

Fall 2025 - RAQA Graduate Program – August 6, 2025

ON-CAMPUS COURSES

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

AFTERNOON COURSE at Fort Washington

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

2:00 pm - 5:30 pm Wednesdays: Sept 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19. Meets 10 times plus final exam. Make-ups, if needed, Dec 3 and 10.

In-class, proctored exam: Oct 15

Faculty: P. Sax

Required texts: 1) *Drugs: From Discovery to Approval*, Ng, 3rd edition, 2015 (ISBN-13:978-1118907276 or ISBN-10:1118907272) and 2) *The Drug Hunters: The Improbable Quest to Discover New Medicines*, Kirsch, 2017.

Not open to students who have completed RAQA 459.

AFTERNOON COURSE at Fort Washington

5592. Food and Drug Law (101) crn: 58833 (ON-CAMPUS COURSE)

2:00 pm - 5:30 pm Thursdays: Sept 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20. Meets 10 times plus final exam. Make-ups, if needed, Dec 4 and 11.

In-class, proctored exam: Oct 16

Faculty: C. Hammes

Required texts: 1) *Food and Drug Law: Cases and Materials*, **FOURTH edition (students may purchase a used book)**, Hutt, et al, West Academic Publishing. 2) *FDCA Statutory Supplement*: Access for free at: <https://uscode.house.gov/view.xhtml?path=/prelim@title21&edition=prelim> (scroll to chapter 9).

Not open to students who have completed RAQA 592.

AFTERNOON 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 16, 23 (Rosh Hashana), 30, Oct 7, 14, 21, 28, Nov 4, 11 (Veterans' Day), 18. Meets 10 times plus final exam. Make-ups, if needed, Dec 2 and 9.

In-class, proctored exam: Oct 14

Faculty: P. Sax

Suggested texts: 1) *The Practice of Management*, Drucker; 2) *the Definitive Drucker*, E.H Edersheim; 3) *Who Moved My Cheese*, S Johnson.

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.

ONLINE (ZOOM) COURSES

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

Temple University uses Zoom as the teaching platform, which is provided for free to all registered Temple students.

Required hardware

RAQA online courses are interactive, so you must have a webcam and microphone to participate. These are essential to provide an excellent online classroom experience for all students. Many laptops have built-in webcams and speakers. If you plan to use a device that does not, you are required to purchase them.

If you're a new student taking an online course, watch the [online course tutorial](#) and include the code at the end on your registration form. Next, schedule a short Zoom meeting with David Brickett (dbrick@temple.edu) or Jessie Chen (jessie.chen@temple.edu) to use our online technology. This ensures that everyone knows how to participate on Zoom during the first class meeting.

Proctorio is an online proctoring service that enables you to take exams at almost any location. If a course uses Proctorio, all students in the course must use that service.

Proctorio exams require a laptop or computer. Chrome notebooks, iPads, cell phones and other devices do not work. You must have **administrative access** to your laptop or computer, which means you can install software. Work computers may have built-in firewalls that prohibit software downloads. Please check this before registering.

1.5 Credit Course

5000. FDA Inspection Readiness (990) (1.5 credits) crn: 58832 (ONLINE)

This course uses Proctorio online proctoring.

7:00 pm - 10:00 pm Tuesdays: Sept 9, 16, 23 (Rosh Hashanah), 30, Oct 7, 14, 21. Meets 6 times plus final exam. Make-ups, if needed Oct 28 and Nov 4.

Proctored exam: Oct 21 (Proctorio)

Faculty: E. Pittman

No required text.

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

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Wednesdays: TENATIVE

Proctored exam:

Suggested text: Drugs: From Discovery to Approval, Ng, 3rd edition, 2015 (ISBN-13:978-1118907276 or ISBN-10:1118907272).

Not open to students who have completed RAQA 459.

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

This course uses Proctorio online proctoring.

