

POST-MASTER'S CERTIFICATE in MEDICAL DEVICES

An Overview of Global and Domestic Medical Device Regulations

BACKGROUND

Temple University's School of Pharmacy continues to be the leader in providing world renowned graduate-level courses in Regulatory Affairs and Quality Assurance. As the program continues to pioneer new curriculum, it recognizes that many graduates with the MS in RAQA want to continue taking courses to keep current with industry issues and meet regulatory requirements for training. The *Post-Master's Certificate in Medical Devices* allows RAQA graduates to pursue additional coursework and receive formal recognition for their work. The certificate is also open to professionals with other master's or doctoral degrees.

The curriculum 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 and QA 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 Regulatory Affairs (RA) and Quality Assurance (QA) disciplines and continues to offer the most comprehensive curriculum of its kind.

Temple's 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 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.

Candidates must formally apply for the *Post-Master's Certificate in Medical Devices* before registering for any courses. To receive the certificate, candidates must complete the required courses and application procedures. Students who completed master's degrees or higher from accredited US institutions of higher learning with extensive pharmaceutical industry experience may also petition the School to pursue the *Post-Master's Certificate in Medical Devices*, but will be required to complete five courses.

Temple's RAQA graduate program is based in Fort Washington, PA. Courses can be videoconferenced to corporate sites. Classes are conveniently scheduled on evenings and weekends for working professionals. Over 60 courses are also offered online.

This certificate may be pursued entirely online.

APPLICATION PROCESS

Temple University Students:

Once you receive your MS from Temple, the University closes your academic file. If you wish to pursue the *Post Master's Certificate in Medical Devices*, you must formally apply, so we can reopen your file and register you. The application is available on the Certificate link of the RAQA homepage.

You will be required to take four courses relating to Medical Devices to complete the Post Master's Certificate in this subject.

Please mail the application to:

Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034

Students with Advanced Science Degrees from Other Schools:

To apply for the *Post-Master's Certificate in Medical Devices*, you must meet the following criteria:

- 1) You must have received an advanced degree (master's level or higher) from an accredited institution of higher learning and must have worked in the pharmaceutical industry for a minimum of three years.
- 2) Please submit the Application Form and write a letter to the Assistant Dean (Temple University, RAQA Graduate Program, 425 Commerce Drive, Suite 175, Fort Washington, PA 19034), indicating which courses you wish to pursue and explaining your experience in the pharmaceutical industry. Include a copy of your resume and copies of transcripts from all undergraduate and graduate programs you have attended. Formal permission to pursue the *Post-Master's*

Certificate in Medical Devices must be received from the Assistant Dean before commencing any courses in the program.

- 3) Students with advanced degrees from other schools will be required to take five Temple University RAQA courses to receive the *Post-Master's Certificate in Medical Devices*. If the candidate subsequently decides to apply for the MS in RAQA within five years, the credits earned in the *Post-Master's Certificate in Medical Devices* will count towards the master's degree, provided a grade of B or higher was earned in each course and the student is accepted into the MS program.

TO RECEIVE THE CERTIFICATE

After you have finished the four (or five) courses, you must submit the **Notice of Completion** (available on the RAQA homepage) to the RAQA Office by mail, fax (267.468.8565), or email (qarareg@temple.edu).

The RAQA Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must notify the RAQA Office **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 Advanced Certificate.

Courses Accepted for the *Post-Master's Certificate in Medical Devices*:

To earn the certificate, four (for Temple U RAQA graduates) or five courses (for students with other advanced degrees) 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: Compliance** (5496)*
- **Regulation of Medical Devices: Submissions** (5502)*
- **Global Medical Device Regulation** (5505)*
- **Process Validation** (5474)
- **Computer Validation** (5498)
- **Quality Audit** (5494)
- **Design Controls for Medical Devices and Combination Products** (5503)
- **Advanced Audit Workshop of Quality Systems** (5511)
- **Pharmaceutical Packaging: Technology and Regulation** (5541)
- **Risk Management of Pharmaceutical and Medical Devices** (5548)
- Either of these **Special Topics** (5650) courses that focus on medical devices:
 - *Current Issues in the Pharmaceutical and Medical Device Industries*
 - *Seminar in Current Topics Affecting Medical Devices*

*Students must take these courses, if they have not already done so.

QUESTIONS AND ANSWERS

Where is the RAQA Program Offered?

The 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

Over 60 courses are also offered online.

When can I start the certificate?

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?

Students should have completed **Food and Drug Law** (5592) (or an equivalent course) before pursuing any other course in this certificate. Once that prerequisite is met, students may take the other courses in any sequence, unless there are stated prerequisites.

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 refer to the RAQA homepage for the most current schedule of classes.

How do I register for classes?

Please make sure you have been formally admitted into the *Post-Master's Certificate in Medical Devices* before registering.

- If you received your MS from Temple, download the registration form from the RAQA homepage: http://www.temple.edu/pharmacy_QARA/forms.htm
You do not need to submit a state residency form, unless you have moved from one state to another.
- If you have not registered for Temple University RAQA courses before, 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 e-mail registrations do not guarantee your spot in a class, since sections do fill quickly. We will contact you if there are problems with your registration. Otherwise you will receive an email confirmation once you are registered and an electronic tuition bill through your Temple email account.

Do I need to take the GREs to complete the *Post Master's Certificate in Medical Devices*?

No. GRE or other advanced test scores are not required for the certificate or the MS.

Can I transfer any credits from another graduate institution towards the *Post-Master's Certificate in Medical Devices*?

Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University's RAQA program. If you have taken identical or very similar courses at another institution, you may request to take an alternate course in its place.

Will the certificate automatically be awarded when I complete the required courses?

No. You must notify the RAQA Office that you have finished the certificate by submitting the Notice of Completion by the stated deadlines each semester. The form is available on the RAQA website, under Certificates.

How much time do I have to complete the *Post-Master's Certificate in Medical Devices*?

You should complete the *Post-Master's Certificate in Medical Devices* within four years. When you have finished your courses, you must submit the **Notice of Completion** to the RAQA Office.

Will new electives be added to the certificate programs?

Yes, the RAQA program continues to expand its curriculum. For a listing of new courses, please consult the RAQA website.

For additional information:

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