on a 4.0 scale

**Previous work experience:** Health care related experience preferred

**International Students:** International students should check with individual programs regarding eligibility for visa sponsorship. Generally, online and hybrid programs are not eligible for student visa sponsorship from GW. This would include transfer students from any other institution with an existing visa.

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. For a list of acceptable foreign credential evaluation services, please click here (<https://www.naces.org/members.php>).

Applicants who are not U.S. citizens are required to submit official test scores for either Test of English as a Foreign Language (TOEFL) or#Pearsons#Test of English (PTE), Academic the academic International English Language Testing System (IELTS) or the Duolingo English Test (DET). The following are the minimum scores for admission consideration:#TOEFL: 600 on paper based, 250 on computer-based, or 100 Internet-based, PTE: overall score of 68, IELTS: an overall band score of 7.0, with no individual band score below 6.0, or DET overall score of 120. \*Scores can be no older than 2 years.

International applicants who meet the following conditions may be considered for admission without submitting TOEFL, PTE or IELTS or DET scores:#They are a citizen of countries where English is the official language (as identified by GW ISO list of Exempt countries) OR; They hold at least a#bachelor#degree from a country where English is the official language as well as language of instruction OR; They hold at least a#bachelor#degree from an institution accredited by a U.S. regional accrediting agency.

**Supporting documents not submitted online should be mailed to:**

George Washington University  
ATTN: Transcript Processing Center  
1415 W 22<sup>nd</sup> St.  
Suite 220  
Oak Brook, IL 60523

Documents may be submitted electronically to: [transcripts@hsprograms.gwu.edu](mailto:transcripts@hsprograms.gwu.edu).

**Contact for questions:**

[hsphora@gwu.edu](mailto:hsphora@gwu.edu)  
202-994-0384 (phone)  
Hours: 9:00 am to 5:00 pm, Monday through Friday

## REQUIREMENTS

The following requirements must be fulfilled: 36 credits, including 21 credits in required core courses and 15 credits in required and elective courses in either the regulatory affairs concentration or the clinical research administration concentration.

Code	Title	Credits
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### Required core courses

HSCI 6264	Epidemiology Translational Research	
COHM 6235	Leadership Development in Healthcare Systems	
COHM 6245	Strategic and Operational Decision Making for Healthcare Leaders	
RCR 6201	Introduction to Global Regulatory Affairs and Clinical Research	
RCR 6202	Regulatory Strategy in the Development of Therapeutics	
RCR 6206	International Regulatory Affairs and Clinical Research	
RAFF 6275	Leadership in Regulatory Affairs	
or CRA 6275	Leadership and Change in Clinical Research Administration	

### Concentration requirements

Students must complete all requirements for either the regulatory affairs concentration or the clinical research administration concentration, as follows:

#### Regulatory affairs concentration

##### Required

RAFF 6203	Regulatory Strategy in the Development of Devices and Diagnostics	
RAFF 6204	Clinical Research for Regulatory Affairs	
RAFF 6205	Regulatory Affairs Compliance	

RAFF 6207	Advertising and Promotion of Regulated Medical Products
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And one course selected from the following:

CRA 6203	Partnerships with Human Subjects
CRA 6209	Quality and Risk Management
CRA 6211	Monitoring, Auditing, and Oversight in Clinical Research
HSCI 6263	Biostatistics Translational Research

#### Clinical research administration concentration

##### Required

CRA 6203	Partnerships with Human Subjects
CRA 6204	The Clinical Research Industry
CRA 6209	Quality and Risk Management
CRA 6211	Monitoring, Auditing, and Oversight in Clinical Research

And one course selected from the following:

HCQ 6201	Building a Quality Culture
HSCI 6263	Biostatistics Translational Research
RAFF 6204	Clinical Research for Regulatory Affairs
RAFF 6205	Regulatory Affairs Compliance
RAFF 6207	Advertising and Promotion of Regulated Medical Products