

 <p>School of Pharmacy TEMPLE UNIVERSITY</p> <p>Quality Assurance/Regulatory Affairs Graduate Program</p>	<p>Temple University - School of Pharmacy 425 Commerce Drive, Suite 175 Fort Washington, PA 19034</p> <p>Phone: 267.468.8560 Fax: 267.468.8565</p>
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Graduate Certificate in GMPs for the 21st Century

DESCRIPTION

The U.S. Food and Drug Administration unveiled a new initiative in 2002 to enhance the regulation of pharmaceutical manufacturing and product quality, thereby bringing a 21st century focus to this FDA responsibility. In response to these new regulations, Temple University's QA/RA graduate program has created the *Certificate in GMPs for the 21st Century* to provide a sound theoretical and hands-on approach to practices used in all of the critical stages of manufacturing.

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 will also learn about process monitoring and controls, including statistical processes needed for process control charting and analysis and an overview of Six Sigma, including discussions on when they should (or should not) be applied. A key required course will focus on statistical design of pharmaceutical experiments. The overall goals of this program 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 four decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Quality Assurance and Regulatory Affairs. 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 QA and RA issues facing the pharmaceutical and related industries by integrating pharmaceutical law and regulation, pharmaceutical technology, and quality assurance practices. Faculty are industry veterans with years of expertise in their specialities, sharing their vast knowledge with students through intimate classroom discussions and hands-on workshops.

The 36-credit hour QA/RA master's program is based in Fort Washington, PA, with courses also offered in Tarrytown (NY), Frazer (PA), and corporate sites (either live or through videoconferencing). Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals.

To receive the certificate, candidates must complete the required courses and application procedures.

ACADEMIC REQUIREMENTS

1. Students pursuing the *Certificate in GMPs for the 21st Century* are expected to have a BS in Pharmacy, Chemistry, Biology or Engineering, and a strong science background, including familiarity with chemistry, biology, and physics. Students should also have a basic understanding of pharmaceutical manufacturing processes.
2. The *Certificate in GMPs for the 21st Century* may be earned on its own or on the way to the MS in QA/RA. To earn the certificate, the following five courses must be successfully complete within a four year period with an overall B (3.0 average):
 - **Regulatory Sciences: Managing the Guidelines for Quality (Pharmaceutics 5575)**
 - **Unit Operations (Pharmaceutics 5622)**
 - **Process Analytical Technology (PAT) (Pharmaceutics 5625)**
 - **Statistical Design of Experiments (DOE) (Pharmaceutics 5627)**
 - **Process Monitoring (Pharmaceutics 5629)**

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

2. All courses must be completed from Temple University's QA/RA graduate program. No transfer credits from other institutions are accepted.
3. Candidates must formally apply and follow the application procedures stated below (application form, photocopies of transcripts and notice of completion).
4. Only one certificate program (*Drug Development, Clinical Trial Management, Medical Device, Basic Pharmaceutical Development, Global Pharmacovigilance: Benefit-Risk Assessment, GMPs for the 21st Century*) may be completed before students receive the MS.
5. Students interested in pursuing the QA/RA MS program may apply all credits earned from the *Certificate in GMPS for the 21st Century* towards their graduate degree, provided they formally apply for admission to the MS program and are accepted by Temple University's Graduate School.

DESCRIPTIONS OF REQUIRED COURSES

The certificate is composed of five 3-credit courses. The first provides the foundation of knowledge for the subsequent courses on GMPs for the 21st Century. It is strongly suggested that students take the courses in the order listed. All courses build upon knowledge in GMPs for the 21st Century and provide students with hands-on knowledge of the field. *Students should start the certificate by taking Regulatory Sciences: Managing the Guidelines for Quality.*

5575. Regulatory Sciences: Managing the Guidelines for Quality

This course provides an overview of ICH Guidelines (including US, EU, and Japan regulations), looking at multi-national strategies and the regulatory aspects of the new GMPs. ICH revolutionized global regulatory filings with the Common Technical Document (CTD) serving as the platform for this format change. Module 3 of the CTD (the Quality Section) pertains to information related to Chemistry, Manufacturing and Control. ICH Quality Guidelines significantly influence the content of this Module. Recent FDA draft guidelines have incorporated and expanded upon ICH concepts. As the term ‘guideline’ implies, such documents should not be generally viewed as regulations, but as ‘recommendations’ to consider when developing the body of scientific information that ensures a thorough scientific understanding and control of product attributes. Proper interpretation of the guidelines based on sound scientific principles is essential to optimize both the quality and quantity of information submitted to global regulatory agencies. Consequently, review of various ICH and FDA Quality guidelines will be supplemented by a discussion of the basic scientific principles that may influence implementation. This course is designed to focus exclusively on guidelines associated with the development of small molecules from Phase 1 through Phase 4 and will not address issues related to biotechnology. After completing this course students should understand the basic expectations set forth in various ICH and FDA Quality Guidelines. They should also realize that the guidelines are subject to interpretation and not definitive regulations. Regulatory agencies are increasingly willing to engage in dialogue when filings are justified by data and clear scientific rationale presented.

5622. Unit Operations

This course will expose students to the current process steps common to the manufacture of modern pharmaceuticals. In particular, the key variables for each step of a process will be discussed. Each class will feature a specific process common to pharmaceutical processing. Specific variables will be discussed, including an analysis of each process. At the end of the course the student should be able to:

1. Describe a process by a series of smaller operations;
2. Describe the key variables for each small operation;
3. Identify key limitations of time and resources in proposed processes;
4. Provide constructive improvements to complex processes.

