

## RAQA Fall 2022 Schedule for Online Courses

### **5000. KENX Conferences (sections 007, 008, 009) 1.5 credit hours each section**

**KENX Conference course can be pursued either in-person or On-Demand. The On-Demand option gives you flexibility with completing approximately 18 hours' worth of conference lectures at your own pace over a 6-week period. To learn more, visit our KENX link on the RAQA website and also the KENX homepage.**

#### **Topics and Options this Fall include:**

- 1) Good Manufacturing: August 22 - 24  
5000, 007 (46338) – in-person, San Diego  
5000, 990 (49580) - Virtual
- 2) Validation & GMPs – to be announced  
5000, 008 (46651) – in-person  
5000, 991 (49582) - Virtual
- 3) Computer Systems Validation & Software Assurance, Dec 6 - 8  
5000, 009 (49408) – in person, Washington, DC  
5000, 992 (49581) - Virtual

### **5459. Drug Development (990) crn: 17910 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Tuesdays: Sept 13, 20, 27, Oct 4 (Yom Kippur), 11, 18, 25, Nov 1, 8, 15, 22, 29. Meets 12 times plus final exam. Make-ups, if needed, Dec 6 and 13.

#### **Proctored exam: Oct 25 (RPNOW)**

Faculty: J. Hayes

Required text: *Drugs: From Discovery to Approval*, Ng, 3<sup>rd</sup> edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272).

In addition, student will be required to choose **one** of the three texts and write a book review.

1.) *A Shot to Save the World: The Inside Story of the Life-or-Death Race for a COVID-19 Vaccine*, G. Zuckerman (ISBN-10: 059342039X0) **OR**

2.) *Empire of Pain: The Secret History of the Sackler Dynasty*, P Radden Keefe (ISBN-10: 0385545681) **OR**

3) *Bottle of Lies: The inside story of the Generic Drug Boom*, K. Eban; (ISBN-10:006233879X)

*Not open to students who have completed RAQA 459.*

### **5459. Drug Development (991) crn: 7407 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Wednesdays: Sept 14, 21, 28, Oct 5 (Yom Kippur), 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-ups, if needed, Dec 14 and 21.

#### **Proctored exam: Oct 26 (RPNOW)**

Faculty: J. Hayes

Required text: *Drugs: From Discovery to Approval*, Ng, 3<sup>rd</sup> edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272).

In addition, student will be required to choose **one** of the three texts and write a book review.

1.) *A Shot to Save the World: The Inside Story of the Life-or-Death Race for a COVID-19 Vaccine*, G. Zuckerman (ISBN-10: 059342039X0) **OR**

2.) *Empire of Pain: The Secret History of the Sackler Dynasty*, P Radden Keefe (ISBN-10: 0385545681) **OR**

3) *Bottle of Lies: The inside story of the Generic Drug Boom*, K. Eban; (ISBN-10:006233879X)

*Not open to students who have completed RAQA 459.*

### **5459. Drug Development (992) crn: 28608 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Thursdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8. Meets 12 times plus final exam. No class Nov 24 (Thanksgiving). Make-ups, if needed, Dec 15 and 20 (Tuesday).

**Proctored exam: Oct 27 (RPNow)**

Faculty: D. Walsh

Required text: *Drugs: From Discovery to Approval*, Ng, 3<sup>rd</sup> edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272).

*Not open to students who have completed RAQA 459.*

**5459. Drug Development (993) crn: 46247 (ONLINE)**

*This course will use PSI Services LLC's RPNow online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

8:30 am - 2:00 pm Saturdays (1/2 hour lunch): Sep 17, Oct 1, 15, 29, Nov 12, Dec 3, 10. Meets 7 times plus final exam. Make-up, if needed, Dec 17.

**Proctored exam: Oct 29 (RPNow)**

Faculty: P. Smith

Required text: *Drugs: From Discovery to Approval*, Ng, 3<sup>rd</sup> edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272).

*Not open to students who have completed RAQA 459.*

**5473. Generic Drug Regulation (ANDAs) (990) crn: 51988**

*This course will use PSI Services LLC's RPNow online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Drug Development (5459).*

6:00 pm - 9:00 pm Tuesdays: Sept 13, 20, 27, Oct 4 (Yom Kippur), 11, 18, 25, Nov 1, 8, 15, 29, Dec 6. Meets 12 times plus final exam. No class Nov 22. Make-ups, if needed, Dec 13 and 20.

