

GRADUATE CERTIFICATE IN REGULATORY AFFAIRS

The regulation of clinical research is, in and of 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 healthcare. The program prepares scientists and regulatory professionals to manage the key elements of the clinical research regulatory process.

The certificate program is ideal for the scientist with an advanced degree who might be at the starting point of entering the regulatory affairs profession within the industry or the government sector. The certificate requires the completion of 12 credits in regulatory affairs coursework, all of which can be counted toward the MSHS degree.

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

ADMISSIONS

Admissions Fall - July 20
Deadlines:

Spring - December 1

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:

Recommendations (2) letters of recommendation.

required: 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: <https://www.naces.org/members> (<https://www.naces.org/members/>).

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 Requirement: Bachelor's degree from a regionally-accredited institution
Cumulative GPA of 3.0 or above on a 4.0 scale

Additional Requirements: Resume is required.
Previous work experience. Healthcare Experience Preferred

International applicants: 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 includes transfer students from any other institution with an existing visa.

Applicants who have not completed a post-secondary degree from an institution where English is the sole language of instruction must submit TOEFL, IELTS, PTE Academic, or the Duolingo English Test scores to be considered for admission. The following are the minimum scores for admission consideration:

- Academic IELTS: An overall band score of 7.0, with no individual band score below 6.0.
- TOEFL: 600 paper-based or 100 internet-based.
- PTE: Overall score of 68
- DET: Overall score of 120

Undergraduate applicants who meet one of the following conditions can be considered for admission without submitting TOEFL, PTE or IELTS or DET scores:

-You have earned an associate's degree or higher from an institution where English is the sole language of instruction

-You are a citizen of an English-speaking country as defined on the SMHS International Applicant page (<https://smhs.gwu.edu/international-applicants> (<https://smhs.gwu.edu/international-applicants/>)).

Scores cannot be more than two years old. To ensure TOEFL scores are sent to GW, use institutional code 5246. An institutional code is not required to send IELTS or PTE scores to GW. DET scores must be submitted via the Duolingo English Test system directly to GW.

Based on their application and the results of the English proficiency examination students can be required to take English for Academic Purposes (EAP) during their first year of study at GW. GW evaluates each application holistically and applicants can be recommended for EAP even if they meet the requirements for exemption. Students placed in EAP courses should anticipate additional tuition expenses as well as possible extension of time needed to complete their degree programs.

RCR 6206	International Regulatory Affairs and Clinical Research
RAFF 6204	Clinical Research for Regulatory Affairs
RAFF 6207	Advertising and Promotion of Regulated Medical Products

Supporting documents not submitted online should be mailed to:

George Washington University

ATTN: Transcript Processing Center
1415 W 22nd St.
Suite 220
Oak Brook, IL 60523

Documents can be submitted electronically
to: transcripts@hsprograms.gwu.edu.

Contact for questions:

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

REQUIREMENTS

Code	Title	Credits
Required		
RCR 6201	Introduction to Global Regulatory Affairs and Clinical Research	
RCR 6202	Regulatory Strategy in the Development of Therapeutics	
or RAFF 6203	Regulatory Strategy in the Development of Devices and Diagnostics	
RAFF 6205	Regulatory Affairs Compliance	

One course selected from the following: