Post-Master's Certificate: Global Pharmacovigilance/Benefit-Risk Management

SCHOOL OF PHARMACY

About the Certificate

The post-master's certificate in Global Pharmacovigilance/Benefit-Risk Assessment is designed for those who hold an MS in Regulatory Affairs and Quality Assurance and want to keep current with industry issues and meet regulatory requirements for training. The certificate program is also open to professionals with other master's or doctoral degrees.

Pharmacovigilance is constantly evolving in a dynamic regulatory, economic and scientific environment. The post-master's certificate in Global Pharmacovigilance/Benefit-Risk Assessment provides a solid scientific and regulatory foundation in the key disciplines necessary for a successful career in the field of pharmacovigilance. It focuses on establishing a platform for continuous learning in pharmacovigilance rather than on an unrealistic goal of seeking total subject mastery. Importantly, it focuses on pharmacovigilance in a global environment.

Time Limit for Certificate Completion: 4 years

Campus Location: Online and Fort Washington

Full-Time/Part-Time Status: The post-master's certificate may be completed on a part-time basis. NOTE: International students may not be eligible to apply for a student visa based on admission to the certificate program. Please contact the School of Pharmacy's program coordinator for more information.

Non-Matriculated Student Policy: Non-matriculated students may take up to 9 credits of coursework before applying to the certificate program.

Admission Requirements and Deadlines

Application Deadline:
Fall and Spring admissions are on a rolling basis. Interested students should contact the School of Pharmacy for permission to enroll in coursework.

APPLY HERE to the post-master's certificate program.

Master's Degree in Discipline/Related Discipline: Applicants must hold a master's degree in a Pharmacy-related field, including but not limited to an MS in Regulatory Affairs and Quality Assurance. Graduates of Temple University's RAQA program take certificate coursework to keep current with industry issues and meet regulatory requirements for training. Applicants with an advanced science degree from an accredited institution of higher learning other than Temple University must have worked in the pharmaceutical industry for a minimum of three years.

Bachelor's Degree in Discipline/Related Discipline: Applicants must hold a bachelor's degree from an accredited institution. While no specific major is required, most applicants should have a background in biological sciences, engineering, healthcare, natural sciences or related discipline.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 15

Required Courses:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>QARA 5508</td>
<td>Good Pharmacovigilance Operations</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5538</td>
<td>Clinical Drug Safety and Pharmacovigilism</td>
<td>3</td>
</tr>
<tr>
<td>or QARA 5571</td>
<td>Post-Marketing Safety Surveillance</td>
<td></td>
</tr>
<tr>
<td>QARA 5573</td>
<td>Pharmacoepidemiology</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5578</td>
<td>Benefit Risk Management and Safety Signaling of Healthcare Products</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5579</td>
<td>Regulatory and Legal Basis of Pharmacovigilance</td>
<td>3</td>
</tr>
</tbody>
</table>

Total Credit Hours 15

Students select alternate coursework to complete the post-master's certificate from the approved QARA courses identified in the grid below if they:
• hold an MS in Regulatory Affairs and Quality Assurance, and
• completed one or more of the courses required for the post-master's certificate in previously fulfilling degree requirements for their master's degree.
Approved QARA Courses for Substitution of Required Coursework Previously Completed

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>QARA 5539</td>
<td>Global Clinical Drug Development</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5547</td>
<td>Project Management for Clinical Trials</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5548</td>
<td>Risk Management of Pharmaceutical and Medical Devices</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5612</td>
<td>Bioethics for Pharmaceutical Professionals</td>
<td>3</td>
</tr>
</tbody>
</table>

GPA Required to be Awarded the Certificate: 3.0 minimum

Contacts

Certificate Program Web Address:

Department Information:
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728
qara@temple.edu
267-468-8560

Mailing Address for Application Materials:
Temple University
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728

Department Contacts:
Admissions:
Wendy Lebing, MALD, MS
Assistant Dean
qara@temple.edu
267-468-8560