**Proctored exam: Oct 25 (RPNow)**

Faculty: C. Ciliberto

No required text.

*Not open to students who have completed RAQA 483.*

**5477. Good Manufacturing Practices (990) crn: 9357 (ONLINE)**

*This course will use PSI Services LLC's RPNow online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:30 pm - 9:30 pm Mondays: Sept 12, 19, 26 (Rosh Hashanah), Oct 3, 10, 17, 24, 31, Nov 7, 14, 21, 28, Dec 5. Meets 12 times plus final exam. Make-ups, if needed, Dec 12 and 19.

**Proctored exam: Dec 5 (RPNow)**

Faculty: M. Noonan

No required text.

*Not open to students who have completed RAQA 487.*

**WEEKEND COURSE**

**5477. Good Manufacturing Practices (991) crn: 34740 (ONLINE)**

*This course is offered both online and on-campus at Fort Washington.*

*This course will use PSI Services LLC's RPNow online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

8:30 am - 5:00 pm Sundays (one hour lunch): Sept 11, Oct 9, 23, Nov 6, 20. Meets 5 times and final exam due by Wed Nov 30. Make-up, if needed, Dec 11 and 18.

**Proctored exam: Oct 30 (RPNow)**

Faculty: T. Ely

No required text.

*Not open to students who have completed RAQA 487.*

**5477. Good Manufacturing Practices (992) crn: 46249 (ONLINE)**

*This course will use PSI Services LLC's RPNow online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Thursdays: Sept 15, 22, 29, Oct 6, 13 (recording), 20, 27, Nov 3, 10, 17, 24 (Thanksgiving, recording), Dec 1. Meets 12 times plus final exam. No class on Oct 13 and Nov 24 but recording will be available. Make-ups, if needed, Dec 8 and 15.

**Proctored exam: Oct 27 (RPNOW)**

Faculty: K. Zimm

No required text.

*Not open to students who have completed RAQA 487.*

**5493. Sterilization Processes (990) crn: 49320 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: strong science background. Include resume with registration form.*

6:00 pm - 9:00 pm Wednesdays: Sept 14, 21, 28, Oct 5, 12, 19, 26, Nov 2, 9, 16, 30, Dec 7, 14. Class meets 12 times plus final exam. No class Nov 23. Make-ups, if needed, Dec 19 (Mon) and 21 (Wed).

**Proctored exam: Dec 14 (RPNOW)**

Faculty: D. Casaburi

Required text: *Validation of Pharmaceutical Processes*, 3<sup>rd</sup> edition, ISBN0:0-8493-7055-8.

*Not open to students who have completed RAQA 493.*

**5494. Quality Audit (990) crn: 25897 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

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

7:00 pm - 10:00 pm Thursdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8, 15. Meets 12 times plus final exam. No class Nov 24 (Thanksgiving). Make-ups, if needed, Dec 19 (Mon) and 20 (Tues).

**Proctored exams: Oct 27 and Dec 15 (RPNOW)**

Faculty: J. Werrmann

Required text: *The ASQ Certified Quality Auditor*, 5<sup>th</sup> edition, Lance B Coleman Sr. Available from ASQ Quality Audit Press: [www.asq.org/quality-press](http://www.asq.org/quality-press), ISBN 978-1-951058-09-8, copyright 2020. (Previous editions released as *The ASQ Audit Handbook*).

*Not open to students who have completed RAQA 494.*

**5494. Quality Audit (991) crn: 51968 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

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

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

Sept 13, 15 - watch recording before Sept 20

Sept 20, 22 - watch recording before Sept 27

Sept 27 (Rosh Hashanah), 29 - watch recording before Oct 4

Oct 4 (Yom Kippur), 6 - watch recording before Oct 11

Oct 11, 13 - watch recording before Oct 18

Oct 18, 20 - watch recording before Oct 25

Oct 25, 27 - watch recording before Nov 1

Nov 1, 3 - watch recording before Nov 8

Nov 8, 10 - watch recording before Nov 15

Nov 15, 17 - watch recording before Nov 22

Nov 22, 29 - watch recording before Dec 6 - No class Nov 24 (Thanksgiving)

Dec 6, 8 (last live class)

Make-ups, if needed, Dec 13 and 15.

