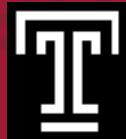


Key Features

- On-Demand courses allow you to earn 1.5 credits in a relatively short period of time and around your busy schedule. You can watch recordings 24/7 and any time of day - while traveling for business, over lunch, late evening or before dawn.

- KENX conferences feature timely and fresh perspectives on critical industry concerns. You'll hear a variety of new perspectives from many different industry and regulatory experts, keeping you up-to-date on the latest challenges and ideas facing industry. You can immediately apply your knowledge to your work and also gain credits towards a certificate or master's degree in RAQA.

- You are welcome to complete two On-Demand courses as part of your RAQA MS degree or specific Certificates. On-Demand courses provide you with greater flexibility in earning credits and finishing your degree program.



Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175 • Fort Washington, PA 19034
Phone: 267.468.8560 • E-Mail: QARA@temple.edu

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KENX and Temple University RAQA On Demand Courses



RAQA On-Demand courses are based on recent KENX conferences, which feature well known FDA and industry experts giving innovative and insightful talks on key quality and regulatory topics.

Course RAQA 5000, section 007 (1.5 credit hours)

We welcome your interest in the new On-Demand courses based on KENX Conferences. These new courses enable you to earn 1.5 graduate credits through the Regulatory Affairs and Quality Assurance (RAQA) graduate program, scheduling your studies around your busy schedule.

What's an On-Demand Course?

RAQA On-Demand courses are based on recent KENX conferences, which feature well known FDA and industry experts giving innovative and insightful talks on key quality and regulatory topics. KENX records every conference talk and makes them available on an online platform, which is accessible 24/7 for a set period of time.

When you sign up for an On-Demand course, you will automatically have access to every lecture presented at a specific KENX conference and are welcome to view them at your convenience. In order to earn 1.5 credits, you must view all 18 hours of the lectures marked Temple Track. The online system automatically records each time you watch Temple Track lectures in their entirety, keeping track of your attendance. Once you complete all 18 hours of Temple Track lectures, you must schedule and complete an online, proctored exam within the next 2 weeks. The exam is open notes, which means you can use the PowerPoint slides provided at the conference, and takes between 2 to 3 hours.

Timing of On-Demand Courses Work

You have 6 weeks to watch all of the Temple Track lectures and another 2 weeks to take the proctored final exam. During the first 6 weeks, you must watch all 18 hours of Temple Track materials, or the exam will not be administered. Once you've watched all recordings, you have another 2 weeks to schedule and complete the online, proctored exam. Grading is usually done and provided within another 2 weeks. You may sign up for an On-Demand course any time of year. Due to University calendars, the RAQA Office will advise you which semester your registration and grade will be recorded.

Tuition and Charges

- You are responsible for paying the KENX conference fee directly to KENX.
- You must pay an additional \$995 to Temple University for the graduate credits you will earn in the On-Demand course.
- You are also responsible for paying a \$15.00 proctoring fee, which is paid directly to RPNOW (an online proctoring service).

Drop/Add Policies

Adding and Dropping the Course

You may add an On-Demand course any time of year but will be registered in a specific semester (Spring, Summer, or Fall).

Once you officially registered, you have a maximum of 3 days to drop the credit portion of the course and receive a complete refund for the \$995 fee, but no refunds are given for the KENX conference fee.

To drop the course, you must submit a signed RAQA drop form (available on the RAQA website under Forms) within 3 days of your initial course registration.

Once those three days have passed, you may withdraw from the course, but you will not receive a tuition refund.

Lecture Topics and Lecturers

KENX will provide the complete list of Temple Track lecturers and topics. Please refer to the KENX website for detailed information. Course Goals and Learning Outcomes are also described on the KENX website.

Topics include:

- Computer & Software Validation and Data Integrity
- Laboratory Issues, Audit Preparation, Stability Studies, QC Lab Data Integrity, Analytical Procedures, Test Method Validation
- Cleaning Validation, including Cleanroom Operations and Disinfection, Critical Processes, Environmental Monitoring & Qualifications
- GMP and Validation Issues, including Documentation Requirements, Validation Statistics, Validation Master Plans (VMPs), Risk Analysis, Sampling and Statistics for PPQ

Refer to the RAQA website for details.

Educational Methods and Active Learning Strategies Used

Most talks include lectures followed by Q&A. Some lecturers use workshops or group sessions, encouraging participants to engage in discussion and debate.

Required text (s) and equipment:

Power Points will be provided electronically by KENX. You are responsible for saving these documents, which you will need for studying and taking the final exam. Temple RAQA will also provide copies of the slides on a course Canvas page.

Graded Assignment

Attendance and class participation (5%)

Attendance is automatically taken each time you watch a Temple Track lecture. To earn 5%, students must watch required lectures within the 6 week deadline.

The Final Exam will consist of 95% of the grade.

The exam will be administered via an online testing and proctoring platform (PSI Remote Proctor Now). You will be responsible for paying a \$15.00 proctoring fee directly to PSI at the start of the exam. Temple's RAQA graduate program will work with you in identifying a convenient time to complete the final exam.

Your work during the exam will be monitored and recorded by PSI. You will have 2-3 hours to complete the exam. The exam must be taken within two weeks of finishing the recordings.

Final grades will be available within two weeks of taking the exam. Students may access their Temple transcript through the University's Banner system.

Recordings

RAQA courses and course materials and KENX Conference materials may not be copied, taped, recorded, or duplicated in any format without prior authorization of the RAQA Graduate Program of the School of Pharmacy and KENX. Conference lectures may not be recorded or downloaded onto electronic devices. Posting lecture materials on the Internet or sharing them with other colleagues is regarded as a violation of the School's Code of Conduct and will be brought before the Graduate Committee and a Disciplinary Committee and could result in dismissal from the program.