

 <p>School of Pharmacy TEMPLE UNIVERSITY</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>
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POST-MASTER'S CERTIFICATE in CLINICAL TRIAL MANAGEMENT

*Designed for Pharmaceutical and Healthcare Professionals who actively
Contribute to the Clinical Trial Process*

BACKGROUND

Temple University's School of Pharmacy continues to be the leader in providing world renowned graduate-level courses in Quality Assurance and Regulatory Affairs. As the program continues to pioneer new curriculum, it recognizes that many graduates with the MS in QA/RA want to continue taking courses to keep current with industry issues and meet regulatory requirements for training. The *Post-Master's Certificate in Clinical Trial Management* allows QA/RA 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 is specifically designed for pharmaceutical and healthcare professionals who actively contribute to the clinical trial process, including physicians, clinical research monitors, investigators, and coordinators, or members of Investigational Review Boards (IRBs). It provides the tools and information needed to understand the basis for new drug discovery, the design and implementation of the clinical protocol, its conduct and effective monitoring strategies, and the auditing of data to ensure the integrity of the trial. Specific courses emphasize protocol development, the bioethics of clinical research and the protection of the human research subject, the informed consent form and process, clinical operations, and the role and responsibilities of the key personnel – the IRB, sponsor, monitor, CRO, and the clinical investigator.

The *Post-Master's Certificate in Clinical Trial Management* provides the tools and information needed to understand how clinical trials must be designed and overseen in the pharmaceutical industry, including writing protocols and consent forms, delving into the requirements of the Good Clinical Practices, and managing budgets and data.

For over 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 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 Clinical Trial Management* 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 other accredited U.S. institutions of higher learning with extensive pharmaceutical industry experience may also petition the School to pursue the *Post-Master's Certificate in Clinical Trial Management*, but will be required to complete five courses.

Temple's QA/RA graduate program is based in Fort Washington, PA. Courses are conveniently scheduled on evenings and weekends for working professionals and can be videoconferenced to corporate sites. Fifty courses are offered online in real time.

This Certificate may be pursued entirely online. To receive the certificate, candidates must complete the required courses and application procedures.

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 Clinical Trial Management*, you must formally apply, so we can reopen your file to register you. The application is available at: www.temple.edu/pharmacy_qara/pdf/PostMS.CTM.App..pdf.

You will be required to take four courses in clinical trials to receive the *Post-Master's Certificate in Clinical Trial Management*.

Please mail the application to:

Temple University School of Pharmacy
QA/RA 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 Clinical Trial Management*, 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 write a letter to the Assistant Dean (Temple University QA/RA 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 the **Application Form** for *Post-Master's Certificate in Clinical*

Trial Management, 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 Clinical Trial Management* must be received from the Assistant Dean before commencing any courses in the program.

- 3) Students with advanced degrees from other schools are required to take five Temple University QA/RA courses to receive the *Post-Master's Certificate in Clinical Trial Management*. If the candidate subsequently decides to apply for the M.S. in Quality Assurance/Regulatory Affairs within five years, the credits earned in the *Post-Master's Certificate in Clinical Trial Management* will count towards the master's degree, provided a grade of B or higher is earned in each course and the student is accepted into the M.S. program.

TO RECEIVE THE CERTIFICATE

After you have finished the four (or five) courses, you must notify the QA/RA Office by filling out the **Notice of Completion** (available on the QA/RA homepage) and sending it by fax (267.468.8565) or email (qarareg@temple.edu) to the QA/RA Office.

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 notify the QA/RA Office **at least one month in advance**. Otherwise you must 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 *Certificate in Clinical Trial Management*:

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

- **Drug Development** (Pharmaceutics 5459)
- **Good Clinical Practices** (Pharmaceutics 5536)
- **Clinical Trial Management** (Pharmaceutics 5537) **or Global Clinical Drug Development** (Pharmaceutics 5539).
- **Bioethics for Pharmaceutical Professionals** (Pharmaceutics 5612)
- **Statistics for Clinical Trials** (Pharmaceutics 5497) **or Project Management for Clinical Trials** (Pharmaceutics 5547) **or Clinical Data Management** (Pharmaceutics 5618) **or Clinical Drug Safety and Pharmacovigilance** (Pharmaceutics 5538) **or Risk Management and Safety Signaling in Healthcare Products** (Pharmaceutics 5578).

It is suggested that students take these courses in the order listed above, though this is not mandatory.

If applicants have already completed the required courses listed above, they may select from the following alternate courses:

- **Fundamental of Pharmacology and Pharmacokinetics** (Pharmaceutics 5401)*
- **Quality Audit** (Pharmaceutics 5494)*

- **Statistics for Clinical Trials** (Pharmaceutics 5497)
- **Clinical Drug Safety and Pharmacovigilance** (Pharmaceutics 5538)*
- **Global Clinical Drug Development** (Pharmaceutics 5539)
- **Project Management for Clinical Trials** (Pharmaceutics 5547)
- **Post Marketing Safety Surveillance** (Pharmaceutics 5571)*
- **Pharmacoepidemiology** (Pharmaceutics 5573)*
- **Risk Management and Safety Signaling in Healthcare Products** (Pharmaceutics 5578)*
- **Regulatory and Legal Basis of Pharmacovigilance** (Pharmaceutics 5579)*
- **Clinical Aspects of Pharmaceutical Medicine I** (Pharmaceutics 5599)*
- **Clinical Aspects of Pharmaceutical Medicine II** (Pharmaceutics 5602)*
- **Bioethics for Pharmaceutical Professionals** (Pharmaceutics 5612)
- **Clinical Data Management** (Pharmaceutics 5618)

* These courses count towards the Post-Master's Clinical Trial Management Certificate only if the student already has the M.S. in QA/RA.

QUESTIONS AND ANSWERS

Where is the QA/RA Program Offered?

Our program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions: www.temple.edu/pharmacy_QARA/map.htm

Courses can be videoconferenced to corporate sites. Fifty courses are also available online in a real time format. It is possible to pursue this program entirely online.

When can I start the certificate?

Courses in the QA/RA 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 starting this certificate with **Drug Development** (Pharmaceutics 5459), if you have not already completed a similar course elsewhere. **Good Clinical Practices** (Pharmaceutics 5536) is a prerequisite for **Clinical Trial Management** (Pharmaceutics 5537). Unless the courses have prerequisites, you may take the remaining courses in any sequence. The QA/RA program offers over 70 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 QA/RA Office if they wish to see a course scheduled in a particular semester.

How do I obtain a current class schedule?

See the QA/RA homepage: www.temple.edu/pharmacy_QARA/schedule.htm

How do I register for classes?

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

- If you received your MS from Temple, download the registration form from the QA/RA homepage: **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 QA/RA courses before, download the Registration and State Residency forms from the QA/RA homepage: **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 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 Clinical Trial Management*?

No. GRE or other advanced test scores are not required for the certificate or the MS in QA/RA.

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

Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University's QA/RA 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 QA/RA Office that you have finished the certificate by submitting the **Notice of Completion** by the stated deadlines. The form is available on the QA/RA website, under **Certificates**.

How much time do I have to complete the *Post-Master's Certificate in Clinical Trial Management*?

You should complete the *Post-Master's Certificate in Clinical Trial Management* within four years. When you have finished your courses, you must submit the **Notice of Completion** to the QA/RA Office.

Will new electives be added to the certificate programs?

Yes, the QA/RA graduate program continues to expand its curriculum. For a listing of new courses, please consult the QA/RA website.

**For additional information:
QA/RA Graduate Program
Temple University School of Pharmacy
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