Topics include: Mixing efficiency, filtration efficiency and effectiveness, elastic, Plastic and Brittle Fracture during compaction, particle size reduction, heat flow, humidification and dehumidification, granulation, lyophilization, and sterilization .

5625. Process Analytical Technology (PAT)

Prerequisite: Unit Operations

The course focuses on state-of-the art utilization of process controls, including multivariate methods and feed-back loops. It will investigate analytical tools, including thermal conductivity, NIR, and Raman spectroscopy. It will also cover process analysis and feedback, as well as batch record analysis.

5627. Statistical Design of Experiments (DOE)

Prerequisite: Unit Operations

This course exposes students to the use of statistical methods for designing optimal processes used in industry, extensively using data sets and data charting. At the end of the course the student should be able to: create an experimental plan to optimize a process; create a screening study to limit the number of experiments; use surface methodology to set process specifications; and use specialized methodology for material analysis.

5629. Process Monitoring

Prerequisite: Unit Operations (Pharmaceutics 5622)

This course reviews Control Charting, Six Sigma, Root Cause Analysis, Risk/Benefit Analysis, Process Capability, and Process Efficiency/Lean Manufacturing

APPLICATION PROCESS

The *Certificate in GMPs for the 21st Century* is part of Temple University's graduate program in Quality Assurance and Regulatory Affairs. It does not require the completion of GREs. To earn the *Certificate in GMPs for the 21st Century*, students must successfully complete the five required courses with an overall B average and formally apply for the certificate. To receive the certificate and letter of completion, students must mail an application form and photocopies of all undergraduate and graduate transcripts (including Temple transcripts for QA/RA courses) to:

QA/RA Graduate Program
Temple University School of Pharmacy
425 Commerce Drive, Suite 175
Fort Washington, PA 19034

TO RECEIVE THE CERTIFICATE

After you have finished the five courses, you must notify the QA/RA Office by fax (215.468.8565) indicating that you are eligible to receive the certificate. Please include your name, TUID, courses completed, daytime phone number, and the certificate you have completed.

Certificates are issued in early February, June, and September. In order to receive your certificate in one of those months, you must notify the QA/RA office by fax **at least one month in advance**. Otherwise you will have to wait until the next time they are processed. The certificate must be completed within four years. Transfer credits are not accepted towards the *Certificate in GMPs for the 21st Century*.

QUESTIONS AND ANSWERS

Where is the QA/RA program offered?

Temple University's QA/RA program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions, visit our website:

http://www.temple.edu/pharmacy_QARA/map.htm

Courses are also offered in Tarrytown, NY, and Frazer, PA. Some corporate sites also videoconference our classes.

When can I start the program?

Courses in the QARA 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 recommend you take the courses in the prescribed order, since many of the concepts presented build upon one another.

How do I obtain a current class schedule?

Please check the QA/RA homepage:

http://www.temple.edu/pharmacy_qara/schedule.htm

How do I register for classes?

Please download the Registration and State Residency Forms from the QA/RA homepage: http://www.temple.edu/pharmacy_QARA/forms.htm

Both are required the first time you register. Faxed and e-mail registrations do not guarantee your spot in a class, since sections fill quickly. We will contact you if there are problems with your registration. Otherwise you will receive a paperless bill through your Temple email account which confirms that you are officially registered.

Do I need to submit GRE scores to complete the certificate?

No. GRE scores are not required for this certificate.

When should I indicate that I plan to pursue the certificate?

You do not need to submit an application form to start taking courses. In fact, you may simply complete the five courses and then submit your application. If you intend to pursue the MS, however, it is important that you complete your application to the MS as soon as possible, so all of your coursework applies to your degree. You may also pursue this certificate after the MS in QA/RA has been earned.

Can I complete both the *Certificate in GMPs for the 21st Century* and the MS in QA/RA?

Yes! You're welcome to complete both programs, but please be aware that the MS in QA/RA has an entirely different application process and requires GREs. For additional information on the Master's of Science in QA/RA, please request a Program Guide and an application form by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *Certificate in GMPs for the 21st Century*?

Sorry, but credits for courses taken at other institutions are not accepted. All five courses must be from Temple University's QA/RA program.

Will the certificate automatically be awarded when I complete the required courses?

No. You must formally apply to receive the certificate. This consists of submitting the application and copies of all undergraduate and graduate transcripts from any schools previously attended. You should complete the *Certificate in GMPs for the 21st Century* within four years. When you have finished your courses, you must notify the QA/RA by

fax (267.468.8565) that you are eligible to receive the certificate. The fax must include your name, TUID, courses completed, daytime phone number, and certificate you have completed. You must submit the fax at least one month before certificates are issued (early in February, June, and September). Otherwise you will have to wait until the next time they are processed.

Can I take other courses in Temple's MS program?

Temple University allows non-matriculated students to complete only one certificate before pursuing the MS in QA/RA. You may complete the *Certificate in GMPs for the 21st Century* and have all of the credits apply towards the MS; however, you must formally apply to the MS program by the time you complete the Certificate. You may also complete the MS in QA/RA, then pursue the *Certificate in GMPs for the 21st Century*.

For additional information:

Temple University School of Pharmacy
QA/RA Office
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