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

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Regulatory Affairs and Quality Assurance Graduate Program
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PHARMACEUTICAL MANUFACTURING: PROCESS DEVELOPMENT AND ANALYSIS CERTIFICATE

(formerly GMPs for the 21st Century Certificate)

BACKGROUND

The ***Pharmaceutical Manufacturing: Process Development and Analysis Certificate*** enhances students' understanding of the science and regulations involved in pharmaceutical manufacturing processes. Students will learn how to set standards for increasing product quality, improve plant efficiency, lower production costs, and meet current domestic and global compliance requirements.

This certificate was first launched in 2006, in response to FDA's 2002 initiative to enhance the regulation of pharmaceutical manufacturing and product quality, bringing a 21st century focus to this Agency responsibility.

The RAQA graduate program relaunched the ***Certificate*** in 2019, changing it to four courses and renaming it the ***Pharmaceutical Manufacturing: Process Development and Analysis Certificate.*** Its curriculum now reflects the culture of continuous manufacturing quality, such as FDA's Quality Metric Guidance document and its focus on data integrity, change control, quality risk management, and IQ, OQ, and PQ (Installation Qualifications, Operational Qualifications, and Performance Qualifications).

Students begin the ***Pharmaceutical Manufacturing: Process Development and Analysis Certificate*** with *Unit Operations* (5622), which reviews the steps and processes used in modern pharmaceutical manufacturing and includes hands-on workshops at a Philadelphia-based manufacturing facility, where students actually mill and process tablets. *Process Monitoring* (5629) discusses why process control is integral to Quality by Design (QbD) and also touches upon lean and Six Sigma, including discussions on when it should or should not be applied. The final capstone course, *Statistical Design of Experiments* (5627), reviews statistical methods used in designing optimal processes for industry, which concludes with students designing an experimental plan to optimize a process.

SCHEDULING OF THE CERTIFICATE

The ***Pharmaceutical Manufacturing: Process Development and Analysis Certificate*** is only available in a traditional classroom format at the RAQA site in Fort Washington, PA. Courses can be videoconferenced to corporate sites but are not available online.

The majority of courses are offered on weekends, which meet all day for either six Saturdays or six Sundays every two weeks. Some ***Pharmaceutical Manufacturing: Process Development and Analysis Certificate*** courses are offered on weeknights.

One of the key required courses, *Unit Operations*, features two mandatory field trips to a Philadelphia-based manufacturing facility, where students practice milling and tableting techniques. While four of the classes can be videoconferenced, students must participate in the two manufacturing facility field trips.

LEARNING OBJECTIVES

Through hands-on and theoretical approaches, students will expand their knowledge of science and engineering principles with information about current regulations. The Certificate covers best practices for process development and analysis best practices. Upon completion, students will understand

- Control analysis and charting via statistical means;
- Control and monitoring;
- Unit operations of modern pharmaceutical manufacturing;
- Various ICH Quality guidelines and the basic scientific principles that may influence implementation;
- Fundamentals of Quality by Design.
- Fundamentals of Six Sigma, a data-driven methodology for minimizing variability.

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

ACADEMIC REQUIREMENTS

PREREQUISITE

Students must have a strong science background, including a Bachelor of Science in Biology, Chemistry, Engineering, Pharmacy, Physics or related fields from an accredited institution of higher learning. In addition, students must have a basic knowledge of pharmaceutical manufacturing processes [such as knowledge and experience with the pharmaceutical industry's cGMPs or completion of *Good Manufacturing Practices* (5477) or *Advanced GMPs – defining "c"* (5479]).

1. The ***Pharmaceutical Manufacturing: Process Development and Analysis Certificate*** may be earned on its own or on the way to the MS in RAQA. To earn the certificate, the following four courses must be successfully completed within a three year period with an overall B (3.0 average).

There are three **required** courses. It is suggested that students take courses in the order listed below, if possible:

- *Unit Operations* (5622) (*must be taken prior to 5629*)
- *Process Monitoring* (5629)
- *Statistical Design of Experiments* (DOE) (5627)

One elective must be completed from the following choices:

- *Process Analytical Technology* (PAT) (5625)
- *Microbiological Concepts in Pharmaceutical Manufacturing* (5512)
- *Risk Management for Pharmaceuticals and Medical Devices* (5548)

If possible, students should take courses in the order listed above. Students must complete any required prerequisites to pursue RAQA graduate-level courses.

