

## **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 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 Clinical Trial Management* 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 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 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 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.

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 RAQA 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. Over sixty 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 on the Certificates link for the RAQA website.

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  
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 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 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 the **Application Form** for the *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 RAQA courses to receive the *Post-Master's Certificate in Clinical Trial Management*. If the candidate subsequently decides to apply for the MS in Regulatory Affairs and Quality Assurance 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 (3.0) or higher is 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 notify the RAQA Office by filling out the **Notice of Completion** (available on the RAQA homepage) and sending it by fax (267.468.8565) or email ([garareg@temple.edu](mailto:garareg@temple.edu)) to the RAQA Office.

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 must wait until the next time they are processed. The Certificate must be completed within four years. Transfer credits are not accepted towards the Post Master's Certificate.

### ***Courses Accepted for the Post Master's 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** (5459)
- **Good Clinical Practices** (5536)
- **Clinical Trial Management** (5537) or **Global Clinical Drug Development** (5539).
- **Bioethics for Pharmaceutical Professionals** (5612)
- **Statistics for Clinical Trials** (5497) or **Clinical Data Management** (5618) or **Project Management for Clinical Trials** (5547) or **Clinical Drug Safety and Pharmacovigilance** (5538) or **Project Management for Clinical Trials** (5547) or **Risk Management and Safety Signaling in Healthcare Products** (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:

- **Fundamentals of Pharmacology and Pharmacokinetics** (5401)\*
- **Quality Audit** (5494)\*
- **Statistics for Clinical Trials** (5497)
- **Clinical Drug Safety and Pharmacovigilance** (5538)\*
- **Global Clinical Drug Development** (5539)

- **Project Management for Clinical Trials** (5547)
- **Post Marketing Safety Surveillance** (5571)\*
- **Pharmacoepidemiology** (5573)\*
- **Risk Management and Safety Signaling in Healthcare Products** (5578)\*
- **Regulatory and Legal Basis of Pharmacovigilance** (5579)\*
- **Clinical Aspects of Pharmaceutical Medicine I** (5599)\*
- **Bioethics for Pharmaceutical Professionals** (5612)
- **Clinical Data Management** (5618)

*\* These courses count towards the Post-Master's Clinical Trial Management Certificate only if the student already has the MS in RAQA.*

*\*\*Students may only receive credit for Clinical Drug Safety and Pharmacovigilance (5538) or Post Marketing Safety Surveillance (5571) for either the Clinical Trial Management Certificate or the MS in RAQA. They may not receive credit for both.*

## QUESTIONS AND ANSWERS

### **Where is the RAQA 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](http://www.temple.edu/pharmacy_QARA/map.htm)

Courses can be videoconferenced to corporate sites. Over sixty 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 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 starting this certificate with **Drug Development** (5459), if you have not already completed a similar course elsewhere. **Good Clinical Practices** (5536) is a prerequisite for **Clinical Trial Management** (5537). Unless the courses have prerequisites, you may take the remaining 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?**

See the Schedule link of the RAQA homepage: [www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA)

### **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 RAQA homepage: [www.temple.edu/pharmacy\\_QARA/forms.htm](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 QA/RA homepage: [www.temple.edu/pharmacy\\_QARA/forms.htm](http://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 RAQA.

**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 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. The form is available on the RAQA 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 RAQA Office.

**Will new electives be added to the certificate programs?**

Yes, the RAQA graduate 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](mailto:QARA@temple.edu)**

**[www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA)**