School of Pharmacy
TEMPLE UNIVERSITY
Regulatory Affairs and Quality Assurance
Graduate Program

Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175 • Fort Washington, PA 19034
Phone: 267.468.8560 • Fax: 267.468.8565
Email: qara@temple.edu • Web: www.temple.edu/pharmacy_QARA

PHARMACEUTICAL LABELING, ADVERTISING, and PROMOTIONS CERTIFICATE

Focusing on the Federal and Global Regulations Governing Pharmaceutical Labeling, Advertising, and Promotions

BACKGROUND

There is an immediate need for pharmaceutical professionals with knowledge of and credentials in the federal and global regulations governing labeling, advertising, and promotions. Temple University's Regulatory Affairs and Quality Assurance graduate program is pleased to launch a new ***Pharmaceutical Labeling, Advertising, and Promotions Certificate*** that focuses specifically on these complex regulations.

In the pharmaceutical industry, *labeling* refers to more than a prescription label or a cardboard container enclosing prescription or over-the-counter (OTC) products: *labeling* also refers to the *Package Insert* (or PI), which is a detailed and complicated product reference sheet, often folded in multiple accordion pleats and included with prescription or OTC products.

In the U.S., each PI is governed by the U.S. Code of Federal Regulations, Title 21, part 200, which stipulate that every aspect of the product be delineated in writing: a description of the drug dosage form and its physical properties; a listing of active ingredients and excipients; the molecular structure of each compound; the pharmacokinetics and toxicology of the drug; the intended patient population; potential side effects and safety concerns; unique storage requirements, and so forth.

The PI must accompany any print ads about prescription drugs that appear in journals and magazines. Attached to each advertisement, the PI must be uniquely coded, since the company is required to keep accurate records of where the ad appeared.

Federal regulations also govern how prescription products can be advertised. Each year pharmaceutical companies spend over $30 billion on direct-to-consumer (DTC) TV ads, which have made many products household names, from *Cymbalta* to *Humera*, from *Nexium* to *Lyrica*. The complexity of creating these ad campaigns, while complying with federal regulations, continues to be a challenging task that combines industry knowledge, regulatory expertise and marketing. Advertising companies alone cannot create the ads; regulatory professionals must be included.

In addition to DTC TV advertising, websites about pharmaceutical products have grown exponentially, particularly those that focus exclusively on one product, serving as a sort of "patient reference page." In some cases, innovator companies even sell products DTC from websites.

Often different countries have unique regulatory requirements for labeling and advertising. For instance, some require labels to display the price of a product the day it

was granted approval by the governing regulatory authority. Or, in other cases, product cartons must be designed to clearly display that pricing. As the types and global reach of product advertising continue to expand, thereby crossing the boundaries of regulatory authorities and patient populations, the need for more global regulatory oversight is increasing.

Recruiters from placement firms frequently call the RA and QA Office, seeking candidates with demonstrated knowledge of the regulations governing advertising and labeling. The ***Pharmaceutical Labeling, Advertising, and Promotions Certificate*** will provide students with credentials from Temple's well respected Regulatory Affairs and Quality Assurance graduate program, giving them a solid grounding in the key federal and global regulations that affect the advertising and labeling of pharmaceutical products.

The certificate is open to both MS applicants and also MS graduates, who can expand their career opportunities with this new credential.

ACADEMIC REQUIREMENTS

1. The ***Pharmaceutical Labeling, Advertising, and Promotions 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:
Food and Drug Law (5592)
Requirements in Product Labeling and Advertising (5533)
Advanced Topics: Regulation of Advertising and Promotions (5611)

One elective from:
Global Labeling Regulation: Principles and Practices (5532)
Advanced Topics in Labeling Development (5535)
Regulation of Non-Prescription Healthcare Products (proposed 5507)
Regulation of Dietary Supplements, Botanicals, and Nutraceuticals (5594)

Students should take *Food and Drug Law* before pursuing other courses in the certificate. It is suggested that *Requirements in Product Labeling and Advertising* be completed next. The remaining 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. Only one certificate program may be completed before students receive the M.S.