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

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

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

5. The certificate must be completed within three years. To receive the certificate, students must submit the Notice of Completion within one year of completing all required coursework for the program.

6. Students interested in pursuing the MS in RAQA may apply all credits earned from the ***Pharmaceutical Manufacturing: Process Development and Analysis 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 ***Pharmaceutical Manufacturing: Process Development and Analysis 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 ***Pharmaceutical Manufacturing: Process Development and Analysis Certificate***, students must successfully complete three required and one elective course 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. 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 four 3-credit courses. Students should start the certificate by taking *Unit Operations*. It is recommended that students 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 be taken before *Process Monitoring*.

REQUIRED COURSES

Students must complete three required courses:

5622. Unit Operations (3 credits)
This course will expose students to the current steps common to the manufacture of modern pharmaceuticals. In particular, the key variables for each step will be discussed. Each class will feature a specific process common to pharmaceutical processing, including an analysis of each process. At the end of the course the student should be able to describe a process by a series of smaller operations; understand the key variables for each small operation; identify key limitations of time and resources in proposed processes: and 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.

5629. Process Monitoring (3 credits)
Prerequisite: Unit Operations (5622)
Students are introduced to process monitoring and controls currently used in the pharmaceutical and biotechnology industries, understanding why process control is an integral part of using Quality by Design. Discussions include process flowcharting and improvement, as well as control charting and process capability analysis that are used to assess process stability and capability. These concepts, methods and tools are integrated into a process performance and product quality monitoring and improvement system. The

course concludes with an introduction to process improvement using lean and Six Sigma methods. Minitab statistical software is used for statistical calculations. Students complete a project that involves collecting and analyzing data that measures the performance of an operational process. At the end of the course students will be able to collect process monitoring data, analyze process data to assess process stability and capability, identify opportunities for improvement, conduct studies to solve problems and create process improvements, and use statistical software to analyze process data.

5627. Statistical Design of Experiments (DOE) (3 credits)
Prerequisite: Unit Operations (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.

ELECTIVE COURSES
Students select one of the following courses:

5625. Process Analytical Technology (PAT) (3 credits)
Prerequisite: Unit Operations (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.

5512. Microbiological Concepts in Pharmaceutical Manufacturing (3 credits)
This course addresses essential microbiology concepts of manufacturing and quality control that form the basis of GMPs 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.

5548. Risk Management of Pharmaceutical and Medical Devices (3 credits)
This survey course focuses on risk management requirements and practices in the pharmaceutical, medical device, and biotech industries. Current regulations and risk management tools will be discussed and utilized to provide students with experience in executing risk assessments.

QUESTIONS AND ANSWERS

Where is the RAQA Program Offered?

The RAQA program is based at Temple University Fort Washington in suburban Montgomery County, PA. We offer courses both on-campus and online in real time. We also transmit our courses via videoconferencing to corporate sites.

The ***Certificate in Pharmaceutical Manufacturing: Process Development and Analysis*** 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?

We offer courses three semesters a year (fall, spring and summer). You may start the ***Certificate*** at your convenience.

What course sequence is recommended?

We suggest you start the certificate with **Unit Operations** (5622), though this is not mandatory. **Unit Operations** should completed before **Process Monitoring** (5629).

We have over 80 different courses in our program. Every course is not offered every semester. Electives are rotated over a 2 to 3 year period. If you wish to take a particular elective, please register for it when it appears on the schedule or ask our Office when it will next be offered.

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?

You may start the ***Certificate in Pharmaceutical Manufacturing: Process Development and Analysis*** before formally applying to the program.

- Download the registration form from the RAQA homepage**:** **www.temple.edu/pharmacy_QARA/forms.htm**

- 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 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 take the GREs to complete the *Certificate in Pharmaceutical Manufacturing: Process Development and Analysis?*

No. GRE scores are not required for the certificate or the MS in RAQA.

Can I transfer any credits from another graduate institution towards the *Certificate in Pharmaceutical Manufacturing: Process Development and Analysis*?
Transfer credits from 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 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 *Certificate in Pharmaceutical Manufacturing: Process Development and Analysis*?
You should complete the ***Certificate*** within three 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.

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