

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.

NEW COURSE – 1.5 Credits

5000. FDA Inspection Readiness (111) crn: 13923 (ONLINE) (1.5 credits) *Proctorio online proctoring.*

6:00 pm - 9:00 pm Tuesdays: May 20, 27, June 3, 10, 17, 24, July 1. Meets 6 times plus final exam. Make-ups, if needed, July 8 and 15.

Proctored exam: July 1 (Proctorio)

Faculty: E. Pittman

No required text.

5000. Critical Case Study Analysis of Mainstream Pharmaceutical Literature (112) (ONLINE) crn: 14468 (1.5 credits) [Click to Learn More](#)

Special note: this is a 1.5 credit course.

6:00 pm - 9:00 pm Thursdays: June 5, 12, 19, 26, July 10, 17. Meets 6 times plus final exam. No class July 3. Make-ups, if needed, July 24 and 31.

Faculty: K Zimm

Required text: *Kill Shot: A Shadow Industry, A Deadly Disease*, Jason Dearen.

5459. Drug Development (990) crn: 2539 (ONLINE) *Proctorio online proctoring.*

6:00 pm - 9:00 pm Wednesdays: May 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30, Aug 6. Meets 12 times plus final exam. Make-ups, if needed, Aug 13 and 20.

Proctored exam: June 25 (Proctorio)

Faculty: C. Ciliberto

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.

WEEKEND COURSE

5459. Drug Development (991) crn: 6040 (ONLINE) *Proctorio online proctoring*

9:00 am - 12:00 pm Sundays: May 18, June 1, 8, 15, 22, 29, July 13, 20 (recording), 27, Aug 3, 10, 17. Meets 12 times plus final exam. No classes on May 25 and July 6. Make-up, if needed, Aug 24.

Proctored exam: July 13 (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.

5472. Pharmaceutical Marketing (990) crn: 13919 (ONLINE) Proctorio online proctoring

6:00 pm - 9:00 pm Wednesdays: May 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30, Aug 6. Meets 12 times plus final exam. Make-ups, if needed, Aug 13 and 20.

Proctored exam: July 2 (Proctorio)

Faculty: D. Hisey

Required text: *Understanding Pharma The Professional's Guide To How Pharmaceutical And Biotech Companies Really Work*, 3rd Edition, John J. Campbell

Not open to students who have completed RAQA 482.

5477. Good Manufacturing Practices (990) crn: 4136 (ONLINE) Proctorio online proctoring.

6:00 pm - 9:30 pm Mondays: May 19, June 2, 9, 16, 23, 30, July 7, 14, 28, Aug 4, 18. Meets 10 times plus final exam. No class May 26 (Memorial Day), July 21, and Aug 11. Make-up, if needed, Aug 25.

Proctored exam: Aug 18 (Proctorio)

Faculty: M. Noonan

No required text.

Not open to students who have completed RAQA 487.

5478. High Purity Water Systems (990) crn: 12414 (ONLINE) Proctorio online proctoring

Prerequisite: college-level chemistry course.

6:00 pm – 9:00 pm Tuesdays: May 20, 27, June 3, 10, 17, 24, July 1, 8, 15, 22, 29, Aug 5, 12. Meets 12 times plus final exam. Make-ups, if needed, Aug 19 and 26.

Proctored exam: Aug 12 (Proctorio)

Faculty: W. Collentro

Reference text (available on Charles Library website for registered students): *Pharmaceutical Water - System Design, Operation, and Validation*, Collentro, 2nd edition, Informa Healthcare, 2011.

Not only to students who have taken RAQA 488.

5479. Advanced Good Manufacturing Practices – Defining “c” (990) crn: 7676 (ONLINE) Proctorio Online proctoring

Prerequisite: successful completion of Good Manufacturing Practices (5477) or permission of the instructor.

6:00 pm - 9:00 pm Wednesdays: May 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30, Aug 6. Meets 12 times plus final exam. Make-ups, if needed, Aug 13 and 20.

Proctored exam: June 25 (Proctorio)

Faculty: K. Zimm

No required text.

5494. Quality Audit (990) crn: 4137 (ONLINE) Proctorio online proctoring

Prerequisite: A Good Practices course (5476 or 5477 or 5479 or 5536).

6:30 pm - 9:45 pm Wednesdays: May 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30, Aug 6, 13. Meets 12 times plus final exam. Make-ups, if needed, Aug 20 and 27.

