

FOOD REGULATORY AFFAIRS AND QUALITY ASSURANCE CERTIFICATE

Focusing on the regulations and manufacturing practices of food

BACKGROUND

As the name of the Food and Drug Administration implies, there are many parallels between the regulation, manufacture, and quality practices for drugs and food. Since the early 1990s, employees of the food industry, as well as industry professionals working in nutritional products, have often pursued the MS in Regulatory Affairs and Quality Assurance to deepen their knowledge of the Food, Drug, and Cosmetic Act, while also learning about quality practices. In response to these student populations, Temple's Regulatory Affairs and Quality Assurance graduate program has developed courses focusing on food law, regulation, and manufacturing practices.

The Food Safety and Modernization Act (FSMA) of 2011 encompassed some of the most sweeping reforms of food safety laws in more than 70 years, shifting the focus of food safety to preventative action rather than just responding to contamination. Food safety vigilance became a primary concern to prevent salmonella outbreaks and occurrences of *e. coli* in produce and meats. As a result, the U.S. Food and Drug Administration (FDA) hired close to 5,000 new inspectors, opening new career venues for professionals with credentials in quality practices and regulation.

The Regulatory Affairs and Quality Assurance graduate program is pleased to offer the three-course certificate in ***Food Regulatory Affairs and Quality Assurance*** to provide students with a broad knowledge of the regulatory and quality practices of food and food medicines. The certificate is designed to foster professional development, while preparing students for supervisory and managerial positions. Key topics include the basics of food quality practices, Good Manufacturing Practices (GMPs), preventive controls, and hazard and risk analysis. Students will develop a working knowledge of the legal and regulatory requirements involved in a food company's processing activities, learning about the key regulatory agencies, which govern food safety: FDA, USDA, and EPA. Faculty and guest speakers include regulators and professionals from the Philadelphia area's extensive food industry, which includes major manufacturers (Campbell Soup, Kraft, Nabisco, Heinz, Lipton, Hershey, and Blommer Chocolate) and distributors (Aramark, Sysco Foods, and Del Monte Fresh).

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 first U.S. institution of higher learning 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 pharmaceutical and related industries by integrating medical device, biotechnology, pharmaceutical law and regulation. 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. All courses in the *Food Regulatory Affairs and Quality Assurance Certificate* are offered online, enabling students throughout the country to participate in this program.

Pursuing courses in Food RA and QA will open additional career avenues for RAQA students. Matriculated students in Temple's RAQA graduate program are welcome to earn the *Food Regulatory Affairs and Quality Assurance Certificate* in addition to one additional certificate before receiving the MS degree. (For instance, a matriculated student could earn both the *Drug Development* and *Food Regulatory Affairs and Quality Assurance Certificate* before receiving the MS.)

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

ACADEMIC REQUIREMENTS

1. The *Food Regulatory Affairs and Quality Assurance Certificate* may be earned on its own or on the way to the MS in RA and QA. To earn the certificate, the following three courses are required and must be completed within a two year period with an overall B (3.0) average:

Food Law (5595)

Food Labeling and Regulatory Affairs (5596)

Food Good Manufacturing Practices (GMPs) (5597)

Courses may be taken in any order.

2. 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.

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

4. Matriculated students may earn the *Food Regulatory Affairs and Quality Assurance Certificate* in addition to one other certificate as they complete the M.S. in RAQA.

5. The certificate must be completed within two years. Students must apply for the certificate no more than one year after completing the course requirements.
6. Students interested in pursuing the RAQA MS degree may apply all credits earned in the *Food Regulatory Affairs and Quality Assurance 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 *Food Regulatory Affairs and Quality Assurance Certificate* is part of Temple University's graduate program in Regulatory Affairs and Quality Assurance. It does not require the GRE. To earn the *Food Regulatory Affairs and Quality Assurance Certificate* students must successfully complete the three 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:

- The **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

Three courses are required:

5595. Food Law (3 credits)

While *Food and Drug Law* (5592) briefly touches on food law, this course examines the major federal statutes and regulations applicable to food in more detail through class discussion and workshops. While emphasis is placed on the role, policies, and regulations of the FDA, the practical working relationships and obligations between the food industry, the USDA, and other government agencies at the state and local level are also examined. Pertinent landmark judicial decisions and concepts that relate to regulation of food and enforcement action against adulterated food are presented. The Food Safety and Modernization Act (FSMA), the most sweeping reform of U.S. food safety laws in more than 70 years, is studied, including new enforcement tools granted to FDA. Preventive Controls for Human and Animal Food, which are revolutionizing food safety programs across the globe, are extensively studied and illustrated. The student project focuses on conducting a Hazard Analysis for a particular food product.

