POST-MASTER’S CERTIFICATE in GMPs FOR THE 21ST CENTURY

Temple developed the first graduate certificate on the 2002 GMP regulations

BACKGROUND

Temple University’s School of Pharmacy continues to be the leader in providing world renowned graduate-level courses in Regulatory Affairs and Quality Assurance. As the program continues to launch new programs, it recognizes that many graduates with the MS in RAQA want to continue taking courses to keep current with industry issues and meet regulatory requirements for training. The Post-Master’s Certificate in GMPs for the 21st Century allows RAQA graduates to pursue additional coursework and receive formal recognition for their work. The certificate is also open to professionals with other master's or doctoral degrees.

This certificate thoroughly covers the key domestic regulations of GMP systems. Starting with Unit Operations, students are exposed to the current process steps common to the manufacture of modern pharmaceuticals. They then learn about process monitoring and controls. Further study involves statistical processes needed for process control charting and analysis, followed by an overview of Six Sigma, including discussions on when they should (or should not) be applied. A key course focuses on statistical design of pharmaceutical experiments.

The goal of this certificate is for participants to enhance their scientific understanding of the manufacturing processes, set standards for increasing product quality, improve plant efficiency, lower production costs, and meet the new compliance requirements (both domestic and global). It challenges students to combine science with the regulatory requirements now demanded of GMPs.

For nearly five decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Regulatory Affairs and Quality Assurance. The School was the original institution of higher learning in the world to create a master’s program in the Quality Assurance (QA) and Regulatory Affairs (RA) disciplines and continues to offer the most comprehensive curriculum of its kind.

Temple’s renowned program specifically examines RA and QA issues facing the pharmaceutical and related industries by integrating pharmaceutical law and regulation, pharmaceutical technology, and quality assurance practices. Faculty are FDA and industry veterans with years of expertise in their specialties, sharing their vast knowledge with students through intimate classroom discussions and hands-on workshops.

Candidates must formally apply for the Post-Master’s Certificate in GMPs for the 21st Century before registering for any courses. To receive the certificate, candidates must complete four courses and the application procedures. Students who completed master’s degrees or higher from accredited U.S. institutions of higher learning with extensive
pharmaceutical industry experience may also petition the School to pursue the Post-Master’s Certificate in GMPs for the 21st Century, but will be required to complete five specific courses (no substitutions are permitted).

Temple's RAQA graduate program is based in Fort Washington, PA. Courses are conveniently scheduled on evenings and weekends for working professionals and can be videoconferenced to corporate sites. Over sixty courses are offered online in real time.

The Post Master's Certificate in GMPs for the 21st Century is only available in a traditional classroom format, since mandatory laboratory sessions are conducted at a manufacturing facility. It is not available online. The majority of the courses are scheduled on weekends, so students may commute to the campus to participate.

**APPLICATION PROCESS**

Candidates must formally apply for the Post-Master’s Certificate in GMPs for the 21st Century before registering for any courses.

**Temple University Students:**
Once you receive your MS from Temple, the University closes your academic file. If you wish to pursue the Post Master's Certificate in GMPs for the 21st Century, you must formally apply, so we can reopen your file and register you. You will find the application at: www.temple.edu/pharmacy_qara/pdf/Application-GMPs-for-21st-Century-Post-Master-Certificate.pdf

You will be required to take five courses relating to GMPs to complete the Post Master's Certificate in this subject.

Please mail the **Application Form** to:
Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA  19034

**Students with Advanced Science Degrees from Other Schools:**
To apply for the Post-Master’s Certificate in GMPs for the 21st Century, you must meet the following criteria:

1) You must have received an advanced degree (master’s level or higher) from an accredited institution of higher learning and must have worked in the pharmaceutical industry for a minimum of three years.

2) Please submit a hard copy of the **Application Form** for the Post Master's Certificate in GMPs for the 21st Century to:
   Temple University School of Pharmacy
   Regulatory Affairs and Quality Assurance Graduate Program
   Attn:  Assistant Dean Lebing
You must include a letter to the Assistant Dean, indicating which courses you wish to pursue and explaining your experience in the pharmaceutical industry.

Include a copy of your resume and copies of transcripts from all undergraduate and graduate programs you have attended. Students who have earned degrees abroad must also include photocopies of a WES report and TOEFL scores.

**Formal permission to pursue the Post-Master’s Certificate in GMPs for the 21st Century must be received from the Assistant Dean before starting the program.**

3) Students with advanced degrees from other schools must complete five required Temple University RAQA courses to receive the Post-Master’s Certificate in GMPs for the 21st Century. If the candidate subsequently decides to apply for the M.S. in Regulatory Affairs and Quality Assurance within five years, the credits earned in the Post-Master’s Certificate in GMPs for the 21st Century will count towards the master’s degree, provided a grade of B or higher was earned in each course and the student is accepted into the M.S. program.