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

Proctored exam: Oct 20 (Proctorio)

Faculty: J. Hayes

Suggested text: Drugs: From Discovery to Approval, Ng, 3rd edition, 2015 (ISBN-13:978-1118907276 or ISBN-10:1118907272).

In addition, students will be required to choose one of the following texts and write a book review:

1. *Ten Drugs*, T. Hager, ISBN: 13-97: 1419735226.
2. *For Blood and Money: Billionaires, Biotech, and the Quest for a Blockbuster Drug*, Vardi; ISBN-13: 978-0393540956.
3. *Making Medicine: Surprising Stories from the History of Drug Discovery*, hardcover – July 2022; Veronese; ISBN-13: 978-1633887534.

Not open to students who have completed RAQA 459.

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

This course uses Proctorio online proctoring.

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

Proctored exam: Oct 18 (Proctorio)

Faculty: M. Rubio

Suggested text: Drugs, From Discovery to Approval, 3rd edition, Rick Ng, ISBN-13:978-1118907276 or ISBN-10: 1118907272.

Not open to students who have completed RAQA 459.

5471. Biotechnology: Bioprocess Basics (990) crn: 58817 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Undergraduate introductory Chemistry and/or Biochemistry courses.

6:00 pm - 9:00 pm Tuesdays: **Sept 16**, 23 (Rosh Hashana), 30, Oct 7, 14, 21, 28, Nov 4, 11 (Veterans' Day), 18, 25, Dec 2. Meets 12 times plus final exam. Make-ups, if needed, Dec 9 and 16.

Proctored exam: Oct 21 (Proctorio)

Faculty: J. Quinn

No required text.

Not open to students who have completed RAQA 481.

5474. Process Validation (990) crn: 54364 (ONLINE)

This course uses Proctorio online proctoring.

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. Please include resume with registration.

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

Proctored exam: Oct 20 (Proctorio)

Faculty: K. Barnthouse

Required texts: 1) Process Validation in Manufacturing of Biopharmaceuticals, 4th edition, Anurag S. Rathore and Gail Softer, editors, CRC Press 2012, AND 2) How to Validate a Pharmaceutical Process, 1st edition, Steven Ostrove, Eisevier, 2016.

Not open to students who have completed RAQA 484.

5476. Good Laboratory Practices (990) crn: 58818 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Wednesdays: 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. Make-ups, if needed, Dec 10 and 17.

Proctored exam: Oct 22 (Proctorio)

Faculty: S. Wilson

No required text.

Not open to students who have completed RAQA 486.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:30 pm Mondays: Sept 8, 15, 22, 29, Oct 6, 20, 27, Nov 3, 10, 17, 24. Meets 10 times plus final exam. No class Oct 13 (Columbus Day). Make-ups, if needed, Dec 1 and Dec 8.

Proctored exam: Nov 24 (Proctorio)

Faculty: M. Noonan

No required text.

Not open to students who have completed RAQA 487.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Thursdays: Sept 11, 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27 (Thanksgiving). Make-ups, if needed, Dec 11 and 18.

Proctored exam: Oct 23 (Proctorio)

Faculty: K. Zimm

No required text.

Not open to students who have completed RAQA 487.

5492. Production of Sterile Products (990) crn: 58819 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Strong science background. Submit resume with registration.

6:00 pm - 9:00 pm Wednesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3, 10.
Meets 12 times plus final exam. No class Nov 26. Make-up, if needed, Dec 17.

Proctored exam: Dec 10 (Proctorio)

Faculty: D. Casaburi

Required text: *Aseptic and Sterile Processing Control, Compliance and Future Trends*, Edited by Tim Sandle and Edward C. Tidswell PDA Bethesda MD, USA ISBN: 978-1-942911-12-8

www.pda.org/bookstore, 301-986-0293

Not open to students who have taken RAQA 492.

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

This course uses Proctorio online proctoring.

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

7:00 pm - 10:00 pm Tuesdays: Sept 9, 16, 23 (Rosh Hashana) 30, Oct 7, 14, 21, 28, Nov 4, 11 (Veterans' Day), 18, Dec 2. Meets 12 times plus final exam. No class Nov 25. Make-ups, if needed, Dec 9 and 16.