5596. Food Labeling and Regulatory Affairs (3 credits)

This course provides students with an in-depth understanding about how food in the U.S. must be labeled regardless of its country of origin. The course describes regulatory affairs functions in the food industry, such as food facility registration, importing, recordkeeping, food additives, reportable food registry, recalls, FDA inspections, and specific food regulation. Rules passed under the Food Safety and Modernization Act (FSMA), such as Sanitary Transportation, Produce Safety, Foreign Supplier Verification Program, Accredited Third Party Certification, and Intentional Adulteration are thoroughly studied. Workshops throughout the course illustrate important labeling and regulatory affairs concepts.

5597. Food Good Manufacturing Practices (Food GMPs) (3 credits)

This course covers cGMPs (current Good Manufacturing Practices) through class discussion and workshops. Food safety regulations under the Food, Drug and Cosmetic Act are covered as well as their impact on personnel, facilities, equipment, and production. Emphasis is placed on preventing food-borne hazards via an understanding of sanitation measures, allergen control, acidification, and low acid canning. A risk-based approach to controlling hazards is presented using HACCP (Hazard Analysis and Critical Control Points) principles, from which new Preventive Controls regulations were derived. The student project focuses on evaluating food safety concerns when an FDA inspection reveals a total quality failure.

Students who wish to pursue additional study in food issues are welcome to take the following course after completing the three-course certificate:

5594. Regulation of Dietary Supplements, Botanicals, and Nutraceuticals (3 credits)

Legal issues surrounding the regulation of dietary supplements, nutraceuticals, and botanicals will be covered. When does a dietary supplement become a drug under the Federal Food, Drug and Cosmetic Act? What are the legal requirements for labeling? How are claims treated? These topics, along with current issues related to the regulations of dietary supplements are explored. The impact of the Dietary Supplement Health and Education Act, the Federal Food, Drug and Cosmetic Act, the FDA Modernization Act (FDAMA), and other relevant laws are examined. The enforcement authority of federal regulatory agencies (FDA and the Federal Trade Commission) is detailed.

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

Courses can also be videoconferenced to corporate sites.

Over 60 courses are available online in real-time. The *Food Regulatory Affairs and Quality Assurance Certificate* is offered entirely online.

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?

Courses may be taken in any order.

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 three 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 a fourth course in the program, so all of your coursework applies to your degree.

Can I complete both the *Food Regulatory Affairs and Quality Assurance Certificate* and another certificate and apply the credits towards the MS in RAQA?

Yes! Matriculated students are welcome to pursue the *Food Regulatory Affairs and Quality Assurance Certificate* plus another certificate before receiving the MS in RAQA.

Please note that only the *Food Regulatory Affairs and Quality Assurance Certificate* may be completed with an additional certificate before receiving the MS degree.

The MS in RAQA has an entirely different application process, and students must be matriculated (or formally accepted into the MS) in order to receive credit for two certificates. 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 *Food Regulatory Affairs and Quality Assurance Certificate*?

Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University's RAQA graduate 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 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 *Food Regulatory Affairs and Quality Assurance Certificate* within **two** 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 pursue the Food Quality Assurance and Regulatory Affairs Certificate with another certificate before completing the MS; however, they must be matriculated in the MS program to do so. Students are also welcome to earn the *Post Master's Food Regulatory Affairs and Quality Assurance Certificate* after completing the MS in RAQA. Courses may only be counted once towards any certificate. Please refer to our homepage for more details: www.temple.edu/pharmacy_QARA/certificates.htm

For additional information:
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RAQA Graduate Program
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Fort Washington, PA 19034

Voice: 267.468.8560
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E-mail: QARA@temple.edu
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