

 School of Pharmacy TEMPLE UNIVERSITY Quality Assurance/Regulatory Affairs <small>Graduate Program</small>	Temple University - School of Pharmacy 425 Commerce Drive, Suite 175 Fort Washington, PA 19034 Phone: 267.468.8560 Fax: 267.468.8565
---	---

**Master of Science in
Quality Assurance/Regulatory Affairs**

Program Requirements

Students are required to take a minimum of 12 courses (36 credits) to receive the MS in QA/RA. Four courses are required:

- Drug Development (Pharmaceutics 5459)
- Food and Drug Law I (Pharmaceutics 5592)
- One Good Practices course from:
 - Good Laboratory Practices (Pharmaceutics 5476)
 - or**
 - Good Manufacturing Practices (Pharmaceutics 5477)
 - or**
 - Advanced GMPs – Defining “c” (Pharmaceutics 5479)
 - or**
 - Good Clinical Practices(Pharmaceutics 5536)

Note: students may take more than one GXP course in pursuing the MS, but at least one is required

- Quality Audit (5494) OR IND/NDA Submissions (5495)

The remaining 8 courses are QA/RA electives of the student’s choosing. To find the complete list of current electives, go to:

http://www.temple.edu/pharmacy_QARA/courses-electives.htm

Bringing Transfer Credits into the QA/RA Program

Temple University permits students to bring a maximum of 6 transfer credits (or two courses) into the MS program, but only under the following circumstances:

1. Requests for transfer credits must be made when the student is applying for matriculation into the QA/RA MS program. Under no circumstances can transfer credits be awarded after a student has been officially admitted into the program or is near completion of the degree.
2. All courses being considered for transfer credits must have been taken within the last five years and be from a fully accredited American college or university. Grades in all courses must be "B" quality or greater.
3. The courses being considered for transfer credits must be identical or very similar to courses currently offered in the QA/RA program. It is the student's responsibility to

provide sufficient documentation demonstrating this similarity, including an official course description from the school (in an official school catalogue), a copy of course syllabi (clearly depicting topics covered), and copies of tests or other assignments which demonstrate that the work is equivalent to an MS degree in QA/RA. Without this documentation, the request for transfer credits will be denied.

4. Transfer credits cannot be earned from industry workshops or conferences. There are no exceptions to this rule.

5. Students are permitted to take no more than three courses (or 9 credits) in the QA/RA program before formally applying for admission. QA/RA courses taken before matriculation may be considered "transfer credits" since the student is not officially admitted to the program. Therefore, additional transfer credits will not be considered if the student has taken more than three QA/RA courses.

6. Since the MS in QA/RA is a science-based program focusing on QA and RA practices within the pharmaceutical industry, transfer credits in business are not accepted.

7. The Graduate Studies Committee will review the request for transfer credits, based on the materials provided by the student. If the transfer credits are approved, the Committee will write a formal letter to the student. The decision of the Committee is final.

Waiving Requirements in the MS Program

A maximum of two required courses may be waived in the QA/RA program, but only if you have completed identical courses in QA/RA at another accredited U.S. institution of higher learning. You must have achieved a minimum grade of "B" (3.0 grade points) and provide a syllabus and other pertinent course materials, demonstrating that the course is identical to a requirement offered in the QA/RA MS program. Your request for waiving a required course (*Drug Development, Food and Drug Law I, GXP's, IND/NDA Submissions, or Quality Audit*) must be made when you submit your application for the MS program. Retroactive requests will not be reviewed or granted. Credit will only be given for academic courses taken within the past five years. The Graduate Studies Committee will send a formal letter indicating whether your request to waive a prerequisite has been formally granted. Students who wish to take *Advanced GMP's* in lieu of *GMP's* must demonstrate that they have a minimum of 5 years of active experience in GMP's. An oral exam may be administered to demonstrate that the student is familiar with basic GMP's.