

ONLINE (ZOOM) and On-CAMPUS 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.

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. Then schedule a short Zoom meeting with David Brickett (dbrick@temple.edu) or Mike Doukas (mdoukas@temple.edu) to review how 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.

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.
Spring topics include:

Microbiology U (San Diego, CA): Tentatively March 4 – 5, 2025

Validation U (Philadelphia, PA): Tentatively March 18 – 20, 2025

Laboratory U (San Diego, CA): Tentatively May 13 – 15, 2025

5459. Drug Development (990) crn: 42713 (ONLINE)

This course uses 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)

Faculty: C. Ciliberto

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: 28687 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Jan 22, 29, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 2, 9. Meets 12 times plus final exam. Make-ups, if needed, Apr 16 (Passover) and 23.

Proctored exam: Mar 5 (Proctorio)

Faculty: J. Hayes

Required text: *Drugs, From Discovery to Approval*, 3rd edition, Rick Ng, 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*, 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.

WEEKEND COURSE

5459. Drug Development (992) crn: 51026 (ONLINE)

This course uses Proctorio online proctoring.

10:00 am – 1:00 pm Saturdays: Jan 18, 25, Feb 1, 8, 15, 22, Mar 1, 8, 15, 22, 29, Apr 5. Meets 12 times plus final exam. Make-ups, if needed, Apr 12 and 19 (Passover).

Proctored exam: Mar 1 (Proctorio)

Faculty: D. Walsh

Required texts: 1) *Drugs: From Discovery to Approval*, Ng, 3rd edition, 2015 (ISBN-13:978-1118907276 or ISBN-10: 1118907272), and 2) *The Great Influenza*, John M. Barry, Penguin 2004-5, (ISBN 0-14-303649-1)

Not open to students who have completed RAQA 459.

5477. Good Manufacturing Practices (990) crn: 3439 (ONLINE)

This course uses Proctorio 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 10 (Proctorio)

Faculty: M. Noonan

No required text.

Not open to students who have completed RAQA 487.

5477. Good Manufacturing Practices (991) crn: 55325 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8. Meets 12 times plus final exam. Make-ups, if needed, Apr 15 (Passover) and 22.

Proctored exam: Feb 25 (Proctorio)

Faculty: R. Phillips

No required text.

Not open to students who have completed RAQA 487.

5493. Sterilization Processes (990) crn: 53063 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: strong science background. Submit resume with registration.

6:00 pm - 9:00 pm Mondays: Jan 27, Feb 3, 10, 17 (Presidents' Day), 24, Mar 3, 10, 17, 24, 31, Apr 7, 14 (Passover), 21. Meets 12 times plus final exam. Make-up, if needed, Apr 28 and May 5.

Proctored exam: Apr 21 (Proctorio)

Faculty: D. Casaburi

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

Not open to students who have completed RAQA 493.

5494. Quality Audit (990) crn: 31574 (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: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8, 15 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 22 and 29.

Proctored exam: Apr 15 (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: 20675 (ONLINE)

This course uses Proctorio online proctoring.

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

6:00 pm – 9:00 pm Mondays: Jan 27, Feb 3, 10, 17 (Presidents' Day), 24, Mar 3, 10, 17, 24, 31, Apr 7, 14 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 21 and 28.

Proctored exam: Mar 10 (Proctorio)

Faculty: A. Smith

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

Not open to students who have completed RAQA 495.

WEEKEND COURSE

5495. IND/NDA Submissions (991) crn: 31567 (ONLINE)

This course uses Proctorio online proctoring.

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

8:30 am – 2:00 pm Saturdays: Jan 18, Feb 1, 15, Mar 1, 15, 29, Apr 12. Meets 7 times plus final exam. Make-up, if needed, Apr 26.

Proctored exam: Mar 1 (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.

5501. Development of Sterile Products (990) crn: 55322 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: a minimum of 2 years of general chemistry, including one organic and one analytical chemistry course. RAQA students must include their resume for written permission to register.

6:00 pm - 9:00 pm Wednesdays: Jan 22, 29, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 2, 9, 16 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 23 and 30.

Proctored exam: Apr 16 (Proctorio)

Faculty: D. Casaburi

No required text:

Not open to students who have completed RAQA 501.