Proctored exam: Oct 21 (Proctorio)

Faculty: J. Werrmann

Required text: *The ASQ Certified Quality Auditor*, 5th edition, Lance B Coleman Sr. Available from ASQ Quality Audit Press: www.asq.org/quality-press, ISBN 978-1-951058-09-8, copyright 2020. (Previous editions released as *The ASQ Audit Handbook*). Note: purchase **a hard copy of the 5th edition**. Do not buy earlier editions or eBooks.

Not open to students who have completed RAQA 494.

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

This course uses Proctorio online proctoring.

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

6:00 pm - 9:00 pm Thursdays: Sept 11, 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27 (Thanksgiving). Make-ups, if needed, Dec 11 and 18.

Proctored exam: Oct 16 (Proctorio)

Faculty: R. Phillips

Required text: *New Drug Development: A Regulatory Overview*, Mathieu, 8th revised edition.

Not open to students who have completed RAQA 495.

5495. IND/NDA Submissions (991) crn: 58820 (ONLINE)

This course uses Proctorio online proctoring.

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

8:30 am - 2:00 pm Saturdays: Sept 13, 27, Oct 11 (Columbus Day weekend), 25, Nov 8, 22, Dec 6. Meets 7 times plus final exam. Make-up, if needed, Dec 13.

Proctored exam: Oct 25 (Proctorio)

Faculty: P. Smith

Required text: *New Drug Development: A Regulatory Overview*, Mathieu, 8th revised edition.

Not open to students who have completed RAQA 495.

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

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Tuesdays: Sept 9, 16, 23 (Rosh Hashana), 30, Oct 7, 14, 21, 28, Nov 4, 11 (Veterans' Day), 18, Dec 2. Meets 12 times plus final exam. No class Nov 25. Make-ups, if needed, Dec 9 and 16.

Proctored exam: Oct 21 (Proctorio)

Faculty: M. Arentz

No text required.

Not open to students who have completed RAQA 496.

5497. Statistics for Clinical Trials (990) crn: 58838 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Sept 9, 16, 23 (Rosh Hashana), 30, Oct 7, 14, 21, 28, Nov 4, 11 (Veterans' Day), 18, Dec 2. Meets 12 times plus final exam. No class Nov 25. Make-ups, if needed, Dec 9 and 16.

Proctored exam: Oct 21 (Proctorio)

Faculty: K. Weiss

No text required.

Not open to students who have completed RAQA 497.

5502. Regulation of Medical Devices: Submissions (990) crn: 58821 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Thursdays: Sept 11, 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27 (Thanksgiving). Make-ups, if needed, Dec 11 and 18.

Proctored exam: Oct 23 (Proctorio)

Faculty: M. Arentz

No text required.

Not open to students who have completed RAQA 500.

5504. Patient-Focused Regulation Policy for Medical Products (990) crn: 56884 (ONLINE)

This course uses Proctorio online proctoring.

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

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

6:00 pm - 9:00 pm Thursdays: Sept 11, 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4, 11. Meets 12 times plus final exam. No class Nov 27 (Thanksgiving). Make-up, if needed, Dec 18.

Proctored exam: Dec 11 (Proctorio)

Faculty: C. Kuehn

Required text: All readings will be posted in Canvas.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3, 10. Meets 12 times plus final exam. No class Nov 26. Make-up, if needed, Dec 17.

Proctored exam: Dec 10 (Proctorio)

Faculty: L. Thomas

Required text: *Cobert's Manual of Drug Safety and Pharmacovigilance: 4th Edition*, Cobert, Gregory, Thomas, and Baldrige, 4th edition., World Scientific. ISBN-10: 9819800218 or ISBN-13: 978-9819800216.

5512. Microbiological Concepts in Pharmaceutical Manufacturing (990) crn: 58822 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Strong science background. Attach resume with registration form.

