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

**Admissions**

**Deadlines:**
- Fall – July 15
- Spring – November 1
- Summer – April 15

**Test Scores:**
- Standardized: Not required
- **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

**Standardized Test Scores:**

**Required:** 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.

**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.

**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 IELTS: 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:**

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) 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.

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

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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.

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