School of Pharmacy
TEMPLE UNIVERSITY
Quality Assurance/Regulatory Affairs
Graduate Program

Temple University - School of Pharmacy
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CERTIFICATE IN CLINICAL TRIAL MANAGEMENT

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

BACKGROUND

The ***Certificate in Clinical Trial Management*** 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). This certificate 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, 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 ***Certificate in Clinical Trial Management*** enables students to sharpen their knowledge of clinical trials without committing to the entire master's degree. The certificate provides the tools and information 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 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 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.

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.

The ***Certificate in Clinical Trial Management Certificate*** may be pursued entirely online. To receive the Certificate, candidates must complete the required courses and application procedures.

ACADEMIC REQUIREMENTS

1. The ***Certificate in Clinical Trial Management*** 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 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 for Research Practitioners** (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 Risk Management** (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.

2. To be considered for the ***Certificate in Clinical Trial Management***, 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. Students who have completed similar courses at other institutions may request that a course be waived and take another elective from Temple University's ***Certificate in Clinical Trial Management*** in its place. The request to waive a Temple course must be submitted and approved by the Assistant Dean of QA/RA before starting the program.

4. Candidates must formally apply and follow the application procedures stated below (**Application Form**, photocopies of transcripts, and **Notice of Completion**).

5. Only one certificate may be completed before students receive the MS.

6. Students must complete the ***Certificate in Clinical Trial Management*** within four years. Students must apply for the certificate within one year of completing all required coursework for the program.

7. Students interested in pursuing the QA/RA MS program may apply all credits earned from the ***Certificate in Clinical Trial Management*** 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 ***Certificate in Clinical Trial Management*** is part of Temple University's graduate program in Quality Assurance and Regulatory Affairs. It does not require GREs. To earn the ***Certificate in Clinical Trial Management***, 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, students must submit:

- **Application Form**
- photocopies of all undergraduate and graduate transcripts, including a Temple transcript for QA/RA courses (copies are acceptable; official transcripts are not required).
- **Notice of Completion**

These items must be mailed to:

Temple University School of Pharmacy
QA/RA 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 a **Notice of Completion** (available on the QA/RA website) either by mail or fax to the QA/RA Office (267.468.8565) indicating that they have finished the required courses.

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 Form**, transcripts, and **Notice of Completion** 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 must wait until the next processing period. It takes the QA/RA 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 QA/RA Office.

DESCRIPTION OF REQUIRED COURSES

5459. Drug Development (3 credits)
This course studies the drug development process from discovery through FDA marketing approval. It reviews the process of drug development and the interrelationships linking the various disciplines, introducing students to the regulations governing the process, including interactions with FDA, ICH, and other regulatory agencies.

5536. Good Clinical Practices (3 credits)
This course examines the federal regulatory requirements and processes necessary to conduct valid drug trials on human volunteers. Emphasis is placed on managing the

clinical drug study and auditing its processes and generated data. The course also addresses ethical issues and volunteer informed consent.

5612. Bioethics for Pharmaceutical Professionals (3 credits)
This course focuses on bioethical issues arising in the regulation and conduct of research. It instills a basic understanding of bioethics and the theories and principles underlying its practices and application to research. It also discusses how bioethical theories and principles provide the foundation for many research regulations. Starting with a brief history of research ethics and regulation, it explores past and present ethical research controversies.

5537. Clinical Trial Management (3 credits)
Prerequisite: Good Clinical Practices (Pharmaceutics 5536) or permission of the instructor.
This course is designed to help the clinical research department member and those familiar with the industry working in related fields to become more effective members of the clinical research team, whether at a company or an investigator's office. This course covers the day-to-day operations of a clinical trial, from site and investigator selection through monitoring and data retrieval. It covers key topics, such as budgeting, protocol preparation, site and investigator selection, monitoring, document and file creation and maintenance, and the participation of key members of the principal investigator's team.

Or

5539. Global Clinical Drug Development (3 credits)
Prerequisites: two of the following: Drug Development (Pharmaceutics 5459) ***or*** *Good Clinical Practices (Pharmaceutics 5536)* ***or*** *Food and Drug Law I (Pharmaceutics 5592)* ***or*** *Global Regulatory Affairs (Pharmaceutics 5591).*
This course focuses on the specific regulatory requirements of clinical development in the European Union, Eastern Europe, Latin America, Canada, India, China and Japan. It will review the efforts of the International Conference on Harmonization (ICH) to unify Good Clinical Practices (GCPs) in these global areas, exploring the differences between cultures, races, and societies, and the impact of socialized medicine. Upon successful completion of this course, students will gain an overview of multinational clinical drug development; gain a basic understanding of cultural differences towards GCPs in various regions of the world; understand key regulatory bodies and concepts governing clinical development in various global markets; and become familiar with the ICH and its legal requirements for global clinical development.
Note: this course may be substituted for Pharmaceutics 5537.