6:00 pm - 9:00 pm Thursdays: Sept 11, 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27 (Thanksgiving). Make-ups, if needed, Dec 11 and 18.

Proctored exam: Nov 6 (Proctorio)

Faculty: R. Saha

No required text. All readings available on the Internet.

Not open to students who completed RAQA 512.

5513. Active Pharmaceutical Ingredients (990) crn: 58827 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459)

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

Proctored exam: Oct 20 (Proctorio)

Faculty: K. Zimm

No required text.

5514. Regulatory eSubmissions (990) crn: 58828 (ONLINE)

This course uses Proctorio online proctoring.

Strongly suggested prerequisite: Drug Development (5459) OR IND/NDA Submissions (5495). Please include your resume with registration.

6:00 pm - 9:00 pm Wednesdays: 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. Make-ups, if needed Dec 10 and 17.

Proctored exam: Oct 22 (Proctorio)

Faculty: R. Arbaugh

No required text.

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

This course uses Proctorio online proctoring.

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

6:00 pm - 9:30 pm Wednesdays: **Oct 8**, 15, 22, 29, Nov 5, 12, 19, 26 (recording), Dec 3, 10. Meets 10 times plus final exam. Make-up, if needed, Dec 17.

Proctored exam: Nov 12 (Proctorio)

Faculty: F. Diana

No required text.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Sept 9, 16, 23 (Rosh Hashana), 30, Oct 7, 14, 21, 28, Nov 4, 11 (Veterans' Day), 18, Dec 2. Meets 12 times plus final exam. No class Nov 25. Make-ups, if needed, Dec 9 and 16.

Proctored exam: Oct 21 (Proctorio)

Faculty: J. Scavone

No required text.

WEEKEND COURSE

5536. Good Clinical Practices (991) crn: 56678 (ONLINE)

This course uses Proctorio online proctoring.

10:00 am – 1:00 pm Saturdays: Sept 13, 20, 27, Oct 4, 11 (Columbus Day weekend), 18, 25, Nov 1, 8, 15, 22, Dec 6. Meets 12 times plus final exam. No class Nov 29. Make-up, if needed, Dec 13.

Proctored exam: Oct 25 (Proctorio)

Faculty: D. Walsh

No required text: All references and readings are available online.

Not open to students who have completed RAQA 536.

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

This course uses Proctorio online proctoring.

Prerequisite: Good Clinical Practices (5536). Students with clinical experience may ask to take the course but must include their resume with registration.

6:00 pm - 9:00 pm Wednesdays: 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. Make-ups, if needed, Dec 10 and 17.

Proctored exam: Oct 22 (Proctorio)

Faculty: J. Scavone

No required text.

Not open to students who have completed RAQA 537.

5543. Good Distribution Practices (990) crn: 56677 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Good Manufacturing Practices (5477)

6:00 pm - 9:00 pm Wednesdays: 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. Make-ups, if needed, Dec 10 and 17.

Proctored exam: Oct 22 (Proctorio)

Faculty: J. Hayes

Required text: **One of these books will be selected in the first week of class.**

- 1) *China Rx: Exposing the Risks of America's Dependence on China for Medicine* (paperback), Rosemary Gibson.
- 2) *Dangerous Doses: A True Story of Cops, Counterfeiters, and the Contamination of America's Drug Supply* (paperback), Katherine Eban.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 10. Meets 12 times plus final exam. No class Nov 26 and Dec 3. Make-up, if needed, Dec 17.

Proctored exam: Oct 22 (Proctorio)

Faculty: D. Schoneker

No required text.

Not open to students who have completed RAQA 546.

5547. Project Management for Clinical Trials (990) crn: 58829 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: Sept 8, 15, 22, 29, Oct 6, 13 (Columbus Day), 20, 27, Nov 3, 10, 17, 24. Meets 12 times plus final exam. Make-ups, if needed, Dec 1 and 8.

