

STERILE PROCESS MANUFACTURING CERTIFICATE

Focusing on the regulation and quality practices of sterile product manufacturing

BACKGROUND

The importance of microbial control dates back to Hippocrates (460 - 377 BC), who recommended irrigating wounds with wine (alcohol) or boiled water to control infections. Progress continued with the discovery of disinfectants in the 1700s. By 1879, the first autoclave was invented by Louis Pasteur's graduate student (Charles Cumberland), and by the mid-1800s, surgical dressings were being sterilized by steam sterilization. During World War II, filtration was implemented to produce potable water, and its use expanded rapidly to sterilize drug products. Ethylene oxide became a sterilizing agent in 1940 and was followed in 1956 with the implementation of gamma irradiation as a sterilizing modality.

Advances in sterilization technologies have allowed the health care industry to develop an increasingly diverse array of products to treat disease states. Sterile product development began with medical devices and has progressed through drug products, in vitro diagnostics, and most recently, human cell and tissue products.

During the last century, multiple products were developed for many common but pernicious diseases. Sterile drugs are just one example of the numerous sterile products that continue to save countless human lives each year or ameliorate debilitating diseases. It would be impossible to run a modern hospital without sterile intravenous saline solutions, intravenous antibiotics, or syringes.

Sterile products must be manufactured in a manner that eliminates or minimizes microbial contamination. Generally, sterile devices are manufactured in clean environments, while sterile drug products are manufactured using aseptic (or free from contamination) process methods where the drug substance, excipients, and vehicle (e.g., saline or water for injection) are combined and filled into a container (such as a syringe). Often times, the final dosage form cannot be sterilized at the end of the manufacturing process, since the drug substance would become degraded: sterility must be assured during the manufacturing process by using microbial controls, sterile filtration and facility design, all of which must follow regulatory guidelines.

Temple University's Regulatory Affairs and Quality Assurance graduate program is pleased to launch the *Sterile Process Manufacturing Certificate* that focuses specifically on the regulations and quality processes that are unique to sterile products.

Courses explore the routes and types of sterile product administration, manufacturing and facility requirements for their design and production, as well as validation and compliance requirements. Attention is also focused on the technical and regulatory aspects of sterilization processes, including thermal, gaseous, radiation, filtration, and aseptic processing methods.

For nearly five decades, the School of Pharmacy at Temple University has provided outstanding graduate-level course work in Regulatory Affairs and Quality Assurance. The School was the first institution of higher learning in the U.S. 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 medical device, biotechnology, pharmaceutical and related industries. Courses discuss current practices and issues in device, biotechnology, and pharmaceutical law and regulation, 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.

The RAQA master's program is based in Fort Washington, PA. Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals. Some courses in this certificate are available online, but all courses can be videoconferenced to participating companies. To receive the certificate, candidates must complete the required courses and application procedures.

The certificate is open to students with bachelor's degrees in the sciences.

ACADEMIC REQUIREMENTS

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

Required:

Microbiological Concepts in Pharmaceutical Manufacturing (5512)
Production of Sterile Products (5492) *OR* **Sterilization Processes** (5493)

Two electives from:

Statistical Quality Control (5451)
Production of Sterile Products (5492)
Sterilization Processes (5493)
Development of Sterile Products (5501)
Vaccines: RA and QA Issues (5572)

It is suggested that students take at least one of the required courses before pursuing other courses in the certificate. The remaining courses may be taken in any order.

2. To be considered for the *Sterile Process Manufacturing Certificate*, candidates must have a degree from an accredited institution of higher learning. (A degree in science or engineering is suggested but not mandatory.)

3. All courses must be completed from Temple University's RAQA graduate program. No transfer credits from other institutions are accepted. If a student has completed an identical course at an accredited U.S. graduate school, the student may petition the RAQA program to waive that course and take another approved elective in its place. This request must be made in writing and approved **before** the student pursues the certificate.
4. Candidates must formally apply and follow the application procedures stated below (**Application Form**, photocopies of transcripts, and **Notice of Completion**).
5. Only one certificate program may be completed before students receive the M.S.
6. The certificate must be completed within three years. Students must apply for the certificate no more than one year after completing the course requirements.
7. Students interested in pursuing the RAQA MS degree may apply all credits earned in the *Certificate in Sterile Process Manufacturing* towards their graduate degree, provided they formally apply for admission to the MS program and are accepted by Temple University's Graduate School.

APPLICATON PROCESS

The *Sterile Process Manufacturing Certificate* is part of Temple University's graduate program in Regulatory Affairs and Quality Assurance. It does not require the GRE. To earn the *Sterile Process Manufacturing Certificate* students must successfully complete the four required courses with an overall B average and formally apply for the certificate. To receive the certificate and letter of completion, the following must be submitted:

- **Application Form.**
- Photocopies of all undergraduate and graduate transcripts from any schools previously attended, including Temple's RAQA program (copies of transcripts are acceptable; official transcripts are not required).
- **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** either by mail or fax to the RAQA Office (267.468.8565) indicating that they have finished the required courses. Photocopies of all undergraduate and graduate transcripts must be included.

The RAQA Office issues certificates in early February, June, and September. In order to receive your certificate in one of these months, you must submit the **Application Form**, transcripts, and **Notice of Completion** 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 will need to wait until the next processing period. It takes the RAQA Office 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.

