

Master of Science in Regulatory Affairs and Quality Assurance

Program Requirements

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

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

Students may take more than one GxP course while pursuing the MS, but at least one is required.

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

The remaining 8 courses are RAQA electives of the student's choosing. The complete list of current electives is available at: www.temple.edu/pharmacy_QARA/courses-electives.htm

Bringing Transfer Credits into the RAQA MS Degree

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

1. Requests for transfer credits must be made when the student is applying for admission to the MS in RAQA. Under no circumstances will 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 from a fully accredited American college or university. Grades in all transfer courses must be "B" quality (3.0 on a 4.0 scale) or greater.
3. The courses being considered for transfer credits must be identical or very similar to courses currently offered in Temple's MS in RAQA graduate program. It is the student's responsibility to provide sufficient documentation to demonstrate the similarity, including a 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 Temple's Master of Science in RAQA. 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 RAQA program before formally applying for admission. Any Temple RAQA courses completed before matriculation are considered "transfer credits" since the student is not officially admitted to the degree program.

6. Since the MS in RAQA is a science-based program focusing on regulatory and quality practices within the pharmaceutical, medical device, biotechnology and related industries, 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 MS in RAQA degree program only if the student has completed identical courses in RAQA at another accredited U.S. institution of higher learning. Students must have earned a minimum grade of "B" (3.0 in a 4.0 scale) and provide a syllabus and other pertinent course materials, demonstrating that the course is identical to a requirement offered in Temple's MS in RAQA degree.

The request to waive a required course (*Drug Development, Food and Drug Law, GxPs, IND/NDA Submissions, or Quality Audit*) must be made when the student submits the application for the MS in RAQA. 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 sends written notification indicating whether the request to waive a prerequisite was granted or denied.

Students who wish to take *Advanced GMPs* in lieu of *GMPs* must demonstrate that they have a minimum of 5 years of active experience in GMPs. An oral exam may be administered to demonstrate that the student is familiar with basic GMPs.