

POST MASTER'S CERTIFICATE IN FOOD REGULATORY AFFAIRS AND QUALITY ASSURANCE

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 ***Post-Master's 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 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 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.

Temple's RAQA graduate 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 *Post Master's Certificate in Food Regulatory Affairs and Quality Assurance* 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. To receive the certificate, candidates must complete the required courses and application procedures.

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 Food RA and QA*, you must formally apply, so we can reopen your file to register you. The application is available on the Certificates link of the RAQA homepage: www.temple.edu/pharmacy_qara

You will be required to take three courses in food RA and QA to complete the Post Master's Certificate in this subject.

Please mail the completed **Application Form** to:

Temple University School of Pharmacy
QA/RA 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 RA and QA*, 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.
- 2) Please write a letter to the Assistant Dean (Temple University 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 Form**, 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 Food RA and QA* 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 three Temple University RAQA courses to receive the ***Post-Master's Certificate in Food RA and QA*** (as specified below). If the candidate subsequently decides to apply for the M.S. in Quality Assurance/Regulatory Affairs within five years, the credits earned in the ***Post-Master's Certificate in Food RA and QA*** will count towards the master's degree, provided a grade of B or higher is earned in each course and the student is accepted into the M.S. 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 (qarareg@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 submit a **Notice of Completion** to the RAQA Office **at least one month in advance**. Otherwise you must wait until the next time they are processed. The certificate must be completed within three years. Transfer credits are not accepted towards the Advanced Certificate.

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 are presented relating to regulation of food and enforcement action against adulterated food. 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.

An optional elective for students is (please obtain permission in advance to have this course count towards your 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 supplement 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

Over 60 courses are available online in real-time. The *Post-Master's Certificate Food Regulatory Affairs and Quality Assurance* 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?

For all of the Post-Master's Certificates, students are required to apply and be formally accepted into the program before starting courses.

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

Anyone who is not matriculated into the MS in RAQA degree must formally apply to pursue more than one Certificate in our program. Students may earn more than one Post-Master's Certificate, once they are matriculated.

Can I transfer any credits from another graduate institution towards the *Post Master's Certificate in Food Regulatory Affairs and Quality Assurance*?

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 *Post Master's Certificate in Food Regulatory Affairs and Quality Assurance* within **two** years. If you need an extension, please email [**qara@temple.edu**](mailto:qara@temple.edu).

For additional information:

Temple University School of Pharmacy

RAQA Graduate Program

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