**Proctored exam: Oct 20 (RPNOW)**

Faculty: T. Preziosi

Required text: *The ASQ Certified Quality Auditor*, 5<sup>th</sup> edition, Lance B Coleman Sr. Available from ASQ Quality Audit Press: [www.asq.org/quality-press](http://www.asq.org/quality-press), ISBN 978-1-951058-09-8, copyright 2020. (Previous editions released as *The ASQ Audit Handbook*).

*Not open to students who have completed RAQA 494.*

**5495. IND/NDA Submissions (990) crn: 46250 (ONLINE)**

*This course will use PSI RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

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

6:00 pm - 9:00 pm Wednesdays: Sept 14, 21, 28, Oct 5 (Yom Kippur), 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-ups, if needed, Dec 14 and 21.

**Proctored exam: Oct 26 (RPNOW)**

Faculty: A. Smith

Required text: *Drugs: From Discovery to Approval*, Ng, 3<sup>rd</sup> edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272) OR *New Drug Development: A Regulatory Overview*, Mathieu, 8<sup>th</sup> edition, (ISBN: 1-882615-85-9).

*Not open to students who have completed RAQA 495.*

**5495. IND/NDA Submissions (991) crn: 32029 (ONLINE)**

*This course will use PSI RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

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

8:30 am - 2:00 pm Saturdays (1/2 hour lunch): Sep 10, 24, Oct 8, 22, Nov 5, 19, Dec 10. Meets 7 times plus final exam. Make-up, if needed, Dec 17.

**Proctored exam: Oct 22 (RPNOW)**

Faculty: A. Traettino

Required text: *Drugs: From Discovery to Approval*, Ng, 3<sup>rd</sup> edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272) OR *New Drug Development: A Regulatory Overview*, Mathieu, 8<sup>th</sup> edition, (ISBN: 1-882615-85-9).

*Not open to students who have completed RAQA 495.*

**5496. Regulation of Medical Devices: Compliance (990) crn: 51969 (ONLINE)**

*This course will use PSI RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Tuesdays: Sept 13, 20, 27, Oct 4 (Yom Kippur), 11, 18, 25, Nov 1, 8, 15, 22, 29. Meets 12 times plus final exam. Make-ups, if needed, Dec 6 and 13.

**Proctored exam: Oct 25 (RPNOW)**

Faculty: M. Arentz

No required text.

*Not open to students who have completed RAQA 496.*

**5502. Regulation of Medical Devices: Submissions (990) crn: 42732 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Thursdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8. Meets 12 times plus final exam. No class Nov 24 (Thanksgiving). Make-up, if needed, Dec 15.

**Proctored exam: Oct 27 (RPNOW)**

Faculty: M. Arentz

No required text.

*Not open to students who have completed RAQA 502.*

**5508. Good Pharmacovigilance Operations (990) crn: 51972 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Clinical Drug Safety and Pharmacovigilance (5538) OR Post Marketing Safety Surveillance (5471).*

5:30 pm - 8:30 pm Mondays: Sept 12, 19, 26, Oct 3, 10, 17, 24, 31, Nov 7, 14, 21, 28, 30 (Wednesday, final exam). Meets 12 times plus final exam. Make-ups, if needed, Dec 5 and 12.

**Proctored exams: Oct 24 (Mon) and Nov 30 (Wed) (RPNOW)**

Faculty: C. Baldrige

Required text: *Colbert's Manual of Drug Safety and Pharmacovigilance*, Cobert, Gregory & Thomas, 3<sup>rd</sup> edition, World Scientific, ISBN: 9813278846 or 9789813278833.