**ACADEMIC REQUIREMENTS**

Courses Accepted for the Post-Master's Certificate in GMPs for the 21st Century
To earn the certificate, five courses must be successfully completed within a four year period with an overall B (3.0) average:

- Regulatory Sciences: Managing the Guidelines for Quality (5575)*
- Unit Operations (5622)*
- Process Analytical Technology (PAT) (5625)*
- Statistical Design of Experiments (DOE) (5627)*
- Process Monitoring (5629)*
- Advanced Good Manufacturing Practices: Defining "c" (5479)**
- Microbiological Concepts in Pharmaceutical Manufacturing (5512)*
- Pharmaceutical Quality Management Systems (5574)**

*Students must take these courses, if they have not already done so.
**This course counts towards the Post-Master's Certificate in GMPs for the 21st Century only if the student already has the MS in QA/RA.

It is suggested that students take the courses in the order listed above. Students must have the required prerequisites to pursue any RAQA graduate-level course.

Students must earn an overall GPA of 3.0 in the five courses to receive the Post-Master’s Certificate in GMPs for the 21st Century.
TO RECEIVE THE CERTIFICATE

Certificates are not automatically conferred when students complete the required courses. After you have finished the five courses, you must notify the RAQA Office by submitting the Notice of Completion (available on the RAQA website) and sending it by fax (267.468.8565), email (qarareg@temple.edu), or hard copy to the RAQA Office. The RAQA Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must submit your Notice of Completion to the RAQA Office by these deadlines:

- Jan 15 for certificates earned in the previous fall semester
- May 15 for certificates earned in the previous spring semester
- Aug 20 for certificates earned during the summer semesters

If you miss the deadline, you must wait until the next processing period. It takes the RAQA approximately 6 weeks to process certificates. If you have not received your certificate by Feb 28, June 30, or Sept 30, please contact the RAQA Office.

QUESTIONS AND ANSWERS

Where is the RAQA Program Offered?
The RAQA program is based at Temple University Fort Washington in suburban Montgomery County, PA. For direction: www.temple.edu/pharmacy_QARA/map.htm

The Post Master’s Certificate in GMPs for the 21st Century is currently only available in a traditional classroom format at Temple University Fort Washington, since mandatory laboratory sessions are conducted at a manufacturing facility. It is not available online. The majority of the courses are scheduled on weekends, so students may commute to the campus to participate.

When can I start the certificate?
Courses in the RAQA program are offered during the fall, spring, and summer semesters every year. You may start the certificate program at your convenience.

What course sequence is recommended?
We suggest you start the certificate with either Regulatory Sciences: Managing the Guidelines for Quality (5575) or Unit Operations (5622), though this is not mandatory. Unit Operations should be completed before Process Monitoring (5629).

Please be aware that the five courses in this certificate are not offered every semester, though generally all of them are offered at least once a year. We urge students to take courses when they are scheduled or to write to the RAQA Office if they wish to see a course scheduled in a particular semester.

How do I obtain a current class schedule?
Please refer to the RAQA website for the most current schedule of classes.
How do I register for classes?
Please make sure you have been formally admitted into the Post-Master’s Certificate in GMPs for the 21st Century before registering.

- If you received your MS from Temple, download the registration form from the RAQA homepage: www.temple.edu/pharmacy_QARA/forms.htm
  You do not need to submit a state residency form, unless you have moved from one state to another.

- If you have not registered for Temple University classes before, download the Registration and State Residency forms from the RAQA homepage: www.temple.edu/pharmacy_QARA/forms.htm
  Both are required the first time you register. Fax, mail, and electronic registrations do not guarantee your spot in a class, since sections do fill quickly. We will contact you if there are problems with your registration. The RAQA Office will send a confirmation statement that you are officially registered. You will also receive a notice via your TUmial account when your tuition statement is available, including the payment due date. Please make sure that you pay your bill by the due date, so you do not incur a late fee.

Do I need to take the GREs to complete the Post-Master's Certificate in GMPs for the 21st Century?
No. GRE or other advanced test scores are not required for the certificate or the MS in RAQA.

Can I transfer any credits from another graduate institution towards the Post-Master’s Certificate in GMPs for the 21st Century?
Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University’s RAQA program. If you have taken identical or very similar courses at another institution, you may request to take an alternate course in its place.

Will the certificate automatically be awarded when I complete the required courses?
No. You must notify the RAQA Office that you have finished the certificate by submitting the Notice of Completion by the stated deadlines each semester. The form is available on the RAQA website under Certificates.

How much time do I have to complete the Post-Master's Certificate in GMPs for the 21st Century?
You should complete the Post-Master’s Certificate in GMPs for the 21st Century within four years. When you have finished your courses, you must submit the Notice of Completion to the RAQA Office.
Will new electives be added to the certificate programs?
Yes, the RAQA program continues to expand its curriculum. For a listing of new courses, please consult the RAQA website.

For additional information:
Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034

Voice: 267.468.8560
Fax: 267.468.8565
E-mail: QARA@temple.edu
www.temple.edu/pharmacy_QARA