Courses in

Food Quality Assurance/Regulatory Affairs

Temple University, which offers the country’s most comprehensive graduate program in Quality Assurance/Regulatory Affairs for professionals in the pharmaceutical industry, is pleased to announce new courses focusing on Food Quality Assurance/Regulatory Affairs.

Due to the many parallels between food and drug regulation, manufacturing practices, and the focus on quality, employees from Philadelphia’s extensive food industry have often participated in the QA/RA graduate program. Temple will soon expand its course offerings in this area.

Receiving more perishable food products than any other U.S. port, Philadelphia is one of the largest national centers for the distribution and processing of imported food and food products. To South American countries, such as Chile, Brazil, Peru, Ecuador, and Argentina, the greater Philadelphia region is more important than New York, since the bulk of their food exports enter the U.S. through Camden, Wilmington, and Philadelphia. Countries such as the Ivory Coast, Indonesia, Malaysia and Ghana ship more cocoa beans to Philadelphia than any other U.S. port city. Whether it’s Australian kiwis and meats, Spanish and Moroccan clementines, or Ecuadorian and Guatemalan bananas, Philadelphia is a port of choice, providing a central location for food distribution throughout the Eastern seaboard due to its transportation infrastructure.

Many major food manufacturers are located in the Philadelphia metropolitan area, including Campbell Soup, Kraft, Hershey, Nabisco, Heinz, Blommer Chocolate, and Lipton. Philadelphia is home to food distribution companies, including Aramark, Sysco Foods, and Del Monte Fresh.

FDA Commissioner, Margaret Hamburg, MD, has announced a renewed regulatory posture for the Agency, which included hiring 5,000 new inspectors, primarily for increased vigilance on food safety. Recent news headlines have focused on e. coli in produce and meats or salmonella outbreaks, leading to recalls. At the same time, the US food industry must comply with increasing regulatory requirements imposed by state, federal, and international law (i.e., the Food Quality Protection Act). Temple’s QA/RA program has a long established relationship with the U.S. FDA at the local and national level and is in a unique position to work closely with the Agency in developing courses for industry and regulatory personnel in food safety issues.

Temple courses in Food Quality Assurance/Regulatory Affairs will target this vital market. It will draw upon the strengths of the pharmaceutical QA/RA graduate program by:

- Offering courses that specifically address the training needs of food manufacturing professionals, including quality issues in Food Regulation, Manufacturing, and Safety Management;

- Incorporating experts from industry, academia, and the government to teach classes, ensuring students receive a wide range of views of current food issues;

- Offering courses in two formats: 1) for graduate credit or 2) non-credit, enabling students to select the option which best meets their career needs.
The first course, offered Fall 2010, will include hands-on application of regulatory and quality practices through active discussions and workshops, enabling students to immediately apply classroom learning to their careers. The curriculum will be designed to help food QA professionals adapt to changes in government regulations, aiding their companies to maintain a competitive edge and assure public safety and consumer confidence in food products.

**COURSES AVAILABLE NOW**

**Food Law and Regulation (3 semester hours)**
*Currently offered Fall 2010: 9:00 am – 4:00 pm Sundays: Sept 12, 26, Oct 10, 23, Nov 7.*
Faculty: Kirk Sooter, Director, FDA Philadelphia District
This course examines the major federal statutes and regulations applicable to food. 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 entities are also examined. Recent efforts to respond to and combat food-borne illnesses are discussed, along with reporting requirements and recalls of defective or injurious products and micro-contamination. The course concludes with the quality practices used by FDA and USDA in the regulation of the global food supply.

**Regulation of Dietary Supplements, Botanicals, and Nutraceuticals**
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.

**PROPOSED FUTURE COURSES**

**Good Manufacturing Practices for Food (3 semester hours)**
What are the currently accepted good manufacturing practices for food and food products, including dietary supplements and their ingredients? How are these practices enforced in the U.S. and globally? This course will focus on manufacturing issues ranging from record keeping to food plant inspections, including pertinent legal decisions and regulatory actions. The Dietary Supplement Health and Education Act and the new GMP regulations for dietary supplements and their ingredients are discussed.

**Internal Quality Management of Food Safety (3 semester hours)**
How can quality assurance in food best be achieved? This course reviews the basic principles of food QA, including safeguards that encompass safety, labeling, and quality specifications to limit exposure to food-borne pathogens. Students will also learn about HACCP and ISO.