5503. Design Controls for Medical Devices and Combination Products (990) crn:48475 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8. Meets 12 times plus final exam. Make-ups, if needed, Apr 15 (Passover) and 22

Proctored exam: Mar 4 (Proctorio)

Faculty: T. Genova

No required text

5505. Global Medical Device Regulation (990) crn: 51059 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Mondays: Jan 27, Feb 3, 10, 17 (Presidents' Day), 24, Mar 3, 10, 17, 24, 31, Apr 7, 14 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 21 and 28.

Proctored exam: Mar 10. (Proctorio)

Faculty: M. Arentz

No required text.

Not open to students who have completed RAQA 5505.

5508. Good Pharmacovigilance Operations (990) crn: 53066 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Jan 22, 29, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 2, 16 (Passover), 23. Meets 12 times plus final exam. No class April 9. Make-up, if needed, Apr 30 and May 7.

Proctored exam: Apr 23 (Proctorio)

Faculty: L. Thomas

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

5509. Pediatric and Orphan Drug Regulations (990) crn: 55323 (ONLINE)

This course uses 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)

Faculty: K. Weiss

No required text.

5512. Microbiological Concepts in Pharmaceutical Manufacturing (990) crn: 55321 (ONLINE)

This course uses Proctorio online proctoring.

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

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 13 (Proctorio)

Faculty: R. Saha.

No required text. All readings available on the Internet.

Not open to students who have completed RAQA 512.

5514. Regulatory eSubmissions (990) crn: 42720 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459) and IND/NDA Submissions (5495) or submit resume indicating industry experience for special permission to register. .

6:00 pm - 9:00 pm Wednesdays: Jan 22, 29, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 2, 9. Meets 12 times plus final exam. Make-ups, if needed, Apr 16 (Passover) and 23.

Proctored exam: Mar 5 (Proctorio)

Faculty: R. Arbaugh

No required text.

ON-CAMPUS COURSE

There is an on-campus section of Good Clinical Practices (5536) at the Fort Washington site offered on Tuesdays this spring. Check the On-Campus schedule for more details.

5536. Good Clinical Practices (990) crn: 51052 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: Jan 27, Feb 3, 10, 17 (Presidents' Day), 24, Mar 3, 10, 17, 24, 31, Apr 7, 14 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 21 and 28.

Proctored exam: Mar 10 (Proctorio)

Faculty: J. Hayes

No required text.

Optional texts (Do not purchase until after the first class meeting):

1. The Autumn Ghost: How the Battle Against a Polio Epidemic Revolutionized Modern Medical Care; H. Wunsch; ISBN-13: 978-1771649452
2. The Breakthrough: Immunotherapy and the Race to Cure Cancer; C. Graeber; ISBN-13: 978-1455568505
3. Frances Oldham Kelsey, the FDA, and the Battle against Thalidomide; C.K. Warsh; ISBN-13: 978-0197632543

Not open to students who have completed RAQA 536.

5537. Clinical Trial Management (990) crn: 20667 (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: Jan 22, 29, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 2, 9. Meets 12 times plus final exam. Make-ups, if needed, Apr 16 (Passover) and 23.

Proctored exam: Mar 5 (Proctorio)

Faculty: J. Scavone

No required text.

Not open to students who have completed RAQA 537.

WEEKEND COURSE

5544. Regulatory Intelligence (990) crn: 51035 (ONLINE)

This course uses Proctorio online proctoring.

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

9:00 am – 3:30 pm Sundays (1/2 hour lunch): Jan 19, Feb 2, 16, Mar 2, 16, 30. Meets 6 times plus final exam.

Make-ups, if needed, Apr 13 and 27.

Proctored exam: Mar 2 (Proctorio)

Faculty: L. Bowen

No required text.

5572. Vaccines: RA and QA Issues (990) crn: 45613 (ONLINE)

This course uses Proctorio online proctoring.

This course has limited seats. If you wish to enroll, send in your registration form right away.

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)

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*, 13th 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, 3rd edition, 2019, Springer. Available in the Temple U Charles Library online.

(4) *Plotkin's Vaccines*, 7th 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.

5573. Pharmacoepidemiology (990) crn: 51062 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:30 pm Mondays: Jan 27, Feb 3, 10, 17 (Presidents' Day), 24, Mar 3, 10, 17, 24,31, Apr 7. Meets 10 times plus final exam. Make-ups, if needed, Apr 14 (Passover) and 21.

Proctored exam: Apr 7 (Proctorio)

Faculty: N. Cossrow

No required text.

