

 <p>School of Pharmacy TEMPLE UNIVERSITY</p> <p>Quality Assurance/Regulatory Affairs Graduate Program</p>	<p>Temple University - School of Pharmacy 425 Commerce Drive, Suite 175 Fort Washington, PA 19034</p> <p>Phone: 267.468.8560 Fax: 267.468.8565</p>
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MEDICAL DEVICE CERTIFICATE
An Overview of Global and Domestic Regulations
of Medical Devices

BACKGROUND

The *Medical Device Certificate* enables students to receive specific training in the medical device field, familiarizing them with its domestic and global regulations. All courses are taught by experts from the industry, including the medical device sector, providing hands-on application of regulations and quality practices.

Pharmaceutical companies market medical and diagnostic devices, with many having separate device divisions or subsidiaries. Example devices include medical diagnostic instruments and kits, surgical sponges, and drug delivery devices (ranging from syringes to transdermal patches). RA professionals in these companies can deepen their understanding by studying the similarities and differences in pharmaceutical and medical device regulations.

FDA's regulation of medical devices has the same objective as its regulation of drugs: protecting public health by ensuring a balance of risk vs. benefit for marketed products. Some high-risk medical devices, such as sutures, contact lenses, and antibiotic sensitivity disks, were regulated as drugs before the 1976 legislation was passed extending FDA's regulatory authority over devices. Because medical devices are highly variable in complexity and technology, a more flexible approach to their regulation has evolved to meet this objective than has evolved for drugs.

The certificate curriculum is designed to review the key aspects of the medical device industry: regulation, compliance, and submissions in the domestic and global realms. Courses are highly interactive with various workshops, enabling students to apply their knowledge immediately to the workplace.

For nearly four decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Quality Assurance and Regulatory Affairs. The School was the original institution of higher learning in the world 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 QA and RA issues facing the pharmaceutical and related industries by integrating pharmaceutical law and regulation, pharmaceutical technology, and quality assurance practices. Faculty are industry veterans

with years of expertise in their specialities, sharing their vast knowledge with students through intimate classroom discussions and hands-on workshops.

The 36-credit hour QA/RA master's program is based in Fort Washington, PA, with courses also offered in Tarrytown (NY), Frazer (PA), and corporate sites (either live or through videoconferencing). Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals.

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

ACADEMIC REQUIREMENTS

1. The *Medical Device Certificate* may be earned on its own or on the way to the MS in QA/RA. To earn the certificate, the following five courses must be successfully complete within a four year period with an overall B (3.0 average):

- *Food and Drug Law I* (Pharmaceutics 5592)
- *Regulation of Medical Devices: Submissions* (Pharmaceutics 5502)
- *Regulation of Medical Devices: Compliance* (Pharmaceutics 5496)
- *Global Medical Device Regulation* (Pharmaceutics 5505)
- **One of the following electives:** *Quality Audit* (Pharmaceutics 5494) **or** *Computer Validation* (Pharmaceutics 5498) **or** *Process Validation* (Pharmaceutics 5474) **or** *Pharmaceutical Packaging: Technology and Regulation* (Pharmaceutics 5541).

It is suggested that students take *Food and Drug Law I* before taking the other classes.

2. All courses must be completed from Temple University's QA/RA graduate program. No transfer credits from other institutions are accepted. If a student has completed *Food and Drug Law I* at another graduate institution, that course may be waived and one of the electives (*Quality Audit*, *Computer Validation*, *Process Validation*, or *Pharmaceutical Packaging: Technology and Regulation*) may be substituted; however, the request to substitute a course must be made by the student and approved before taking any classes in the *Medical Device 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 (*Drug Development*, *Clinical Trial Management*, *Medical Device*, or *Basic Pharmaceutical Development*) may be completed before students receive the MS.

5. Students interested in pursuing the QA/RA MS program may apply all credits earned from the *Medical Device Certificate* towards their graduate degree, provided they formally apply for admission to the MS program and are accepted by Temple University's Graduate School.

DESCRIPTIONS OF REQUIRED COURSES

5592. Food and Drug Law I (3 credits)

This course examines the governance of intrastate 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.

5496. Regulation of Medical Devices: Compliance (3 credits)

This course examines the broad scope of the medical device industry and its quality assurance practices, covering the preclinical, clinical, manufacturing, post-market reporting, and device-tracking compliance regulations in the U.S. and other major world markets.

5502. Regulation of Medical Devices: Submissions (3 credits)

This course provides an overview of medical device submissions. The course begins with a review of laws specific to medical devices such as the requirement for pre-market submissions. Specific topics include device classification, investigational device exemption (IDE) applications, pre-market notification submissions [510(k)s], pre-market approval applications (PMAs), humanitarian device exemptions (HDEs), product development protocols (PDPs), STED and an overview of Global Harmonization Task Force recommendations.

5505. Global Medical Device Regulation (3 credits)

This course provides an overview of international medical device regulations. Beginning with a discussion of the similarity of global requirements (including both voluntary and mandatory standards and directives and progressing to in-depth analyses of market specific requirements), the course provides students with resources to meet the regulatory requirements for the largest world markets. The Medical Device Directive, the In Vitro Diagnostic Directive and the Active Implantable Medical Device Directive will be discussed, as well as initiatives by the Global Harmonization Task Force related to the classification, development, and complaint handling for medical devices. As part of this course, the student will learn the quality system requirements of ISO13485, risk management according to ISO14971, and how to CE mark their product. Country-specific regulatory requirements for Canada, EU, Australia and Japan are included.

