

THURSDAY 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 Thursday courses offered in the RAQA Graduate program during the Fall 2024 semester. Refer to the main schedule for complete details about assigned faculty, makeup dates, required texts and previous course numbers.

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

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

5459. Drug Development (990) crn: 17910 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm - 9:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5. No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. **Proctored exam: Oct 24 (RPNOW)**

5474. Process Validation (990) crn: 54364 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisites: BS in Pharmacy, Chemistry, Biology or Engineering and strong science background, including familiarity with chemistry, biology, and physics. Students should also have a basic understanding of pharmaceutical manufacturing processes.

6:00 pm - 9:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5. No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. **Proctored exam: Oct 17 (RPNOW)**

5477. Good Manufacturing Practices (991) crn: 34730 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm - 9:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5. No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. **Proctored exam: Oct 24 (RPNOW)**

5495. IND/NDA Submissions (990) crn: 46250 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisite: Drug Development (5459) or Food and Drug Law (5592).

6:00 pm - 9:00 pm Thursdays: Sept 12, 19, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5, 12. Meets 12 times plus final exam. No class on Sept 26 and Nov 28 (Thanksgiving). Make-up date, if needed, Dec 19.

Proctored exam: Oct 24 (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 1, 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), Make-ups, if needed, Dec 10 and 12. **Proctored exam: Oct 17 (RPNOW)**

5504. Patient-Focused Regulatory Policy for Medical Products (990) crn: (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisites: Drug Development (5459) and Food and Drug Law (5592).

Suggested prerequisites: Regulation of Medical Devices Submissions (5502), IND/NDA Submissions (5495).

6:00 pm - 9:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5, 12.

Meets 12 times plus final exam. Makeup, if needed, Dec 19. No class Nov 28 (Thanksgiving). **Proctored exam: Dec 12 (RPNOW)**

This course provides an overview of patient-focused regulatory policy that impacts the global regulation of medicines and medical devices. It covers the legislative and regulatory history of patient-focused policy at U.S. FDA, such as Patient Preference Information and Patient Focused Drug Development. It also surveys patient-focused policy efforts in countries such as Canada, Australia, and the European Union, among others. Students will review literature related to patient engagement, patient preference, and patient experience to understand the subtle methodological and policy-specific differences between these concepts. Topics include evidence for the value of patient engagement in product development, examples of medical products cleared or approved using patient input, and expectations by regulators for the use of patient-generated data to support regulatory submissions. The value of including the patient voice in regulatory decision-making, the impact of patient-focused policy on regulatory decisions, and current policy issues, challenges, and opportunities will also be discussed.

5538. Clinical Drug Safety & Pharmacovigilance (990) crn: 56672 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisite: GCPs (5536 or P383) or appropriate industry experience in GCPs (include resume).

7:00 pm – 10:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5, 12 (final). No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. Makeup, if needed, Dec 19.

Proctored exam: Dec 12 (RPNOW)

5595. Food Law (990) crn: 54379 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm – 9:30 pm Thursdays: Sept 12, 19, 26, Oct 10, 17, 24, Nov 7, 14, 21, Dec 5, 12. Meets 10 times plus final exam. No class Oct 3 (Rosh Hashanah), Oct 31, or Nov 28 (Thanksgiving). **Proctored exam: Dec 12 (RPNOW)**

5612. Bioethics for Pharmaceutical Professionals (990) crn: 42739 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm - 9:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5. No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. **Proctored exam: Oct 24 (RPNOW)**

PHARMACEUTICAL SCIENCE COURSES – strong science background required

5492. Production of Sterile Products (990) crn: 56673 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisite: strong science background. Submit resume with registration.

6:00 pm - 9:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17, 24, 31, Nov 7, 14, 21, Dec 5, 12. No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. **Proctored exam: Dec 12 (RPNOW)**

PHARMACEUTICAL SCIENCE COURSE - strong science background required

8005. Pharmaceutical Biotechnology (990) crn: 54372 (ONLINE)

Strong science background required, including a minimum of 2 years of general chemistry, including one organic and one analytical chemistry course. RAQA students must submit their resume for permission to register.

6:00 pm – 9:00 pm Thursdays: Sept 12, 19, 26, Oct 3 (Rosh Hashanah), 10, 17 (proctored midterm), 24, 31, Nov 7, 14, 21, Dec 5, 12 (final). No class Nov 28 (Thanksgiving). Meets 12 times plus final exam. **Proctored exams: Oct 17 and Dec 12 (proctored through Zoom)**