5. The certificate must be completed within three 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 ***Pharmaceutical Labeling, Advertising, and Promotions Certificate*** 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 ***Pharmaceutical Labeling, Advertising, and Promotions Certificate*** is part of Temple University's graduate program in Regulatory Affairs and Quality Assurance. It does not require the GRE. To earn the ***Pharmaceutical Labeling, Advertising and Promotions 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:

- An **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

TO RECEIVE THE CERTIFICATE

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 those months, you must submit your **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.

DESCRIPTION OF REQUIRED COURSES

Students must complete the following three courses:

5592. Food and Drug Law (3 credits)
This course studies the governance of intra- and interstate commerce in foods, drugs, cosmetics, and medical devices and the effects of the Federal Food, Drug and Cosmetic Act upon research, manufacture, marketing, and distribution of drugs.

5533. Requirements for Product Labeling and Advertising (3 credits)
Prerequisite: Food and Drug Law (5592) or permission of the instructor.
This course examines strategies for creating drug labeling during new product development, for updating existing product labeling, and for creating "harmonized" core data sheets for products marketed globally. Students gain insight and awareness of current trends in advertising and promotional regulation.

5611. Advanced Topics: Regulation of Advertising and Promotions (3 credits)
This course reviews the regulatory and legal fundamentals of advertising FDA-regulated products, including prescription pharmaceuticals, OTCs, and biologicals. Discussions will include how these regulations differ from those applicable to restricted medical devices and food products.

ELECTIVE COURSES

Students must select one elective from the following:
5532. Global Labeling Regulation: Principles and Practices (3 credits)
Suggested prerequisite: Drug Development (5459)
This course provides a detailed analysis of corporate labeling practices in the United States and European Union (EU). It compares and contrasts FDA regulations with more recent EU and International Congress on Harmonization (ICH) regulations, including the impact on corporate labeling documents. A significant portion of the course will be devoted to new guidelines from FDA and the pharmacovigilance guidelines for the EU market and ICH.

OR

5535. Advanced Topics in Labeling Development (3 credits)
Prerequisite: Requirements for Product Labeling and Advertising (5533) or permission of the instructor.
This course reviews the regulatory and legal fundamentals of labeling FDA-regulated products, specifically, prescription pharmaceuticals, emphasizing the direct application of the regulations to actual practice. It analyzes case studies and current practices, providing an overview of legal, regulatory, and marketing concepts affecting labeling. It discusses the application of current knowledge and explores new trends in the legal and regulatory framework surrounding the development and implementation of drug labeling. As a class

project, students are assigned to drug development teams (Regulatory Affairs, Marketing and Clinical) and provided with the known data of their compounds. Teams determine what information is needed to complete the draft labeling for NDA submission, and develop a final label; they hold mock negotiations (internal and with the Agency) and propose changes to labeling in response to post-marketing safety surveillance.

OR

5594. Regulation of Dietary Supplements, Botanicals and Nutraceuticals (3 credits)
The course focuses on legal issues surrounding the regulation of dietary supplements, nutraceuticals, and botanicals. 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 other federal regulatory agencies, that is, the FDA and the Federal Trade Commission, is detailed.

OR

Temple School of Pharmacy is developing a course on Non-Prescription Drugs (OTCs), which will serve as an elective in the certificate.

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, visit 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.

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 *Food and Drug Law* (5592), since this course serves 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 simply 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 as soon as possible, so all of your coursework applies to your degree.

Can I complete both the *Pharmaceutical Labeling, Advertising, and Promotions 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 *Pharmaceutical Labeling, Advertising, and Promotions Certificate*?
Sorry, but credits for courses taken at other institutions are not accepted. All four 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 ***Pharmaceutical Labeling, Advertising, and Promotions Certificate*** will have to be taken in its place. To waive a course, please submit a letter to the Assistant Dean for approval.

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 ***Certificate in Pharmaceutical Labeling, Advertising, and Promotions*** within three years. If you need an extension, please email qara@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 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 Pharmaceutical Labeling, Advertising, and Promotions*** (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:
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