5497. Statistics for Clinical Trials (3 credits)
No prerequisites. This course assumes no previous experience with statistics, though those with statistical backgrounds are welcome.
Assuming no previous courses in statistics, this introductory course reviews topics of interest in statistical evaluation of clinical trials. Students will learn what statistical methods should be used based on the available date. Topics include probability, descriptive statics, variability, sampling, factorial and repeated measures, sequential designs, inferential statistics, confidence intervals, analysis of variances, non-parametric

analysis (and so forth).

Or

5547. Project Management for Clinical Trials (3 credits)

Prerequisite: Drug Development (Pharmaceutics 5459) or Good Clinical Practices (Pharmaceutics 5536). Clinical Trial Management (Pharmaceutics 5537) is also suggested.

This course focuses on the Project Management of clinical trials by looking at ways to lead, manage and operate, starting with the development of a clinical development plan through the completion of supporting clinical studies. Designed to familiarize the clinical research professional and those in related fields with project management and predictable planning practices, the course helps students learn to be effective members of a clinical research team. The material covered will be a mix of basic project management methodology, drug development best practices, and the "soft skills" needed to successfully lead and manage a clinical trial team. Much of the time will be allocated for hands-on application of the topics. Material covers a review of clinical development planning and the design of an appropriate clinical study. The course also discusses the efficient initiation, planning, execution, monitoring/controlling, and closing of a study. Working on teams throughout the course, students develop a Clinical Plan, both in and outside of class that will be presented at the end of the semester.

Or

5618. Clinical Data Management (3 credits)

Prerequisites: Drug Development (Pharmaceutics 5459) and Good Clinical Practices (Pharmaceutics 5536).

The data from clinical research studies is the crux of a regulatory submission for a new drug or biologic – without it, there would be nothing upon which to base the therapeutic claim. The success of a submission depends on quality data management practices and strict adherence to regulatory requirements. This course is designed to teach the student how to go from collecting data for the first protocol to ultimate submission to a regulatory agency from a data collection, management, and reporting perspective.

Or

5538. Clinical Drug Safety and Risk Management (3 credits)

Prerequisite: Drug Development (Pharmaceutics 5459).

This course provides students with an in-depth understanding of what pre-marketing clinical safety and risk management (CSRM) mean in the context of both American (FDA) and international (ICH-E2C) regulatory requirements. It covers the historical overview of IND and international safety requirements, the processes and systems in place to support compliance, strategic documentation for applications, and the role of risk management and epidemiological methods to identify signals, quantify, assess, and communicate adverse drug reactions (ADR). Clinical trial policy issues, investigator, patient, IRB, DSMB, privacy, informed consent, and other related matters are discussed.

Or

5578. Risk Management and Safety Signaling of Healthcare Products (3 credits)

This course provides a basic understanding of the principles involved in developing, negotiating, and implementing Benefit-Risk Management Plans. While the focus will be on the EU and US, the general principles are applicable across multiple jurisdictions. Starting with the background needed to develop effective benefit-risk management

programs, the course will provide an overview of the many factors contributing to the development of such programs. The sources and methods of interpretation of data as part of a benefit-risk management strategy will be included. Importantly, students will acquire practice in development sections of benefit-risk management programs, enabling them to acquire the skills necessary in evaluating the utility and reliability of such programs.

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:
www.temple.edu/pharmacy_QARA/map.htm

Courses can be videoconferenced to corporate sites. Fifty courses are available online in real time. This Certificate may be pursued entirely online.

When can I start the certificate?

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 **Drug Development** (Pharmaceutics 5459), since this course provides an overview of the pharmaceutical industry and serves as the foundation of knowledge for the program. You should then take **Good Clinical Practices** (Pharmaceutics 5536), so you have the fundamental knowledge to proceed with other courses in the program. Students must have completed **Good Clinical Practices** (Pharmaceutics 5536) before taking **Clinical Trial Management** (Pharmaceutics 5537).

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?

Please check the QA/RA homepage: **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: **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. The QA/RA 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 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 or other advanced test scores are not required for this certificate or for the MS in QA/RA.

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 *Certificate in Clinical Trial Management* 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. For additional information on the Master's of Science in QA/RA, please request a **Program Guide** and an **Application for Graduate Study** by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *Certificate in Clinical Trial Management*?
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 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 undergraduate and graduate transcripts from any schools previously attended; and 3) the **Notice of Completion**.

When you have finished your courses, you must submit a **Notice of Completion** by mail or fax (267.468.8565) indicating that you are eligible to receive the certificate. These materials must be submitted by the stipulated deadline (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 ***Certificate in Clinical Trial Management*** within four years. If you need an extension, please email **qara@temple.edu**.

Can I complete two certificates in Temple's QA/RA 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 Clinical Trial Management*** (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:

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