

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 five decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Regulatory Affairs and Quality Assurance. 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 RA and QA issues facing the pharmaceutical and related industries by integrating pharmaceutical law and regulation, pharmaceutical technology, and quality assurance practices. Faculty are FDA and industry veterans with years of expertise in their specialties, sharing their vast knowledge with students through intimate classroom discussions and hands-on workshops.

The RAQA master's program is based in Fort Washington, PA, and videoconferenced to corporate sites. Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals. Students may also complete the *Medical Device Certificate* entirely online.

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 RAQA. To earn the certificate, the following five courses must be successfully completed within a four year period with an overall B (3.0 average):

- **Food and Drug Law** (5592)
- **Regulation of Medical Devices: Submissions** (5502)
- **Regulation of Medical Devices: Compliance** (5496)
- **Global Medical Device Regulation** (5505)

Plus one of the following electives:

Quality Audit (5494)

Computer Validation (5498)

Process Validation (5474)

Design Controls for Medical Devices & Combination Products (5503)

Pharmaceutical Packaging: Technology and Regulation (5541)

Risk Management of Pharmaceutical and Medical Devices (5548)

Special Topics (any **Special Topics** course [5650] directly related to medical device issues)

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

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 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.

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.

6. Students interested in pursuing the RAQA 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 Regulatory Affairs and Quality Assurance. 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 (3.0) average and formally apply for the certificate. To receive the certificate and letter of completion, the following must be submitted:

- **Application Form**
- Photocopies of all undergraduate and graduate transcripts from any schools previously attended, including Temple's RAQA program. (Official transcripts are not required.)
- **Notice of Completion**

These items must be mailed to:

Temple University School of Pharmacy
RAQA Graduate Program
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 the **Notice of Completion** either by mail or fax to the RAQA Office (267.468.8565) indicating that they have finished the required courses.

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 and notify the RAQA Office that you have completed the certificates 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.

REQUIRED COURSES

Students must complete the following four courses:

5592. Food and Drug Law (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 pre-clinical, 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)

Prerequisites: Strong science background (such as a BS in pharmacy, chemistry, biology or engineering). Familiarity with chemistry, biology, and physics. Students should also have a basic understanding of pharmaceutical manufacturing processes.

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 (GLPs) or 5477 (GMPs), 5479 (Advanced GMPs - Defining "c") or 5536 (GCPs)]

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).

5503. Design Controls for Medical Devices and Combination Products (3 credits)

This course focuses on design control requirements and practices in the medical device and combination products industry. Class discussions will include design control requirements as they apply to medical devices and combination products. Current regulations and practices will be discussed and utilized to provide students with experience in executing design control activities for a range of products.

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, packaging processing methods are covered. A review of the applicable regulatory environment and the submission requirements for drug products are included. Submission needs are covered, including the impact of the Common Technical Document (CTD). The course includes a required trip to a manufacturing facility of an industry supplier.

5548. Risk Management of Pharmaceutical and Medical Devices (3 credits)

This survey course focuses on risk management requirements and practices in the pharmaceutical, medical device, and biotech industries. Current regulations and risk management tools will be discussed and utilized to provide students with experience in executing risk assessments.

5650. Special Topics (3 credits)

Either of the two **Special Topics** courses that relate directly to medical devices:

- Current Issues in the Pharmaceutical and Medical Device Industries
- Seminar in Current Topics Affecting Medical Devices

QUESTIONS AND ANSWERS

Where is the 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:

www.temple.edu/pharmacy_QARA/map.htm

Courses are also offered videoconferenced to corporate sites. Over 60 courses are also available in a real-time, online format.

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 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.

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 website: www.temple.edu/pharmacy_qara

How do I register for classes?

Please download the Registration and State Residency Forms from the RAQA website: 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 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 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 RAQA, please request a **Program Guide** 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 RAQA program. It is possible to have a requirement

waived; however, another *approved* Temple University RAQA 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**; 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**.

When you have finished your courses, you must submit the **Notice of Completion** to the RAQA Office by 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 **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 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 receiving 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 Medical Devices** (or another post-master's certificate) after earning the MS. Courses may only be counted towards one certificate. See: www.temple.edu/pharmacy_QARA/certificates.htm

For additional information:

**Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program**

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Fort Washington, PA 19034

Voice: 267.468.8560

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E-mail: QARA@temple.edu

www.temple.edu/pharmacy_QARA