

WEDNESDAY 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 Wednesday 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 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

5459. Drug Development (101) crn: 49409 (ON-CAMPUS COURSE)

2:00 pm – 5:30 pm Wednesdays: Sept 18, 25, Oct 2 (Rosh Hashanah), 9, 16, 23, 30, Nov 6, 13, 20. Meets 10 times plus final exam. **In-class, proctored exam: Oct 16.**

5459. Drug Development (991) crn: 7407 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm - 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 2 (Rosh Hashanah), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27. **Proctored exam: Oct 23 (RPNOW)**

5496. Regulation of Medical Devices Compliance (990) crn: 51969 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm – 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 2, 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27. **Proctored exam: Oct 23 (RPNOW)**

5515. Biologics/Biosimilars-Regulatory Overview (990) crn: 28574 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisites: Drug Development (5459). Science background required (students should include resume.)

6:00 pm - 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 2, 9, 16, 23, 30 (recording), Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27. **Proctored exam: Oct 23 (RPNOW)**

5534. Regulatory Aspects-Biomedical/Technical Communication (990) crn: 56688 \$15.00 RPNOW Proctoring Fee

Prerequisite: Drug Development (5459) or Food and Drug Law (5592) or permission of the instructor.

6:00 pm - 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 2 (Rosh Hashanah), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27. **Proctored exam: Oct 23 (RPNOW)**

5537. Clinical Trial Management (990) crn: 49401 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisite: GCPs (5536). Students with clinical experience may request permission to take the course.

6:00 pm - 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 2, 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27. **Proctored exam: Oct 23 (RPNOW)**

5546. Global Excipient Regulation (990) crn: 46254 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm – 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 9, 16, 23 (recording), 30, Nov 6, 13, 20, Dec 4, 11. Meets 12 times plus final exam. No class Oct 2 and Nov 27. **Proctored exam: Oct 30 (RPNOW)**

5579. Regulatory and Legal Basis of Pharmacovigilance (990) crn: 56674 (ONLINE) \$15.00 RPNOW Proctoring Fee

Prerequisite: Clinical Drug Safety and Pharmacovigilance (5538) or Post Marketing Safety Surveillance (5571) or permission of RAQA Office (forward resume).

6:00 pm - 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 2 (Rosh Hashanah), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4, 11. Meets 12 times plus final exam. No class Nov 27. **Proctored exam: Dec 11 (RPNOW)**

5591. Global Regulatory Affairs (990) crn: 23442 (ONLINE) \$15.00 RPNOW Proctoring Fee

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

6:00 pm – 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 2 (Rosh Hashanah), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27. **Proctored exam: Oct 16 (RPNOW)**

5592. Food and Drug Law (990) crn: 7202 (ONLINE) \$15.00 RPNOW Proctoring Fee

6:00 pm - 9:00 pm Wednesdays: Sept 11, 18, 25, Oct 2 (Rosh Hashanah), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27. **Proctored exam date: Oct 23 (RPNOW)**