

## POST MASTER'S CERTIFICATE IN STERILE PROCESS MANUFACTURING

*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 *Post Master's Certificate in Sterile Process Manufacturing* that focuses 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. It continues to be the leader in providing outstanding graduate-level courses in 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.

Candidates must formally apply for the *Post-Master's Certificate in Sterile Process Manufacturing* before registering for any courses. To receive the certificate, candidates must complete the required courses and 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 Sterile Process Manufacturing*.

Temple's RAQA graduate program is based in Fort Washington, PA.

## APPLICATION PROCESS

### 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 Sterile Process Manufacturing*, you must formally apply, so we can open your file to register you. The application is available on the **Certificates** link of the RAQA homepage.

You will be required to take four courses relating to Sterile Process Manufacturing to complete the Post Master's Certificate in this subject.

Please mail the application 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 Sterile Process Manufacturing*, 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. Degrees in science or engineering are preferred.
- 2) Please write a letter to the Assistant Dean (Temple University School of Pharmacy, RAQA Graduate Program, 425 Commerce Drive, Suite 175, Fort Washington, PA 19034), indicating which courses you wish to pursue and explaining your experience in the pharmaceutical industry. Include the **Application** for the *Post-Master's Certificate in Sterile Process Manufacturing*, a copy of your resume, and copies of transcripts from all undergraduate and graduate programs you have attended. Formal permission to pursue the *Post-Master's Certificate in Sterile Process Manufacturing* must be received from the Assistant Dean before commencing any courses in the program.
- 3) Students with advanced degrees from other schools will be required to take five Temple University RAQA courses to receive the *Post-Master's Certificate in Sterile Process Manufacturing*. If the candidate subsequently decides to apply for the MS in Regulatory Affairs and Quality Assurance within five years, the credits earned in the *Post-Master's Certificate in Sterile Process Manufacturing* will count towards the master's degree, provided a grade of B (3.0) or higher is earned in each course and the student is accepted into the MS program.

### TO RECEIVE THE CERTIFICATE

After you have finished the required courses, fill out the **Notice of Completion** (available on the RAQA website) and forward it to the RAQA Office by fax (267.468.8565), email ([garareg@temple.edu](mailto:garareg@temple.edu)), or hard copy.

The RAQA Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must notify the RAQA Office **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 Advanced Certificate.

### **Courses Accepted for the Post-Master's Certificate in Sterile Process Manufacturing**

To earn the certificate, the following courses must be successfully completed within a four 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 (or three) 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)

\*Students must take the two required courses, if they have not already done so. If courses were taken as part of the MS in RAQA, students may substitute other courses in the Post-Master's Certificate in Sterile Process Manufacturing curriculum.

## **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 directions, visit our website:

[http://www.temple.edu/pharmacy\\_QARA/map.htm](http://www.temple.edu/pharmacy_QARA/map.htm)

Courses can be videoconferenced directly to corporate sites. Over 60 courses are available online in real time.

Some courses in this certificate are available online. Please check the schedule.

### **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 recommend starting this certificate with the required courses before pursuing electives.

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 see the Schedule link of the RAQA homepage:

[www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA)

### **How do I register for classes?**

You must be formally admitted to the *Post-Master's Certificate in Sterile Process Manufacturing* before registering for any courses.

- If you received your MS from Temple, download the registration form from the RAQA homepage: [http://www.temple.edu/pharmacy\\_QARA/forms.htm](http://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 RAQA courses before, download the Registration and State Residency forms from the RAQA homepage: [http://www.temple.edu/pharmacy\\_QARA/forms.htm](http://www.temple.edu/pharmacy_QARA/forms.htm)  
Both are required the first time you register. Fax, mail, and email registrations do not guarantee your spot in a class, since sections do fill quickly. You will receive an email confirmation once you are registered and an electronic tuition bill through your Temple email account.

**Do I need to take the GREs to complete the *Post-Master's Certificate in Sterile Process Manufacturing*?**

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 Sterile Process Manufacturing*?**

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. The form is available on the RAQA website, under Certificates.

**How much time do I have to complete the *Post-Master's Certificate in Sterile Process Manufacturing*?**

You should complete the *Post-Master's Certificate in Sterile Process Manufacturing* 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.

**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](mailto:QARA@temple.edu)**

**[www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA)**