

TUESDAY COURSES
RAQA Graduate Programs – Fall 2024

Note: Due to visa requirements, international students must attend courses on-campus, which includes taking online courses in the Ft Washington computer lab.

This is a truncated listing of Tuesday courses offered in the RAQA Graduate program during the Fall 2024 semester. Refer to the main schedule for complete details about assigned faculty, required texts, makeup dates, and previous course numbers.

Don't forget, you can earn credits at KENX conferences this summer:

5000. KENX Conferences 1.5 credit hours each section \$15.00 Proctoring Fee per Conference

Did you know that you can earn 1.5 credits towards the MS in RAQA by attending specific KENX conferences in Chicago (IIL), Research Triangle Park (NC), or Washington, DC this fall? Each conference meets over 2.5 days. You attend the sessions marked “Temple Track,” then take a proctored open-book final exam within 6 weeks. For more information on conference topics, see: kenx.org/conferences KENX Topics this fall:

- **Sept 17-19, 2024: Medical Device Validation, Chicago, IL (in-person only)**, section 007, crn: 46338.
- **Oct 22-24, 2024: GMP U, RTP, NC (in-person only)**, section 008 crn: 54373
- **Dec 10-12, 2024, CSV and CSA, Washington, DC, (in-person only)**, section 009, crn: 54387

AFTERNOON ON-CAMPUS COURSE at Fort Washington

5650. Pharmaceutical Regulatory Leadership (101) crn: 56675 (ON-CAMPUS COURSE)

Suggested prerequisite: Drug Development (5459) OR Food and Drug Law (5592).

2:00 pm – 5:30 pm Tuesdays: Sept 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19. **In-class, proctored exam: Oct 15.**

Description: Leading in the pharmaceutical industry requires more than regulatory knowledge: it requires key skills to get the job done with various constituents, including coworkers, employees, and management. This course provides insights, rules, tools and requirements needed to lead in the highly regulated pharmaceutical industry. Students will study organizational principles and practices within the framework of the Code of Federal Regulations (specifically 21 CFR 210, 211, 312, 600 and 820). While these regulations provide what is required, they do not describe how to accomplish it. That task is the job of leadership. Using recommended texts, case studies, class lectures, discussions, and individual research, students will learn how to lead and manage in a regulated industry. Participants will gain the insights to support career goals with new understandings of the work and responsibilities that go along with the titles.

5494. Quality Audit (990) crn: 25897 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisite: a good practices course: GLPs (5476), GMPs (5477), Advanced GMPs (5479), or GCPs (5536).

7:00 pm - 10:00 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, 26, Dec 3. Meets 12 times plus final exam. **Proctored exam: Dec 3 (RPNOW)**

5497. Statistics for Clinical Trials (990) crn: 54366 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm - 9:00 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, 26. Meets 12 times plus final exam. **Proctored exam: Oct 22 (RPNOW)**

DAYTIME ONLINE COURSE with recordings

5498. Computerized Systems Validation (990) crn: 54367 (ONLINE) \$15.00 RPNOW Proctoring Fee

Noon - 1:00 pm Tuesdays and Thursdays (Eastern time), plus one hour recording each week, which students must watch before the next scheduled class:

Sept 10, 12 - watch recording before Sept 17, Sept 17, 19 - watch recording before Sept 24

Sept 24, 26 - watch recording before Oct , Oct 1, 3 (Rosh Hashanah) - watch recording before Oct 8

Oct 8, 10 – watch recording before Oct 15, Oct 15, 17 - watch recording before Oct 22

Oct 22, 24 - watch recording before Oct 29, Oct 29, 31 - watch recording before Nov 5
Nov 5, 7 - watch recording before Nov 12, Nov 12, 14 - watch recording before Nov 19
Nov 19 and 21 - watch recording before Dec 3, No class Nov 26 and 28 (Thanksgiving holiday)
Dec 3 and 5 (last live class) **Proctored exam: Oct 17 (RPNOW)**

5533. Requirements for Product Labeling/Advertising (990) crn: 51974 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisite: Food and Drug Law (5592).

6:00 pm – 9:00 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, 26, Dec 3. Meets 12 times plus final exam. **Proctored exam date: Dec 3 (RPNOW)**

5536. Good Clinical Practices (990) crn: 9358 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm - 9:00 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3. Meets 12 times plus final exam. No class Nov 26. **Proctored exam: Oct 22 (RPNOW)**

5545. Post Approval Changes (PAC) (990) crn: 56689 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisite: Drug Development (5459).

6:00 pm – 9:00 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3. Meets 12 times plus final exam. No class Nov 26. **Proctored exam: Oct 22 (RPNOW)**

5577. Global CMCs: Biopharmaceuticals (990) crn: 28578 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm - 9:00 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, 26. Meets 12 times plus final exam. **Proctored exam: Oct 15 (RPNOW)**

5592. Food and Drug Law (991) crn: 23754 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm - 9:00 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3. Meets 12 times plus final exam. No class Nov 26. **Proctored exam date: Oct 22 (RPNOW)**

PHARMACEUTICAL SCIENCE COURSE

8003. Preformulation - Small Molecules (990) crn: 54371 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisite: Strong science background required. RAQA students must submit their resume for permission to register.

5:30 pm - 8:30 pm Tuesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, 26. Meets 12 times plus final exam. **Proctored exam: Oct 22 (RPNOW)**