DESCRIPTIONS OF ELECTIVE COURSES

5474. Process Validation (3 credits)

Since the concept of validation originally appeared in GMP regulations, it has extended to every step in product manufacturing from building the plant to the methods used for testing and releasing its products. The course exposes students to all aspects of validation. FDA Guides and Guidelines, as well as the current emphasis on validation concerns by FDA (as identified in 483 and Warning Letter observations), will be incorporated. Students develop acceptable validation protocols and learn what constitutes an acceptable validation report.

Or

5494. Quality Audit (3 credits)

Prerequisite: A Good Practices course (5476, 5477, 5479 or 5536)

This course covers topics in quality assurance principles, audit techniques, audit types, audit presentation and reports, auditing procedures for GMPs, GCPs, and GLPs.

Or

5498. Computer Validation (3 credits)

This course focuses on the application of computer validation concepts to computer systems operating within a pharmaceutical research and development environment. It presents the specific needs and responsibilities of the various regulatory requirements and guidelines (both domestic and global).

Or

5541. Pharmaceutical Packaging: Technology and Regulation (3 credits)

This course focuses on the complexities of packaging for the pharmaceutical industry, covering commonly used packaging systems (bottle/blister packaging for Oral solids) as well as niche applications (such as sterile/parenteral, inhalation, and nasal systems). In addition to the container/closure systems, some of the packaging processing methods will be covered. A review of the applicable regulatory environment and the submission requirements for drug products will be included. The submission needs will be covered, with a focus on the needs of the newly implemented Common Technical Document (CTD). A visit to a manufacturing facility of one of the industry's suppliers will be required.

APPLICATION PROCESS

The *Medical Device Certificate* is part of Temple University's graduate program in Quality Assurance and Regulatory Affairs. It does not require the completion of GREs. To earn the *Medical Device Certificate*, students must successfully complete the five required courses with an overall B average and formally apply for the certificate. To receive the certificate and letter of completion, students must mail an application form and photocopies of all undergraduate and graduate transcripts (including Temple transcripts for QA/RA courses) to:

QA/RA Graduate Program
Temple University School of Pharmacy
425 Commerce Drive, Suite 175
Fort Washington, PA 19034

TO RECEIVE THE CERTIFICATE

After you have finished the five courses, you must notify the QA/RA Graduate Program by fax (267.468.8565) indicating that you are eligible to receive the certificate. Please include your name, TUID, courses completed, daytime phone number, and the certificate you have completed.

The Graduate Studies Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must notify the Graduate Studies office by fax **at least one month in advance**. Otherwise you will have to wait until the next time they are processed. The certificate must be completed within four years. Transfer credits are not accepted towards the *Medical Device Certificate*.

QUESTIONS AND ANSWERS

Where is the QA/RA program offered?

Temple University's QA/RA 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 are also offered in Tarrytown, NY, and Frazer, PA. Some corporate sites also videoconference our classes.

When can I start the program?

Courses in the QARA 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 I* (Pharmaceutics 5592), since this course provides an overview of the pharmaceutical industry and serves as the foundation of knowledge for the program. You may then take the other courses in any sequence.

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?

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. Faxed and e-mail registrations do not guarantee your spot in a class, since sections fill quickly. We will contact you if there are problems with your registration. Otherwise you will receive a paperless bill through your Temple email account which confirms that you are officially registered.

Do I need to submit GRE scores to complete the certificate?

No. GRE scores are not required for this certificate.

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 five 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 *Medical Device Certificate* and the MS in QA/RA?

Yes! You're welcome to complete both programs, but please be aware that the MS in QA/RA has an entirely different application process and requires GREs. For additional information on the Master's of Science in QA/RA, 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 *Medical Device Certificate*?

Sorry, but credits for courses taken at other institutions are not accepted. All five courses must be from Temple University's QA/RA program. It is possible to have a requirement waived; however, another *approved* Temple University QA/RA elective from the *Medical Device Certificate* will have to be taken in its place. To waive a course, please submit a letter to the Office of Graduate Studies 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 the application and copies of all undergraduate and graduate transcripts from any schools previously attended. You should complete the *Medical Device Certificate* within four years. When you have finished your courses, you must notify the QA/RA Office by fax (267.468.8565) that you are eligible to receive the certificate. The fax must include your name, TUID, courses completed, daytime phone number, and certificate you have completed. You must submit the fax at least one month before certificates are issued (early in February, June, and September). Otherwise you will have to wait until the next time they are processed.

Can I take other courses in Temple's MS program?

Temple University allows non-matriculated students to complete only one certificate before pursuing the MS in QA/RA. You may complete the *Medical Device Certificate* and have all of the credits apply towards the MS; however, you must formally apply to the MS program by the time you complete the Certificate.

For additional information:

Temple University School of Pharmacy

QA/RA Office

425 Commerce Drive, Suite 175

Fort Washington, PA 19034-2713

Voice: 267.468.8560

Fax: 267.468.8565

E-mail: QARA@temple.edu

www.temple.edu/pharmacy_QARA