Proctored exam: Oct 13 (Proctorio)

Faculty: J. Sheldon

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

Not open to students who have taken RAQA 5615: Project Management for Pharmaceutical Professionals.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: Sept 8, 15, 22, 29, Oct 6, 13 (Columbus Day), 20, 27, Nov 3, 10, 17, 24. Meets 12 times plus final exam. Make-ups, if needed, Dec 1 and 8.

Proctored exam: Oct 20 (Proctorio)

Faculty: T. Genova

No required text.

5571. Post-Marketing Safety Surveillance (990) crn: 58830 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: **Sept 15**, 22, 29, Oct 6, 13 (Columbus Day), 20, 27, Nov 3, 10, 17, 24, Dec 1. Meets 12 times plus final exam. Make-ups, if needed, Dec 8 and 15.

Proctored exam: Nov 3 (Proctorio)

Faculty: V. Patadia

Required text: *Mann's Pharmacovigilance*, Edited by Elizabeth B. Andrews, Nicholas Moore (ISBN: 978-0-470-67104-7), Publisher Wiley Blackwell Edition: 3rd Edition

Not open to students who have completed RAQA 571.

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

This course uses Proctorio 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 - 9:30 pm Wednesdays: Sept 10, 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12. Meets 10 times plus final exam. Make-ups, if needed, Nov 19 and Dec 10.

Proctored exam: Oct 8 (Proctorio)

Faculty: K. Surowitz

Required texts and class references (**all available on-line through TU Library**).

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*, "The Pink Book." 14th Ed. 2021. US Centers for Disease Control and Prevention. Available free on-line and as a bound paperback through CDC at a small cost.
<https://www.cdc.gov/vaccines/pubs/pinkbook/index.html>
3. *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals and other Biologics*, John Geigert, 4th edition, 2023, Springer. Available in the Temple U Charles Library online.
4. *Plotkin's Vaccines*, 8th edition, 2018, Plotkin, Orenstein, Offit, Edwards, Editors. 2024, 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 uses Proctorio online proctoring.

Prerequisites: Drug Development (5459)

6:00 pm - 9:30 pm Mondays: Sept 8, 15, 22 (recording), Oct 6, 13 (Columbus Day), 20, 27, Nov 3, 10, 17. No class Sept 29. Meets 10 times plus final exam. Make-ups, if needed, Nov 24 and Dec 1.

Proctored exam: Oct 20 (Proctorio)

Faculty: M. Labruto

No required text.

5578. Risk Management and Safety Signaling of Healthcare Products (990) crn: 58831 (ONLINE)

This course uses Proctorio online proctoring.

7:00 pm - 10:00 pm Thursdays: Sept 11, 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4, 11. Meets 12 times plus final exam. No class Nov 27 (Thanksgiving). Make-up, if needed, Dec 18.

Proctored exam: Dec 11 (Proctorio)

Faculty: J. Robinson

No required text.

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

This course uses Proctorio online proctoring.

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

6:00 pm – 9:00 pm Tuesdays: Sept 9, 16, 23 (Rosh Hashana), 30, Oct 7, 14, 28, Nov 4, 11 (Veterans' Day), 18, Dec 2, 9. Meets 12 times plus final exam. No class Nov 25. Make-up, if needed, Dec 16.

Proctored exam: Oct 14 (Proctorio)

Faculty: D. Larkins

No text required.

Not open to students who have completed RAQA 591.

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

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Wednesdays: 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. Make-ups, if needed, Dec 10 and 17.

Proctored exam: to be determined (Proctorio)

Faculty: G. Pilgrim

Required text: *Food and Drug Law: Cases and Materials*, 5th edition, hard copy only, Hutt, et al, West Academic Publishing. Purchase the hard copy of the 5th edition. Do not buy earlier editions or eBooks. West Academic Publishing gives a 15% discount and free ground shipping to students for these texts. You must create an account, use promo code HESTUDENT, and place your order directly through www.westacademic.com.

Not open to students who have completed RAQA 592.

