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 prepare 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 may 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 may 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:

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<th>Course</th>
<th>Deadlines</th>
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<tbody>
<tr>
<td>Spring</td>
<td>December 1</td>
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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: (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.

Degree and GPA Requirements:

Bachelor’s degree from a regionally-accredited institution

Cumulative GPA of 3.0 or above on a 4.0 scale

Additional Requirement: Resume is required.

International Applicants: This program can be completed fully online and is not visa eligible.

Please follow this link - https://graduate.admissions.gwu.edu/international-student-application-requirements (https://graduate.admissions.gwu.edu/international-student-application-requirements/) - to review the International Applicant Information carefully for details on required documents and English language requirements. Applicants who are not U.S. citizens are required to submit official test scores for either Test of English as a Foreign Language (TOEFL), 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: 250 computer-based or 100 Internet-based;
- PTE: overall score of 68
- IELTS: overall band score of 7.0, with no individual band score below 6.0; or DET overall score of 120

International applicants who meet the following conditions may be considered for admission without submitting TOEFL, PTE, IELTS, or DET scores:
- They are a citizen of a country 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 22nd St.
Suite 220
Oak Brook, IL 60523

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**

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<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
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<tbody>
<tr>
<td><strong>Required</strong></td>
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<tr>
<td>RCR 6201</td>
<td>Introduction to Global Regulatory Affairs and Clinical Research</td>
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<tr>
<td>RCR 6202</td>
<td>Regulatory Strategy in the Development of Therapeutics</td>
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<tr>
<td>or RAFF 6203</td>
<td>Regulatory Strategy in the Development of Devices and Diagnostics</td>
<td></td>
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<tr>
<td>RAFF 6205</td>
<td>Regulatory Affairs Compliance</td>
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One course selected from the following:

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<tr>
<th>Code</th>
<th>Title</th>
<th>Credits</th>
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<tbody>
<tr>
<td>RCR 6206</td>
<td>International Regulatory Affairs and Clinical Research</td>
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<tr>
<td>RAFF 6204</td>
<td>Clinical Research for Regulatory Affairs</td>
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</tr>
<tr>
<td>RAFF 6207</td>
<td>Advertising and Promotion of Regulated Medical Products</td>
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