Pharmaceutical Regulatory Sciences MS

SCHOOL OF PHARMACY

About the Program

The MS in Pharmaceutical Regulatory Sciences (MSPRS) blends two disciplines, pharmaceutical and regulatory sciences, providing a unique and critical academic path for professionals in the pharmaceutical, medical device and biologics industries:

• Pharmaceutical science courses focus on the core science principles involved in the development and manufacturing of therapeutic products.
• RAQA courses provide a strong framework of regulations and quality practices, addressing scientific methods needed to ensure safety, efficacy, quality and consistent performance.

The MSPRS program is designed to prepare a cadre within the pharmaceutical industry of senior regulatory professionals who are familiar with both the pharmaceutical sciences and worldwide regulatory practices as they interact with the U.S. Food and Drug Administration (FDA) and other global regulators in bringing new chemical entities and biologics to market.

Time Limit for Degree Completion: 5 years

Campus Location: Online, in a hybrid format with some in-person instruction but the majority of learning online

Full-Time/Part-Time Status: The degree program can be completed on a full- or part-time basis.

Interdisciplinary Study: The program fosters interdisciplinary study with the pharmaceutical sciences and technology.

Job Prospects: The program prepares graduates for positions in the global marketplace related to the pharmaceutical and regulatory sciences.

Non-Matriculated Student Policy: Non-matriculated students are able to take up to 9 credits before formal application must be made to the program.

Financing Opportunities: Master's students are generally not considered for financial support.

Admission Requirements and Deadlines

Application Deadline:

Fall: March 1; December 15 international
Spring: November 1; September 1 international
Summer I: March 1; January 15 international

Applications are processed throughout the year. Late applications may be considered for admission. However, the entire application packet must be received by the Graduate Studies Office before it is reviewed by the Admissions Committee. Applicants are responsible for making sure that all materials have been received.

APPLY to this graduate program, submitting the application to QARA2@temple.edu. For more information, visit https://www.temple.edu/pharmacy_qara/applyingtoMS.html.

Letters of Reference:
Number Required: 2

From Whom: Letters of recommendation should be obtained from supervisors or college/university instructors familiar with the student’s academic competence.

Bachelor’s Degree in Discipline/Related Discipline: A baccalaureate degree in Pharmacy, Biochemistry, Biology, Chemistry, Chemical Engineering or Mechanical Engineering is required.

Applicants who did not achieve a 3.0 undergraduate GPA in a science discipline may be admitted after taking three of the four courses listed below and earning an overall 3.33 (B+) GPA in the coursework:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>PS 8002</td>
<td>Pharmaceutical Analysis</td>
<td>3</td>
</tr>
<tr>
<td>PS 8005</td>
<td>Pharmaceutical Biotechnology</td>
<td>3</td>
</tr>
<tr>
<td>PS 8006</td>
<td>Physical Pharmacy I</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5575</td>
<td>Regulatory Sciences: Managing the Guidelines to Quality</td>
<td>3</td>
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</table>
Statement of Goals: Describe your career goals and objectives in 500 to 1,500 words.

Standardized Test Scores:
Applicants who earned their baccalaureate degree from an institution where the language of instruction was other than English, with the exception of those who subsequently earned a master’s degree at a U.S. institution, must report scores for a standardized test of English that meet these minimums:

- TOEFL iBT: 85
- IELTS Academic: 7.0
- PTE Academic: 58

Resume: Current resume or CV required.

Transfer Credit: Students may transfer a maximum of 6 credits into the MS program. These credits must be similar or identical to courses offered by the Temple University School of Pharmacy and applicable to the MS in Pharmaceutical Regulatory Sciences. In addition, the student must request the transfer credits at the time of application to the MS program, providing copies of course syllabi. The maximum number of credits a student may transfer is 6.

Program Requirements

General Program Requirements:
Number of Credits Required Beyond the Baccalaureate: 30

Required Courses:

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<tr>
<td>PS 8003</td>
<td>Pharmaceutical Manufacturing I: Preformulation/Formulation</td>
<td>3</td>
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<tr>
<td>PS 8004</td>
<td>Solid Dosage Forms - Small Molecules</td>
<td>3</td>
</tr>
<tr>
<td>PS 8005</td>
<td>Pharmaceutical Biotechnology</td>
<td>3</td>
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<tr>
<td>QARA 5468</td>
<td>Validation of Facilities, Utilities and Equipment (FUE)</td>
<td>3</td>
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<tr>
<td>QARA 5495</td>
<td>Investigational New Drug/New Drug Application Submissions</td>
<td>3</td>
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<tr>
<td>QARA 5575</td>
<td>Regulatory Sciences: Managing the Guidelines to Quality</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5576</td>
<td>Global CMC Issues and Regulatory Dossier (Or QARA 5577 )</td>
<td>3</td>
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<tr>
<td>QARA 8006</td>
<td>Physical Pharmacy I</td>
<td>3</td>
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Pharmaceutical Sciences Elective
Select one from the following:

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<th>Title</th>
<th>Credit Hours</th>
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</thead>
<tbody>
<tr>
<td>PS 8002</td>
<td>Pharmaceutical Analysis</td>
<td>3</td>
</tr>
<tr>
<td>PS 8007</td>
<td>Applied Biopharmaceutics</td>
<td>3</td>
</tr>
</tbody>
</table>

Regulatory Affairs and Quality Assurance Elective
Select one from the following:

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<tr>
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</thead>
<tbody>
<tr>
<td>QARA 5474</td>
<td>Process Validation</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5478</td>
<td>High Purity Water Systems</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5498</td>
<td>Computerized System Validation</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5515</td>
<td>Biologics/Biosimilars: A Regulatory Overview</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5572</td>
<td>Vaccines: Regulatory Affairs and Quality Assurance Issues</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5577</td>
<td>Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5606</td>
<td>Regulatory Strategy: Discovery to Approval</td>
<td>3</td>
</tr>
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</table>

Total Credit Hours 30

Culminating Event: Successful completion of coursework is required to earn the MS in Pharmaceutical Regulatory Sciences.

Contacts

Program Web Address:
https://www.temple.edu/pharmacy_qara/Pharmaceutical_Regulatory_Sciences.html
Department Information:
Pharmaceutical Regulatory Sciences Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728
qara@temple.edu
267-468-8560

Submission Address for Application:
QARA2@temple.edu

Mailing Address for Application Materials:
Temple University
Pharmaceutical Regulatory Sciences 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

Graduate Chairperson:
Swati Nagar, PhD
phscgrad@temple.edu

Assistant Dean:
Wendy Lebing, MALD, MS
wiebing@temple.edu
267-468-8560