Graduate Certificate: Pharmaceutical Labeling, Advertising and Promotions

SCHOOL OF PHARMACY

About the Certificate

The graduate and post-master's certificate in Pharmaceutical Labeling, Advertising and Promotions is intended to produce well-qualified experts with knowledge of the U.S. and global regulations governing the labeling, advertising, and promotions of pharmaceuticals and related products. Coursework addresses the complexity of the PI (Package Insert), showing how it must delineate every aspect of the product, from its dosage form to its unique storage requirements and dosage information. Topics include how the PI must be incorporated into print and internet advertising and promotions for products and also the requirements for television ads. Differences in the regulations in key world markets are also discussed.

Time Limit for Certificate Completion: 4 years

Campus Location: Fort Washington and Online

Full-Time/Part-Time Status: The certificate may be completed on a part-time basis. NOTE: International students may not be eligible to apply for a student visa based on admission to the certificate program. Please contact the School of Pharmacy's program coordinator for more information.

Non-Matriculated Student Policy: Non-matriculated students may take up to 9 credits of coursework before applying to the post-baccalaureate certificate program. The post-master's certificate cannot be taken on a non-matriculated basis.

Admission Requirements and Deadlines

Application Deadline:
Fall and Spring admissions are on a rolling basis.

APPLY HERE to the post-baccalaureate certificate program.

APPLY HERE to the post-master's certificate program.

Master’s Degree in Discipline/Related Discipline: Applicants completing the certificate program to earn a post-master's certificate must hold a master's degree in Regulatory Affairs and Quality Assurance.

Bachelor’s Degree in Discipline/Related Discipline: Applicants completing the certificate program to earn a post-baccalaureate certificate must hold a B.S. degree in Biochemistry, Biology, Chemistry, Physics, or a health-related discipline.

Other: Applicants who did not earn their master's degree from Temple University's School of Pharmacy must have sufficient industry experience and familiarity with the basic tenets of regulatory affairs and quality assurance to pursue the post-master's certificate. As part of the application, these applicants must include:

• a letter of request to the Assistant Dean of Regulatory Affairs and Quality Assurance indicating the courses to be pursued and citing the applicant's industry experience;
• a copy of their resume; and
• a photocopy of their final transcript from the institution where the master's or doctoral degree was earned.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 12

Required Courses:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credit Hours</th>
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<tbody>
<tr>
<td>QARA 5532</td>
<td>Global Labeling Regulation: Principles and Practices</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5533</td>
<td>Requirements for Product Labeling and Advertising</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5592</td>
<td>Food and Drug Law</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5611</td>
<td>Regulation of Advertising and Promotions</td>
<td>3</td>
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Total Credit Hours: 12
Post-master's students who have already completed one or more of the required certificate courses as part of the M.S. in Regulatory Affairs and Quality Assurance may, with prior written approval of the RAQA Office, complete one or more of the following electives: QARA 5507 Regulation of Non-Prescription Healthcare Products, QARA 5535 Advanced Topics in Labeling Development, QARA 5544 Regulatory Intelligence, QARA 5605 Advanced Topics in Food and Drug Law, and/or, when the special topic relates to issues of labeling, advertising, and promotions, QARA 5650 Special Topics in Regulatory Affairs and Quality Assurance.

Graduate students who earned their M.S. in Regulatory Affairs and Quality Assurance at Temple University are expected to have completed QARA 5592 as part of the M.S. program. They may, with prior written approval of the RAQA Office, substitute one of the following electives as their fourth course in the certificate: QARA 5507 Regulation of Non-Prescription Healthcare Products, QARA 5535 Advanced Topics in Labeling Development, QARA 5544 Regulatory Intelligence, QARA 5594 Regulation of Dietary Supplements and Functional Foods, or QARA 5606 Regulatory Strategy: Discovery to Approval.

GPA Required to be Awarded the Certificate: 3.0 minimum

Contacts

Certificate Program Web Address:
https://www.temple.edu/pharmacy_qara/certificates.htm

Department Information:
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728
qara@temple.edu
267-468-8560

Mailing Address for Application Materials:
Temple University
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728

Department Contacts:
Admissions:
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