5574. Quality Management Systems (990) crn: 51029 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459)

6:00 pm – 9:30 pm Mondays: Jan 27, Feb 3, 10, 17 (Presidents' Day), 24 (recording), Mar 3, 10, 17, 24, Apr 7. Meets 10 times plus final exam. No class Mar 31 Make-ups, if needed, Apr 14 (Passover) and 21.

Proctored exam: Mar 3 (Proctorio).

Faculty: M. LaBruto

No required text.

5575. Regulatory Sciences: Managing the Guidelines for Quality (990) crn: 53069 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: strong science background required. Include resume with registration for approval.

5:30 pm – 8:30 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8. Meets 12 times plus final exam. Make-ups, if needed, Apr 15 (Passover) and 22.

Proctored exam: Mar 4 (Proctorio)

Faculty: T. Schultz

No required text.

Not open to students who have completed RAQA 580.

5577. Global CMCs – Biopharmaceuticals and Other Biologics (990) crn: 55328 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8. Meets 12 times plus final exam. Make-ups, if needed, Apr 15 (Passover) and 22.

Proctored exam: Feb 25 (Proctorio)

Faculty: J. Quinn

Required text: *The Challenge of CMC Regulatory Compliance for Biopharmaceuticals*, J. Geigert, 2024

<https://link.springer.com/book/10.1007/978-3-031-31909-9>

5578. Risk Management and Safety Signaling of Healthcare Products (990) crn: 53070 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Clinical Drug Safety and Pharmacovigilance (5538) or Post Marketing Safety Surveillance (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 (Proctorio)

Faculty: J. Robinson

No required text.

5591. Global Regulatory Affairs (990) crn: 20671 (ONLINE)

This course uses Proctorio online proctoring.

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

6:00 pm – 9:00 pm Mondays: Jan 27, Feb 3, 10, 17 (Presidents' Day), 24, Mar 3, 10, 17, 24, 31, Apr 7, 14 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 21 and 28.

Proctored exam: Mar 3 (Proctorio)

Faculty: D. Larkins

No required text.

Not open to students who have completed RAQA 591.

5592. Food and Drug Law (101) crn: 51042 – There is an on-campus section of Food and Drug Law at Fort Washington on Wednesdays this spring. Check the On-Campus schedule for more details.

5592. Food and Drug Law (990) crn: 9424 (ONLINE)

This course uses Proctorio online proctoring.

Special note Dr. Pilgrim will not be teaching this summer. If you wish to take her Food and Drug Law course, sign up this spring or wait until Fall 2025.

6:00 pm - 9:00 pm Wednesdays: Jan 22, 29, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 2, 9. Meets 12 times plus final exam. Make-ups, if needed, Apr 16 (Passover) and 23.

Proctored exam: Mar 5 (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: 25838 (ONLINE)

This course uses Proctorio online proctoring.

Special note Dr. Pilgrim will not be teaching this summer. If you wish to take her Food and Drug Law course, sign up this spring or wait until Fall 2025.

6:00 pm - 9:00 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8. Meets 12 times plus final exam. Make-ups, if needed, Apr 15 (Passover) and 22.

Proctored exam: Mar 4 (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.

5594. Regulation of Dietary Supplements and Functional Food (990) crn: 42729 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Wednesdays: Jan 22, 29, Feb 5, 12, 19, 26 (recording), Mar 5, 12, 19, 26, Apr 2, 9. Meets 12 times plus final exam. Make-ups, if needed, Apr 16 (Passover) and 23.

Proctored exam: Mar 5 (Proctorio)

Faculty: D. Schoneker

No required text

Not open to students who have completed RAQA 594.

5597. Food Good Manufacturing Practices (990) crn: 51045 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm – 9:30 pm Mondays: **Feb 3**, 10, 17 (Presidents' Day), 24, Mar 3, 10, 17, 24, 31, Apr 7, 21. Meets 10 times plus final exam. No class Jan 27 or Apr 14. Make-ups, if needed, Apr 28 and May 5.

Proctored exam: Apr 21 (Proctorio)

Faculty: M. Noonan

No required text.

5611. Regulation of Advertising & Promotions (990) crn: 51038 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm – 9:00 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8, 15 (Passover). Meets 12 times plus final exam. Make-ups if needed, Apr 22 and 29.

Proctored exam: Apr 15 (Proctorio)

Faculty: D. Cooke

Required text: 1) *Promotion of FDA-Regulated Medical Products*, J. Hawana, B. Hills, B. Zegarelli, 2019; and 2) *Effective Review and Approval of Digital Promotional Tactics*, 2nd edition, Cooke, Dale, 2017.

