School of Pharmacy
TEMPLE UNIVERSITY
Regulatory Affairs and Quality Assurance
Graduate Program

Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
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GMPs FOR THE 21st CENTURY CERTIFICATE

Temple offers the first specialized certificate on the 2002 GMP regulations

BACKGROUND

In 2002, the U.S. Food and Drug Administration unveiled a new initiative 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 Regulatory Affairs and Quality Assurance graduate program has created the ***GMPs for the 21st Century Certificate*** 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 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.

This certificate enables 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 QA and RA 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.

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 60 courses are offered online in real time.

The ***GMPs for the 21st Century Certificate*** is currently only available in a traditional classroom format at Temple University Fort Washington, since one course has mandatory

laboratory sessions conducted at a manufacturing facility. The majority of the courses are scheduled on weekends, so students may commute to the campus to participate. Courses can also be videoconferenced to corporate sites.

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

ACADEMIC REQUIREMENTS

1. The ***GMPs for the 21st Century Certificate*** may be earned on its own or on the way to the MS in RAQA. To earn the certificate, the following 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) or **Microbiological Concepts in Pharmaceutical Manufacturing** (5512)
- **Statistical Design of Experiments (DOE)** (5627)
- **Process Monitoring** (5629)

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

2. Students pursuing the ***GMPs for the 21st Century Certificate*** are expected to have a strong science background, including familiarity with chemistry, biology and physics. They should have a BS in pharmacy, chemistry, biology or engineering from an accredited institution of higher learning. In addition, they should have a basic understanding of pharmaceutical manufacturing processes.

3. All courses must be completed from Temple University's RAQA graduate program. No transfer credits from other institutions are accepted.

4. Candidates must formally apply, following the application procedures below (**Application Form**, photocopies of transcripts and **Notice of Completion**).

5. Only one certificate may be completed before students receive the MS.

6. The certificate must be completed within four years. Students must apply for the certificate within one year of completing all required coursework for the program.

7. Students interested in pursuing the MS in RAQA may apply all credits earned from the ***GMPS for the 21st Century Certificate*** towards their graduate degree, provided they formally apply for admission to the MS program and are accepted by Temple University's Graduate School.

APPLICATION PROCESS

The ***GMPs for the 21st Century Certificate*** is part of Temple University's graduate program in Regulatory Affairs and Quality Assurance. It does not require the completion of GREs. To earn the ***GMPs for the 21st Century Certificate***, students must successfully complete the five required courses with an overall B (3.0) average and formally apply for the certificate. To receive the certificate and letter of completion, students must submit the following:

- **Application Form**
- photocopies of all undergraduate and graduate transcripts (including Temple transcripts for RAQA courses)
- a current CV or resume
- **Notice of Completion**

These items must be mailed to:

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

Certificates are not automatically conferred when students complete the required courses. Students must formally apply and must also forward the **Notice of Completion** by mail or fax to the RAQA Office (267.468.8565) indicating that they have finished the required courses.

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 the **Application Form**, transcripts, and **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.

DESCRIPTIONS OF REQUIRED COURSES

The certificate is composed of five 3-credit courses. Students should start the certificate by taking **Regulatory Sciences: Managing the Guidelines for Quality** since it provides the foundation of knowledge for the subsequent courses in the certificate, or **Unit Operations**. It is best for students to take the courses in the order listed, since each builds upon knowledge of GMPs for the 21st Century, but this is not mandatory. **Unit Operations** should definitely be taken before **Process Monitoring**. The Certificate provides students with hands-on knowledge of the field.

5575. Regulatory Sciences: Managing the Guidelines for Quality (3 credits)
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 (3 credits)
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) (3 credits)
Prerequisite: Unit Operations(Pharmaceutics 5622).
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.

OR

5512. Microbiological Concepts in Pharmaceutical Manufacturing (3 credits)
This course addresses essential microbiology concepts of manufacturing and quality control that form the basis of Good Manufacturing Practices for both sterile and non-sterile pharmaceuticals. Emphasis is placed on a review of the following from a microbiological perspective: manufacturing technologies and techniques, building quality into processes, influence of raw material quality on finished products, the meaning of the qualification and validation studies conducted by drug firms, and key microbiological tests performed at in-process and finished product stages. The course stresses practical matters and includes case studies to prepare students for daily issues arising in industry.

5627. Statistical Design of Experiments (DOE) (3 credits)
Prerequisite: Unit Operations(Pharmaceutics 5622).
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 (3 credits)
Prerequisite: Unit Operations (5622)
This course reviews Control Charting, Six Sigma, Root Cause Analysis, Risk/Benefit Analysis, Process Capability, and Process Efficiency/Lean Manufacturing

QUESTIONS AND ANSWERS

Where is the RAQA graduate program offered?
Temple University's RAQA graduate program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions, visit our website: **www.temple.edu/pharmacy_QARA/map.htm**

Courses can be videoconferenced to corporate sites.

The ***GMPs for the 21st Century Certificate*** 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 or ask to have the program videoconferenced to a corporate site.

When can I start the program?
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 recommend you take the courses in the prescribed order, since curriculum concepts build upon one another. It is best to start the certificate with **Regulatory Sciences: Managing the Guidelines for Quality** (5575) or **Unit Operations** (5622), but this is not mandatory. **Unit Operations** (5622) 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 download the Registration and State Residency Forms from the RAQA website: **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 fill quickly. We will contact you immediately if there are problems with your registration. The RAQA Office will send a confirmation when you are officially registered. You will also receive a notice via your TUmail 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 submit GRE scores to complete the certificate?
No. GRE or other advanced test scores are not required for this certificate or for the MS in RAQA.

When should I indicate that I plan to pursue the certificate?
You do not need to submit the 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 RAQA has been earned.

Can I complete both the *GMPs for the 21st Century Certificate* and the MS in RAQA?
Yes! You're welcome to complete both programs, but please be aware that the MS in RAQA has an entirely different application process. For additional information on the Master of Science in RAQA, please request a **Program Guide** and an **Application for Graduate Study** by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *GMPs for the 21st Century Certificate*?
Sorry, but credits for courses taken at other institutions are not accepted. All five courses must be from Temple University's RAQA 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 Form**, copies of all undergraduate and graduate transcripts from any schools you previously attended, and the **Notice of Completion**.

When you have finished your courses, you must submit the **Notice of Completion** by mail or fax (267.468.8565) indicating that you are eligible to receive the certificate. The Notice of Completion must be submitted by the stipulated semester deadlines (Jan 15, May 15, Aug 20). Otherwise you will need to wait until the next processing period.

Is there a deadline for completing the courses?
You should complete the ***GMPs for the 21st Century Certificate*** within four years. If you need an extension, please email **QARA@temple.edu.**

Can I complete two certificates in Temple's MS program?
Temple's RAQA program offers certificates in eleven specialties. Students may complete only one certificate before pursuing the MS in RAQA; however, you are welcome to earn additional certificates after earning the MS in RAQA. Thus, if you prefer to earn the ***Drug Development Certificate*** before completing the MS, you may subsequently earn the ***Post-Master's Certificate in GMPs for the 21st Century*** (or another post-master's certificate) after earning the MS. Courses may only be counted once towards any certificate. Please refer to our homepage for more details:
www.temple.edu/pharmacy_QARA/certificates.htm

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