

 <p>School of Pharmacy <small>TEMPLE UNIVERSITY</small></p> <p>Quality Assurance/Regulatory Affairs <small>Graduate Program</small></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>
---	--

MEDICAL DEVICE CERTIFICATE

An Overview of Global and Domestic Medical Device Regulations

BACKGROUND

Our *Medical Device Certificate* focuses on the domestic and global regulations governing the medical device field. Many pharmaceutical companies have separate device divisions or entire subsidiaries that focus on marketing medical and diagnostic devices, such as diagnostic instruments and kits, surgical sponges, and drug delivery devices, ranging from syringes to transdermal patches. RA professionals pursuing this certificate will deepen their understanding of the device field by exploring the similarities and differences in pharmaceutical and 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 reviews key aspects of the medical device industry: regulation, compliance, and submissions in the domestic and global realms. Instructors are experts from the medical device sector who conduct highly interactive classes with hands-on 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 specialties, 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)
- Computer Validation* (Pharmaceutics 5498)
- Process Validation* (Pharmaceutics 5474)
- Pharmaceutical Packaging: Technology and Regulation* (Pharmaceutics 5541)

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

2. To be considered for the Medical Device Certificate, candidates must have a bachelor's degree from an accredited institution of higher learning.
3. 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 an identical course at an accredited U.S. graduate school, the student may petition the QA/RA 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 MS.
5. Students must complete the certificate within four years. Students must apply for the certificate within one year of completing all required coursework for the program.
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.

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, the following must be submitted:

- An application form.
- Photocopies of all undergraduate and graduate transcripts from any schools previously attended, including Temple's QA/RA program. (Official transcripts are not required).

These items must be mailed to:

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

Certificates are not automatically conferred when students complete the required courses. Students must formally apply and must also forward a *notice of completion* either by mail or fax to the QA/RA Office (267.468.8565) indicating that they have finished the required courses. The notice of complete must include the student's name, TUID, courses completed, certificate being requested, and a daytime phone number.

The QA/RA 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 and notify the QA/RA Office that you have completed the certificates by these deadlines:

Jan 15th for certificates earned in the previous fall semester

May 15th for certificates earned in the previous spring semester

Aug 20th 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 QA/RA approximately 6 weeks to process certificates. If you have not received your certificate by Feb 28th, June 30th, or Sept 30th, please contact the QA/RA Office.

REQUIRED COURSES

Students must complete the following four 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.

ELECTIVE COURSES

Students must select one elective from the following:

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.

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.

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).

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.

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), Frazer (PA) and some corporate sites.

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 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, and 2) copies of all undergraduate and graduate transcripts from any schools previously attended. Photocopies are acceptable. Original transcripts are not required.

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 by the stipulated deadlines (Jan 15th, May 15th, or Aug 20th). 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 *Medical Device Certificate* within four years. If you need an extension, please email qara@temple.edu.

Can I complete two certificates in Temple's MS program?

Temple's QA/RA program now offers certificates in seven specialties. Students may complete only one certificate before pursuing the MS in QA/RA; however, you are

welcome to earn additional certificates after earning the MS in QA/RA. Thus, if you prefer to earn the *Drug Development Certificate* before completing the MS, you may subsequently earn the *Post-Master's Certificate in Medical Devices* (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:

QA/RA Graduate Program
Temple University School of Pharmacy
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