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

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Tuesdays: Sept 9, 16, 23 (Rosh Hashana), 30, Oct 7, 14, 21, 28, Nov 4, 11 (Veterans' Day), 18, Dec 2. Meets 12 times plus final exam. No class Nov 25. Make-ups, if needed, Dec 9 and 16.

Proctored exam: to be determined (Proctorio)

Faculty: G. Pilgrim

Required text: *Food and Drug Law: Cases and Materials*, 5th edition, hard copy only, Hutt, et al, West Academic Publishing. Purchase the hard copy of the 5th edition. Do not buy earlier editions or eBooks. West Academic Publishing gives a 15% discount and free ground shipping to students for these texts. You must create an account, use promo code HESTUDENT, and place your order directly through www.westacademic.com.

Not open to students who have completed RAQA 592.

5595. Food Law (990) crn: 54379 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:30 pm Thursdays: Sept 11, 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20. Meets 10 times plus final exam. Make-ups, if needed, Dec 4 and Dec 11.

Proctored exam: Nov 20 (Proctorio)

Faculty: M. Noonan

No required text.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Thursdays: Sept 11, 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4. Meets 12 times plus final exam. No class Nov 27 (Thanksgiving). Make-ups, if needed, Dec 11 and 18.

Proctored exam: Oct 23 (Proctorio)

Faculty: D. Walsh

Required text: *Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary*, Emanuel, Crouch, Arras, Moreno and Grady, Johns Hopkins University Press, 2003.

Not open to students who have completed RAQA 610.

PHARMACEUTICAL SCIENCE COURSE

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

This course uses Proctorio online proctoring.

Prerequisite: Strong science background. 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 permission to register.

5:30 pm - 8:30 pm Mondays: Sept 8, 15, 22, 29, Oct 6, 13 (Columbus Day), 20, 27, Nov 3, 10, 17, Dec 1, 8. No class Nov 24. Meets 12 times plus final exam. Make-up, if needed, Dec 15.

Proctored exams: Oct 20 and Dec 8 (via Zoom)

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

No required text.

Not open to students who completed Pharmaceutics 411.

8003. Preformulation - Small Molecules (990) crn: 54371 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Strong science background is required. RAQA students must include resume with registration form.

5:30 pm - 8:30 pm Tuesdays: Sept 9, 16, 23 (Rosh Hashana), 30, Oct 7, 14, 21, 28, Nov 4, 11 (Veterans' Day), 18, Dec 2. Meets 12 times plus final exam. No class Nov 25. Make-ups, if needed, Dec 9 and 16.

Proctored exam: Oct 21 (Proctorio)

Faculty: T. Schultz

Required text: Aulton's *Pharmaceutics: The Design and Manufacture of Medicines*, Taylor & Aulton, 4th edition, 2013, Churchill Livingstone, (ISBN: 9780702042904 OR 9780702053931).

Not open to students who have completed Pharmaceutics 406.

8005. Pharmaceutical Biotechnology (990) crn: 58834 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Strong science background required. 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 permission to register.

6:00 pm - 9:00 pm Thursdays: Sept 11, 18, 25, Oct 2 (Yom Kippur), 9, 16, 23, 30, Nov 6, 13, 20, Dec 4, 11. Meets 12 times plus final exam. No class Nov 27 (Thanksgiving). Make-up, if needed, Dec 18.

Proctored exams: Oct 23 and Dec 11 (via Zoom)

Faculty: T. Parry

Required text: *Pharmaceutical Biotechnology: Fundamentals and Applications*, Crommelin, Sindelar & Meibohm, editors, any of the 3rd through 6th editions should be ordered, Informa Healthcare 2007 (ISBN 10: 1420044370, ISBN 13 978 1420044379). Paperback recommended.

Suggested: *Biochemistry and Biotechnology*, Walsh, G., 2nd edition, (ISBN 0 472 84327 6), available online. Students should have access to textbooks in biochemistry and or molecular biology.

Not open to students who have completed Pharmaceutics 475.