**5512. Microbiological Concepts in Pharmaceutical Manufacturing (990) crn: 51973 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisites: 1) Strong science background, 2) Food and Drug Law (5592), 3) Any GxPs (5476, 5477, 5479, or 5536)*

6:30 pm - 8:00 pm Tuesdays and Thursdays: Sept 13, 15, 20, 22, 27, 29, Oct 4 (Rosh Hashanah), 6, 11, 13, 18, 20, 25, 27, Nov 1, 3, 8, 10, 15, 17, 22, 29 (No class Nov 24, Thanksgiving), Dec 1, 6. Class meets 24 times plus final exam. Make-ups, if needed, Dec 8 and 13.

**Proctored exam: Oct 20 (RPNOW)**

Faculty: R. Saha

Required text: to be announced.

*Not open to students who have completed RAQA 512.*

**5513. Active Pharmaceutical Ingredients (APIs) (990) crn: 49389 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Drug Development (5459)*

6:00 pm – 9:00 pm Mondays: Sept 12, 19, 26 (Rosh Hashanah), Oct 3, 10 (recording), 17, 24, 31, Nov 7, 14, 21, 28. Meets 12 times plus final exam. No class on Oct 10 but recording will be available. Make-ups, if needed, Dec 5 and 12.

**Proctored exam: Oct 24 (RPNOW)**

Faculty: K Zimm

No required text.

**5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 28574 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Drug Development (5459) and a strong science background. Include resume with registration form.*

6:00 pm – 9:00 pm Wednesdays: Sept 14, 21, 28, Oct 5 (Yom Kippur), 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-ups, if needed, Dec 14 and 21.

**Proctored exam: Oct 26 (RPNOW)**

Faculty: F. Diana

No required text.

**5516. Cleaning Validation (990) crn: 46251 (ONLINE)**

*This course is offered both online and on-campus at Fort Washington.*

9:00 am - 3:30 pm Sundays (1/2 hour lunch): Sept 11, 25 (Rosh Hashanah), Oct 9, 23, Nov 6, 20 (mandatory field trip), Dec 11. Meets 6 times plus final exam. Make-up, if needed, Dec 18.

**Proctored exam: Dec 11 (via Zoom)**

**Mandatory field trip on Nov 20.**

Faculty: A. Walsh

Required text: *Cleaning Validation: Science, Risk and Statistics-based Approaches*, A. Walsh. Order from: [www.centerforpharmaceuticalcleaninginovation.org/textbook-page.html](http://www.centerforpharmaceuticalcleaninginovation.org/textbook-page.html)

**5533. Requirements for Product Labeling and Advertising (990) crn: 51974 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Food and Drug Law (5592) or permission of instructor.*

6:00 pm - 9:00 pm Tuesdays: Sept 13, 20, 27, Oct 4 (Yom Kippur), 11, 18, 25, Nov 1, 8, 15, 22, 29. Class meets 12 times plus final exam. Make-ups, if needed, Dec 6 and 13.

**Proctored exam: TBA (RPNOW)**

Faculty: D. Cooke and S. Desai

No required text.

*Not open to students who have completed RAQA 533.*

**5536. Good Clinical Practices (990) crn: 9358 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm – 9:00 pm Wednesdays: Sept 14, 21, 28, Oct 5 (Yom Kippur), 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-ups, if needed, Dec 14 and 21.

**Proctored exam: Oct 26 (RPNOW)**

Faculty: D. Weiss

No required text.

*Not open to students who have completed RAQA 536.*

**5537. Clinical Trial Management (990) crn: 49401 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Good Clinical Practices (5536) or permission of RAQA Office (include resume with registration).*

6:00 pm - 9:00 pm Tuesdays: Sept 13, 20, 27, Oct 4 (Yom Kippur), 11, 18, 25, Nov 1, 8, 15, 22, 29. Meets 12 times plus final exam. Make-ups, if needed, Dec 6 and 13.

**Proctored exam: Nov 1 (RPNOW)**

Faculty: J. Scavone

No required text.

*Not open to students who have completed RAQA 537.*

**5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 51975 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Good Clinical Practices (5536) or appropriate experience in industry GCP (forward resume).*

7:00 pm - 10:00 pm Wednesdays: Sept 14, 21, 28, Oct 5, 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus exam. No class Nov 23. Make-ups, if needed, Dec 14 and 21.