**Global Quality Management of Food Safety (2 semester hours)**
The global health issues involved with food misbranding, false nutritional and health claims, food additives, toxins, hormones in animal foods, and genetic engineering will be among the fascinating topics covered in this course. Special focus will include audits, vendor certifications and reliances.

**ELECTIVES RELATED TO FOOD REGULATION**

Environmental Law and Regulation (EPA)
This course explores regulations applied to the agricultural and chemical industries, covering basic environmental laws and regulations as well as key federal agencies (e.g., EPA, NRC, USFWS) influencing the chemical industry. The development, registration and manufacturing of EPA-related products such as pesticides are discussed as well as the global impact of pesticide regulation and registration requirements for international quality assurance (EU/OECD, MJAFF).

**KEY OBJECTIVES OF THESE COURSES**

- Providing students with a broad knowledge of the regulatory practices of the food industry to foster their professional development and prepare them for supervisory and managerial positions;
- Teaching students the basics of quality practices including Good Manufacturing Practices (GMPs) and Total Quality Management (TQM);
- Helping students develop a working knowledge of the legal and regulatory requirements involved in a food company’s processing activities;
- Maintaining contacts with the industry and key regulatory agencies (FDA, EPA, USDA) to ensure program direction is commensurate with the industry’s needs;
- Offering an interdisciplinary curriculum that draws upon the university’s knowledge and expertise in pharmaceutical, legal, technological, and health sciences;
- Keeping students informed of the latest FDA regulatory changes and providing them with continued training in new trends and developments of the food industry;

Students who complete the courses will bring invaluable skills to their companies by having a broad overview of regulatory and quality control issues affecting the food industry.

**TUITION AND FEES**

This program is available in two formats: for graduate credit or non-credit. Courses are conveniently scheduled on weekends and will eventually be offered in an on-line format.

**Cost to receive graduate credits:** $2,712 for PA residents  
$3,600 for non-PA residents  
*Students are also responsible for the University Services Fee.*

**Non-credit fee per course:** call for information
For Non-Credit Registration ONLY – there is a 10% discount when three or more individuals register for the same course at the same time. The 10% discount will be applied to the total non-credit registration tuition.

Cancellation policy: a non-credit participant who withdraws from a course in writing up to one week prior to the start date of the course will receive a refund less a $25 withdrawal fee. No refunds will be given after that time. You may email your withdrawal to gara@temple.edu or fax it to 267.468.8565. If the course is canceled for any reason, you will be notified and your entire tuition fee will be refunded.

**QUESTIONS AND ANSWERS**

Where are the courses in Food Quality Assurance/Regulatory Affairs offered?
Temple University’s QA/RA program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions: http://www.temple.edu/pharmacy_QARA/map.htm

**When can I start the courses?**
The first course is *Food Law and Regulation*, offered five Sundays from 9:00 to 2:00 pm (Sept 12, 26, Oct 10, 24, Nov 7) during the fall. The instructor is Kirk Sooter, Director, Philadelphia District of the U.S. FDA.

**What course sequence is recommended?**
We recommend you start by taking *Food Law and Regulation* (Pharmaceutics 5595), which provides an overview of food regulation and serves as the foundation of knowledge for the program. You may take subsequent courses in any order.

**How do I obtain a current class schedule?**
Please check the QA/RA homepage: http://www.temple.edu/pharmacy_QARA/schedule.htm

**How do I register for classes?**
**For graduate credit:**
Please download the Registration and State Residency Forms from the QA/RA homepage: http://www.temple.edu/pharmacy_QARA/forms.htm Both are required the first time you register. We will confirm your registration, and you will receive a paperless bill through your Temple email account.

**For non-credit:**
Please complete the special non-credit registration form available on the QA/RA website.

**Do I need to submit GRE scores to take courses?**
No. GRE scores are not required.

**May I take just one course?**
Yes. Students are welcome to take any individual course offered in *Food Quality Assurance and Regulatory Affairs* either for graduate credit or for non-credit.

**Can I complete courses in Food Quality Assurance/Regulatory Affairs and the MS in QA/RA?**
Yes! Please be aware that only one course (or 3 credits) earned in Food Quality Assurance/Regulatory Affairs will count towards the MS in QA/RA. The MS in QA/RA has a separate application process and requires GREs. For additional information on the MS in QA/RA, please request an information packet by calling 267.468.8560.

**For additional information:**
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