REQUIRED COURSES

Two courses are required:

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 product, 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.

5492. Production of Sterile Products (3 credits)

This course reviews the theory and practice involved in the preparation of sterile injectable products, covering formulation, manufacturing, facility requirements, validation and regulatory issues. Upon completion of the course, students will develop an understanding of the routes of administration of injectable drugs and the types of injections, current formulation methods, aseptic manufacturing processes, requirements for sterile manufacturing facilities, and validation, compliance and regulatory issues.

OR

5493. Sterilization Processes (3 credits)

This course surveys sterilization processes used in the pharmaceutical, medical device, in-vitro diagnostic, and biotech industries. Current methods of sterilization are discussed, including thermal, gaseous, radiation, filtration, and aseptic processing. Students learn basic aspects of sterilization science as well as the design, review, and audit of sterilization validations and processes according to industry practices.

ELECTIVE COURSES

Students select two electives from the following:

5451. Statistical Quality Control (3 credits)

An introduction to statistical concepts, this course reviews control charts for variables, probability theory, control charts for attributes, and acceptance sampling systems. Class discussions include application to quality control of pharmaceutical manufacturing.

5492. Production of Sterile Products (3 credits) (if not taken as a required course)

This course reviews the theory and practice involved in the preparation of sterile, injectable products, covering formulation, manufacturing, facility requirements, validation and regulatory issues. Upon completion of the course, students will develop an understanding of the routes of administration of injectable drugs and the types of injections, current formulation methods, aseptic manufacturing processes, requirements for sterile manufacturing facilities, and validation, compliance and regulatory issues.

5493. Sterilization Processes (3 credits) (if not taken as a required course)

This course surveys sterilization processes used in the pharmaceutical, medical device, in-vitro diagnostic, and biotech industries. Current methods of sterilization are discussed, including thermal, gaseous, radiation, filtration, and aseptic processing. Students learn basic aspects of sterilization science as well as design, review, and audit of sterilization validations and processes according to industry practices.

5501. Development of Sterile Products (3 credits)

A study of the theory and practice in the development of parenteral products; dosage form design, formulation, solubility/physical pharmacy, excipients, assays, stability, physicochemical properties of biomolecules, delivery systems for controlled/sustained release and manufacturing methods.

5572. Vaccines: RA and QA Issues (3 credits)

This course addresses the history, research and development, manufacture, marketing, and medical impact of vaccines. Various public policy, regulatory, ethical, and legal issues in this area are discussed as they pertain to the U.S. and, to some extent, international markets. Beginning with the eradication of smallpox, this course covers the development of widely used vaccines against once common diseases (*e.g.*, polio, mumps, varicella, etc.), to the development of newer vaccines against HIV, anthrax, and certain types of cancer.

QUESTIONS AND ANSWERS

Where is Temple's RAQA program offered?

Temple University's RAQA program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions, refer to our website:

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

All courses can also be videoconferenced to corporate sites. Over 60 courses are available online in real-time. Some courses in the *Sterile Process Manufacturing Certificate* are available online. Check the schedule or call the RAQA Office for additional information.

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 start by taking at least one of the required courses first, since these courses serve as the foundation of knowledge for the program. You may then take the other courses in any sequence.

The RAQA program offers over 80 different courses, which are rotated over a 2 to 3 year period. Courses are not necessarily offered every semester. 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 check the RAQA homepage: www.temple.edu/pharmacy_QARA

How do I register for classes?

Please download the Registration and State Residency Forms from the RAQA homepage: http://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 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 an application form to start taking courses. In fact, you may complete the four 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 before you begin the fourth course, so all of your coursework applies to your degree.

Can I complete both the *Sterile Process Manufacturing 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 Regulatory Affairs and Quality Assurance, 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 *Sterile Process Manufacturing Certificate*?

Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University's RAQA graduate program. It is possible to have a requirement waived; however, another *approved* Temple University RAQA elective from the *Sterile Process Manufacturing Certificate* will have to be taken in its place. To waive a course, please submit a letter to the Assistant Dean for approval, **before** you begin the certificate.

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

No. You must formally apply to receive the certificate. This consists of submitting 1) the **Application Form**; 2) copies of all undergraduate and graduate transcripts from any schools previously attended (photocopies are acceptable; original transcripts are not required); and 3) the **Notice of Completion** form.

When you have finished your courses, you must submit the **Notice of Completion** to the RAQA Office via fax (267.468.8565) by the stipulated deadlines (Jan 15, May 15, or Aug 20). Otherwise you will have to wait until the next time they are processed.

Is there a deadline for completing the courses?

You should complete the *Sterile Process Manufacturing Certificate* within three years. If you need an extension, please email gara@temple.edu.

Can I complete two certificates in Temple's MS program?

Temple's RAQA program now offers certificates in eleven specialties. Students may complete only one certificate before pursuing the MS in RAQA; however, you are welcome to earn additional post-master's 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 Sterile Process Manufacturing Certificate* (or another post-master's certificate) after earning the MS. Courses may only be counted towards one certificate. Please refer to our homepage for more details: www.temple.edu/pharmacy_QARA/certificates.htm

For additional information:
RAQA Graduate Program
Temple University School of Pharmacy
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