**Proctored exam: Oct 26 (RPNOW)**

Faculty: J. Robinson

*Not open to students who have completed RAQA 538. GCPR students may take 5538 or 5571 but not both-*

**5539. Global Clinical Drug Development (990) crn: 51991 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Mondays: Sept 12, 19, 26 (Rosh Hashanah), Oct 3, 10, 17, 24, 31, Nov 7, 14, 21, 28. Class meets 12 times plus final exam. Make-ups, if needed, Dec 5 and 12.

**Proctored exam: Oct 24 (RPNOW)**

Faculty: K. Weiss

No required text.

*Not open to students who have completed RAQA 539.*

**5546. Global Pharmaceutical Excipient Regulation (990) crn: 46254 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Wednesdays: Sept 21, 28, Oct 5 (Yom Kippur), 12, 19, 26, Nov 2, 9, 16, 30, Dec 7, 14. Meets 12 times plus final exam. No class Nov 23. Make-ups, if needed, Dec 19 (Monday) and Dec 21.

**Proctored exam: Nov 2 (RPNOW)**

Faculty: D. Schoneker

No required text.

*Not open to students who have completed RAQA 546.*

**5547. Project Management for Clinical Trials (990) crn: 51976 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Not open to students who have completed Project Management for Pharmaceutical Professionals (5615).*

6:00 pm - 9:00 pm Thursdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8. Meets 12 times plus final exam. No class Nov 24 (Thanksgiving). Make-ups, if needed, Dec 15 and 20 (Tuesday).

**Proctored exam: Oct 20th (RPNOW)**

Faculty: J. Sheldon

Recommended text: *Project Management for the Pharmaceutical Industry*, June 2011, revised reprint. Available on the Temple University Charles Library website.

**5548. Risk Management for Pharmaceutical and Medical Devices (990) crn: 42737 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Mondays: Sept 12, 19, 26 (Rosh Hashanah), Oct 3, 10, 17, 24, 31, Nov 7, 14, 21, 28. Meets 12 times plus final exam. Make-ups, if needed, Dec 5 and 12.

**Proctored exam: Oct 24 (RPNOW)**

Faculty: T. Genova

No required text.

**5572. Vaccines: RA and QA Issues (990) crn: 39783 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Drug Development (5459).*

6:00 pm - 9:00 pm Tuesdays: Sept 13, 20, 27, Oct 4 (Yom Kippur), 11, 18, 25, Nov 1, 8, 15, 22, 29. Meets 12 times plus final exam. Make-ups, if needed, Dec 6 and 13.

**Proctored exam: Oct 18 (RPNOW)**

Faculty: K. Surowitz

Required texts: **Do not purchase texts** until AFTER hearing discussion in the first class.

(1) *Autism's False Prophets*, Paul Offit, 2008, Columbia University Press. Available in the Temple U Charles Library online.

(2) *Epidemiology and Prevention of Vaccine Preventable Diseases*, 13<sup>th</sup> edition, U.S. Centers for Disease Control (CDC). Students may download individual chapters for free or purchase the paperback from the CDC.

(3) *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals and other Biologics*, John Geigert, 2<sup>nd</sup> edition, 2013, Springer. Available in the Temple U Charles Library online.

(4) *Plotke's Vaccines*, 7<sup>th</sup> edition, 2018, Plotkin, Orenstein, Offit, Edwards, editors, Elsevier. Available in the Temple U Charles Library online.

*Not open to students who have completed RAQA 572.*

**5574. Pharmaceutical Quality Management Systems (990) crn: 46256 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Drug Development (5459).*

6:00 pm - 9:30 pm Tuesdays: Sept 13, 20 (recording), Oct 4, 11, 18, 25, Nov 1, 8, 15, 22. No class Sept 27. Meets 10 times plus final exam. Make-ups, if needed, Nov 29 and Dec 6.

**Proctored exam: Oct 25 (RPNOW)**

Faculty: M. Labruto

No required text.

Required text: *Quality Systems and Control for Pharmaceuticals*, Sarkar, Dipak, K., 2008 (ISBN: 978-0470056929).

