Regulatory Affairs and Quality Assurance, M.S.

SCHOOL OF PHARMACY

About the Program

Since its establishment in 1968, Temple's Regulatory Affairs and Quality Assurance program has played a significant role in training pharmaceutical company personnel in regulations and quality principles and practices. Its courses meet the career requirements of professionals in the pharmaceutical and related industries. The program provides students with a broad knowledge of the industry, fostering their professional development and preparing them for supervisory and managerial positions.

Time Limit for Degree Completion: 5 years

Campus Location: Fort Washington

The M.S. is offered in its entirety on evenings and weekends at Fort Washington.

Full-Time/Part-Time Status: Students complete the degree program through classes offered after 4:30 p.m. The degree program can be completed on a full- or part-time basis.

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

Affiliation(s): Each year the program sponsors a major conference with the pharmaceutical industry and the U.S. FDA, focusing on current regulatory and quality issues.

Ranking: Temple's master's degree in Regulatory Affairs and Quality Assurance is widely recognized as the oldest, most comprehensive, and most respected academic program of its type in the world.

Areas of Specialization: This is a non-thesis M.S. program. Faculty members are specialists in many areas, such as auditing; clinical trial management and operations; global regulation; IND/NDA submissions; manufacturing; pharmaceutical, food, and device law; pharmaceutical labeling and advertising; quality assurance; regulatory affairs; and validation.

Job Prospects: Students find positions in all areas of the pharmaceutical industry, including big Pharmaceutical Research and Manufacturers of America (PhRMA) and generic companies, biotechnology, clinical research organizations, and medical devices and packaging. Employment is also found with government agencies, including the FDA, and healthcare providers.

Non-Matriculated Student Policy: Students may complete a maximum of 9 credits before they must formally apply for admission. Before taking any electives, new students are strongly encouraged to take QARA 5459 Drug Development and QARA 5592 Food and Drug Law.

Financing Opportunities: Students in the Regulatory Affairs and Quality Assurance program are generally working professionals. Therefore, funding for assistantships and academic internships is limited.

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 Regulatory Affairs and Quality Assurance 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: One letter should be obtained from the candidate's direct supervisor, indicating that the supervisor is aware of and supports the candidate's involvement in Temple's Regulatory Affairs and Quality Assurance graduate program.

Bachelor's Degree in Discipline/Related Discipline: A B.S. degree in Biochemistry, Biology, Chemistry, Physics, or a health-related discipline is required.
Applicants who earned a degree at a non-U.S. institution must submit an equivalency evaluation of their transcript(s) through a third-party provider, either World Education Services (WES) or Educational Credential Evaluators (ECE).

**Statement of Goals:** Describe your experience in the pharmaceutical or related industries, indicating how the Regulatory Affairs and Quality Assurance M.S. program will help you achieve your career objectives.

**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: 6.5
- PTE Academic: 58

**Resume:** Current resume or CV required.

**Transfer Credit:** Students may transfer a maximum of 6 credits into the M.S. program. These credits must be similar or identical to courses offered in Temple’s Regulatory Affairs and Quality Assurance program. In addition, the student must request the transfer credits at the time of application to the M.S. 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:* 36

**Required Courses:**

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<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credit Hours</th>
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<tbody>
<tr>
<td>QARA 5459</td>
<td>Drug Development</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5494</td>
<td>Quality Audit</td>
<td>3</td>
</tr>
<tr>
<td>or QARA 5495</td>
<td>Investigational New Drug/New Drug Application Submissions</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5592</td>
<td>Food and Drug Law</td>
<td>3</td>
</tr>
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**Good Practices Course**

Select one of the following:

- QARA 5476 | Good Laboratory Practices
- QARA 5477 | Good Manufacturing Practices
- QARA 5479 | Advanced Good Manufacturing Practices - Defining "c"
- QARA 5536 | Good Clinical Practices

**Electives**

24

**Total Credit Hours**

36

1 Upon completion of the four required courses, students may concentrate their electives in either Regulatory Affairs or in Quality Assurance. Alternately, students may select courses from both disciplines to broaden their portfolio.

**Culminating Events:**
This program has no culminating events beyond completion of coursework.

**Contacts**

**Program Web Address:**
https://www.temple.edu/pharmacy_qara/

**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
Submission Address for Application:
QARA2@temple.edu

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:
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