RAQA THURSDAY COURSES – SPRING 2025

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

5000. KENX Conferences 1.5 credit hours each section

Did you know that you can earn 1.5 credits towards the MS in RAQA by attending designated KENX conferences across the U.S.? 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 about conference topics, see: kenx.org/conferences. **Topics for Spring 2025 will be announced shortly.**

- **5459.** Drug Development (990) crn: 42713 (ONLINE) Proctorio Online Proctoring 6:00 pm 9:00 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27, Apr 3, 10. Meets 12 times plus final exam. Make-ups, if needed, Apr 17 (Passover) and 24. Proctored exam: Mar 6 (Proctorio)
- **5477.** Good Manufacturing Practices (990) crn: **3439** (ONLINE) Proctoring Online Proctoring 6:00 pm 9:30 pm Thursdays: Jan 23, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27, Apr 3, 10. Meets 10 times plus final exam. No class Jan 30. Make-ups, if needed, Apr 24 and May 1. **Proctored exam: Apr 21** (**Proctorio**)
- **5509.** Pediatric and Orphan Drug Regulations (990) crn: **55323 (ONLINE)** Proctorio Online Proctoring 6:00 pm 9:00 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27, Apr 3, 10. Meets 12 times plus final exam. Make-ups, if needed, Apr 17 (Passover) and 24. **Proctored exam: Mar 6 (Proctorio)**
- **5512.** Microbiological Concepts in Pharmaceutical Manufacturing (990) crn: 55321 (ONLINE) Proctorio *Prerequisite: strong science background.*6:00 pm 9:00 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27, Apr 3, 10. Meets 12 times plus final exam. Make-ups, if needed, Apr 17 and 24. **Proctored exam: May 13 (Proctorio)**
- **5572.** Vaccines: RA and QA Issues (990) crn: 45613 (ONLINE) Proctoring Online Proctoring Prerequisite: Drug Development (5459). Students are also expected to have a college-level background in general biology and chemistry and some knowledge of general microbiology and/or immunology.

 6:00 pm 9:00 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13 (recording), 20, 27, Apr 3, 10. Meets 12 times plus final exam. Make-ups, if needed, Apr 17 (Passover) and 24. **Proctored exam: Feb 27 (Proctorio)**
- 5578. Risk Management & Safety Signaling of Healthcare Products (990) crn: 53070 (ONLINE) Proctorio Prerequisite: either 5538 or 5571.

 7:00 pm 10:00 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27, Apr 3, 10, 17 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 24 and May 1. Proctored exam: Apr 17.
- **5612.** Bioethics for Pharmaceutical Professionals (990) crn: 28699 (ONLINE) Proctorio Online Proctoring 6:00 pm 9:00 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27, Apr 3, 10. Meets 12 times plus final exam. Make-ups, if needed, Apr 17 (Passover) and 24. Proctored exam: Mar 6 (Proctorio)

AFTERNOON On-CAMPUS COURSE at Fort Washington

5650. Pharmaceutical Regulatory Leadership (101) crn: 53077 (ON-CAMPUS COURSE)

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

2:00 pm - 5:30 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27. Meets 10 times plus final exam. Make-ups, if needed, Apr 3 and 10. **In-class, proctored exam: Feb 20.**

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.

8005. Pharmaceutical Biotechnology (990) crn: 51044 (ONLINE)

Strong science background required

6:00 pm – 9:00 pm Thursdays: Jan 23, 30, Feb 6, 13, 20, 27, Mar 6, 13, 20, 27, Apr 3, 10, 17. Meets 12 times plus final exam. Make-up, if needed, Apr 24 and May 1. **Proctored exams: Mar 6 and Apr 17 (using Zoom)**