**5575. Regulatory Sciences: Managing the Guidelines for Quality (990) crn: 49404 (ONLINE)**

*This course is offered both online and on-campus at Fort Washington.*

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: strong science background required. Include resume with registration form.*

5:30 pm – 8:30 pm Tuesdays: Sept 13, 20, 27, Oct 4 (Yom Kippur), 11, 18, 25, Nov 1, 8, 15, 22, 29. Meets 12 times plus final exam. Make-ups, if needed, Dec 6 and 13.

**Proctored exam: Oct 25 (RPNOW).**

Faculty: T. Schultz

No required text.

*Not open to students who have completed RAQA 575.*

**5577. Global CMCs – Biopharmaceuticals and Other Biologics (990) crn: 28578 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Mondays: Sept 12, 19, 26 (Rosh Hashanah), Oct 3, 10, 17, 24, 31, Nov 7, 14, 21, 28. Meets 12 times plus final exam. Make-ups, if needed, Dec 5 and 12.

**Proctored exam: Oct 17 (RPNOW)**

Faculty: J. Quinn

Required text: *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics*, John Geigert, 3rd edition, 2019, Science & Media, NY, ISBN-13: 978-3030137533).

**5579. Regulatory and Legal Basis of Pharmacovigilance (990) crn: 46257 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Suggestions prerequisite: Post Marketing Safety Surveillance (5571) or Clinical Drug Safety and Pharmacovigilance (5538).*

6:00 pm - 9:00 pm Thursdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8, 15. Meets 12 times plus final exam. No class Nov 24th. Make-up, if needed, Dec 20 (Tuesday).

**Proctored exam: Dec 15 (RPNOW)**

Faculty: R. Patel and C. Keel

No required text.

**5591. Global Regulatory Affairs (990) crn: 23442 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

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

6:00 pm - 9:00 pm Wednesdays: Sept 14, 21, 28, Oct 5 (Yom Kippur), 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-ups, if needed, Dec 14 and 21.

**Proctored exam: Oct 19 (RPNOW)**

Faculty: D. Larkins

No required text.

*Not open to students who have completed RAQA 591.*

**5591. Global Regulatory Affairs (991) crn: 46258 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

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

8:30 am - 3:00 pm Saturdays (1/2 hour lunch): Sep 17, Oct 1, 15, 29, Nov 12, Dec 3. Meets 6 times plus final exam. Make-up, if needed, Dec 17.

**Proctored exam date: Oct 29 (RPNOW)**

Faculty: R. Phillips

No required text.

*Not open to students who have completed RAQA 591.*

**5592. Food and Drug Law (990) crn: 7202 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Wednesdays: Sept 14, 21, 28, Oct 5 (Yom Kippur), 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-ups, if needed, Dec 14 and 21.

**Proctored exam: Oct 12 (RPNOW)**

Faculty: G. Pilgrim

Required text: *Food and Drug Law: Cases and Materials*, 4<sup>th</sup> edition, Hutt, et al, West Academic Publishing, (ISBN: 1609301757). Only purchase the 4<sup>th</sup> edition (and not earlier editions).

Recommended text: *Statutory Supplement*, Hutt, West Academic Publishing, (ISBN: 9781634591904). Note: a 2012 edition or later of this text is acceptable. West Academic Publishing gives a 15% discount and free ground



shipping to students ordering these texts. You must create an account, use promo code HESTUDENT, and place our order directly through [www.westacademic.com](http://www.westacademic.com).  
*Not open to students who have completed RAQA 592.*

**5592. Food and Drug Law (991) crn: 23754 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm – 9:00 pm Tuesdays: Sept 13, 20, 27, Oct 4 (Yom Kippur), 11, 18, 25, Nov 1, 8, 15, 29, Dec 6. Meets 12 times plus final exam. No class Nov 22. Make-ups, if needed, Dec 13 and 20.

**Proctored exam: Oct 11 (RPNOW)**

Faculty: G. Pilgrim

Required text: *Food and Drug Law: Cases and Materials*, 4<sup>th</sup> ed, Hutt, et al, West Academic Publishing, (ISBN: 1609301757). Only purchase the 4<sup>th</sup> edition (and not earlier editions).

Recommended text: *Statutory Supplement*, Hutt, West Academic Publishing, (ISBN: 9781634591904). Note: a 2012 edition or later of this text is acceptable.