Not open to students who have completed RAQA 611.

5612. Bioethics for Pharmaceutical Professionals (990) crn: 28699 (ONLINE)

This course uses 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)

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 completed RAQA 512.

5615. Project Management for Pharmaceutical Professionals (990) crn: 31575 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: at least four courses in the RAQA program, including Drug Development (5459) and Food and Drug Law (5592).

6:00 pm - 9:00 pm Mondays: Jan 27, Feb 3, 10, 17 (Presidents' Day), 24, Mar 3, 10, 17, 24, 31, Apr 7, 14 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 21 and 28.

Proctored exam: Mar 3 (Proctorio)

Faculty: J. Sheldon

Not open to students who have completed RAQA 615 or RAQA 5547 - Project Management for Clinical Trials).

5650. Pharmaceutical Regulatory Leadership (101) crn: 53077 – There is an on-campus section of Pharmaceutical Regulatory Leadership being offered on Thursday afternoons this spring at the Fort Washington site. Check the On-Campus schedule for details.

5650. Critical Analysis of Media Coverage of the Pharmaceutical Industry (990) crn: 45587 (ONLINE)

To learn more: <https://raqa-sierra.temple.edu/PVideos/RAQA5650.mp4>

This course has limited enrollment. If you wish to enroll, make sure you forward your registration form early.

6:00 pm – 9:00 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8. Meets 12 times plus final exam. Make-ups, if needed, Apr 15 (Passover) and 22.

Faculty: K. Zimm

Required text: *Bottle of Lies*, Eban. Purchase online: [https://www.amazon.com/Bottle-Lies-Inside-Story-
Generic/dp0062338781](https://www.amazon.com/Bottle-Lies-Inside-Story-Generic/dp0062338781). Also available through the Temple U Charles Library.

5650. Special Topics: Regulation of Artificial Intelligence & Machine Learning (AI/ML) Medical Devices (991) crn: 55327 (ONLINE)

This course uses Proctorio online proctoring.

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

Suggested prerequisites (NOT required): Regulation of Medical Devices: Submissions (5502) and/or IND/NDA Submissions (5459).

6:00 pm - 9:00 pm Tuesdays: Jan 21, 28, Feb 4, 11, 18, 25, Mar 4, 11, 18, 25, Apr 1, 8, 15 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 22 and 29.

Proctored exam: Apr 15 (Proctorio)

Faculty: C. Kuehn and K. Fuh

No required text.

Description: An overview of the regulation of artificial intelligence and machine learning-enabled (AI/ML) medical devices by various regulatory authorities with emphasis on the U.S. and E.U. Starting with the basics of an AI/ML-enabled medical device, the course dives into how devices are characterized/classified and the special considerations that must be accounted for in their design, development, and deployment. Topics include rapidly evolving legislative and global frameworks to regulate AI/ML devices, the need for harmonization, and the challenges regulators face with constant AI/ML advances. Examines several types of AI/ML-enabled devices that have been cleared/approved and the potential for new innovations. Reviews the data used to train AI/ML models for use in medical devices, a detailed overview of locked versus learning models, and the impact of bias in training, validating, testing, and deploying models, and the need for equity, diversity, and representativeness in AI/ML model development. Includes a discussion on the role of industry in developing safeguards for the use of AI/ML in medical devices, ethical considerations, and recent developments in global regulatory policies.

PHARMACEUTICAL SCIENCE COURSE - strong science background required

8004. Solid Dosage Forms – Small Molecules (990) crn: 55324 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Strong science background, including a degree in pharmacy, chemistry, biochemistry, biology, or chemical engineering. RAQA students must include resume with registration form.

6:00 pm - 9:00 pm Wednesdays: Jan 22, 29, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 2, 9. Meets 12 times plus final exam. Make-ups, if needed, Apr 16 (Passover) and 23.

Proctored exam: Mar 5 (Proctorio)

Faculty: K. Zimm

No required text.

Not open to students who have completed Pharmaceutics 407.

PHARMACEUTICAL SCIENCE COURSE - strong science background required

8005. Pharmaceutical Biotechnology (990) crn: 51044 (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: 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-up, if needed, Apr 24 and May 1.

Proctored exams: Mar 6 and Apr 17 (proctored through 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: *Biopharmaceutical: Biochemistry and Biotechnology*, Walsh, G., 2nd edition, (ISBN 0 470 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.