West Academic Publishing gives a 15% discount and free ground shipping to students ordering these texts. You must create an account, use promo code HESTUDENT, and place your order directly through [www.westacademic.com](http://www.westacademic.com)

*Not open to students who have completed RAQA 592.*

**5597. Food Good Manufacturing Practices (GMPs) (990) crn: 51978 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:30 pm – 9:30 pm Thursdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8, 15. Meets 12 times plus final exam. No class Nov 24. Make-ups, if needed, Dec 19 (Monday) and 21 (Wednesday).

**Proctored exam: Dec 15 (RPNOW)**

Faculty: M. Noonan

No required text.

**5612. Bioethics for Pharmaceutical Professionals (990) crn: 42739 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

10:00 am – 1:00 pm Saturdays: 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 (Thanksgiving weekend). Make-ups, if needed, Dec 10 and 17.

**Proctored exam: Oct 22 (RPNOW)**

Faculty: D. Walsh

Required text: *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary*, Emmanuel, Crouch, Arras, Moreno and Grady, Johns Hopkins University Press, ISBN: 0:0801878136 or 13:9780801878138.

*Not open to students who have completed RAQA 610.*

**5612. Bioethics for Pharmaceutical Professionals (991) crn: 46282 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

6:00 pm - 9:00 pm Mondays: Sept 12, 19, 26 (Rosh Hashanah), Oct 3, 10, 17, 24, 31, Nov 7, 14, 21, 28. Meets 12 times plus final exam. Make-ups, if needed, Dec 5 and 12.

**Proctored exam: Oct 17 (RPNOW)**

Faculty: K. Childers

Required text: *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary*, Emmanuel, Crouch, Arras, Moreno and Grady, Johns Hopkins University Press, ISBN: 0:0801878136 or 13:9780801878138.

Other readings will be available through the Temple U Charles Library.

*Not open to students who have completed RAQA 610.*

**5627. Statistical Design of Experiments (DOE) crn: 51979 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: familiarity with basic math. A statistical program (Minitab) will be used.*

8:30 am - 2:00 pm Sundays (1/2 hour lunch): Sep 18, Oct 2, 16, 30, Nov 13, Dec 4, Dec 11. Meets 7 times plus final exam. Make-up, if needed, Dec 18.

**Proctored exam: Oct 30 (RPNOW)**

Faculty: R. Snee

Required text: *Design and Analysis of Experiments*, D.C. Montgomery, 2017, 9<sup>th</sup> Edition.

**5655. Analytical Chemistry in Pharmaceutical Laboratories (990) crn: 51980 (ONLINE)**

*This course will use PSI Services LLC's RPNOW online proctoring. Students are responsible for paying a \$15.00 fee directly to PSI via credit card at the start of the proctored exam.*

*Prerequisite: Drug Development (5459). Students are expected to have some laboratory background in chemistry or related science and familiarity with laboratory practices.*

6:00 pm - 9:00 pm Thursdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8. Meets 12 times plus final exam. No class Nov 24th. Make-ups, if needed, Dec 15 and 20 (Tuesday).

**Proctored exam: Oct 27 (RPNOW)**

Faculty: F. Diana and K. Huynh-Ba

Required text: Available online from the Temple U Charles Library: *Analytical Testing for the Pharmaceutical GMP Laboratory*, Huynh-Ba (Editor), 2022, ISBN: 978-1-119-12091-9.

**8002. Pharmaceutical Analysis (990) crn: 46377 (ONLINE)**

*This course is offered both online and on-campus at Fort Washington.*

*Prerequisite: strong science backgrounds. This consists of a minimum of 2 years of general chemistry, including one organic and one analytical chemistry course. RAQA students must submit their resume for written permission to register.*

5:30 pm - 8:30 pm Mondays: Aug 29, Sept 12, 19, 26 (Rosh Hashanah), Oct 3, 10, 17, 24, 31, Nov 7, 14, 15, 28. Meets 12 times plus final exam. No class Sept 5 and Nov 21. Make-ups, if needed, Dec 5 and 12.

**Proctored exams: Oct 17 and Nov 28 (via Zoom)**

Faculty: D. Canney, A. Fermier, S. Mehrman

No required text.

*Not open to students who have completed Pharmaceutics 411.*