Proctored exam: Aug 13 (Proctorio)

Faculty: S. Van Valkenburg

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.

WEEKEND COURSE

5495. IND/NDA Submissions (990) crn: 13915 (ONLINE) Proctorio online proctoring

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

8:30 am – 2:00 pm Saturdays: May 17, 31, June 14, 28, July 12, 26, Aug 9. Meets 7 times plus final exam. Make-up, if needed, Aug 16.

Proctored exam: June 28 (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: 14469 (ONLINE) Proctorio online proctoring

6:00 pm - 9:00 pm Thursdays: May 22, 29, June 5, 12, 19, 26, July 10, 17, 24, 31, Aug 7, 14. Meets 12 times plus final exam. No class July 3. Make-ups, if needed, Aug 21 and 28.

Proctored exam: July 10 (Proctorio)

Faculty: M. Arentz

No required text.

Not open to students who have completed RAQA 496.

5514. Regulatory eSubmissions (990) crn: 13918 (ONLINE) Proctorio online proctoring.

Strongly Suggested Prerequisite: Drug Development (5459) OR IND/NDA Submissions (5495) OR forward your resume indicating familiarity with drug development or IND/NDA processes.

6:00 pm - 9:00 pm Tuesdays: May 20, 27, June 3, 10, 17, 24, July 8, 15, 22, 29, Aug 5, 12. Meets 12 times plus final exam. No class July 1. Make-ups, if needed, Aug 19 and 26.

Proctored exam: June 24 (Proctorio)

Faculty: R Arbaugh

No required text.

5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 14470 (ONLINE) Proctorio online proctoring

Prerequisites: Drug Development (5459). Science background required.

6:00 pm - 9:00 pm Wednesdays: May 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30, Aug 6. Meets 12 times plus final exam. Make-ups, if needed, Aug 13 and 20.

Proctored exam: July 9 (Proctorio)

Faculty: F. Diana

No required text.

5536. Good Clinical Practices (990) crn: 3423 (ONLINE) Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: May 19, June 2, 9, 16, 23, 30, July 7, 14, 21, 28, Aug 4, 11. Meets 12 times plus final exam. No class May 26 (Memorial Day). Make-ups, if needed, Aug 18 and 25.

Proctored exam: July 7 (Proctorio)

Faculty: J. Hayes

Optional texts (Students will be required to **choose one of the following** after the first class):

1) *Polio: An American Story*; D.M. Oshinsky.

2) *Do You Believe in Magic? (The Sense and Nonsense of Alternative Medicine (Vitamins, Supplements, and All Things Natural: A Look Behind the Curtain)*, P. Offit;

3) *The Chimp & the River: How AIDS Emerged from an African Forest*, D. Quammen;

4) *The Speckled Monster: a Historical Tale of Battling Smallpox*, J.L Carrell

Not open to students who have completed RAQA 536.

5537. Clinical Trial Management (990) crn: 5872 (ONLINE) 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 Tuesdays: May 20, 27, June 3, 10, 17, 24, July 1, 8, 15, 22, 29, Aug 5. Meets 12 times plus final exam. Make-ups, if needed, Aug 12 and 19.

Proctored exam: July 1 (Proctorio)

Faculty: J. Scavone

No required text.

Not open to students who have completed RAQA 537.

5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 13333 (ONLINE) Proctorio online proctoring.

Suggested prerequisite: Good Clinical Practices (5536)

7:00 pm - 10:15 pm Thursdays: May 29, June 5, 12, 19, 26, July 10, 17, 24, 31, Aug 7, 14, 21. Meets 11 times plus final exam. No class July 3. Make-up, if needed, Aug 28.

Proctored exam: Aug 21 (Proctorio).

Faculty: J. Robinson

Recommended text: Cobert's Manual of Drug Safety and Pharmacovigilance, 4th edition only, Feb 2025, Cobert, Gregory, Thomas, Baldrige: <https://www.worldscientific.com/worldscibooks/10.1142/13970#t=aboutBook>

5543. Good Distribution Practices (990) crn: 14471 (ONLINE) Proctorio online proctoring

Prerequisite: Good Manufacturing Practices (5477)

6:00 pm - 9:00 pm Wednesdays: May 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23, 30, Aug 6. Meets 12 times plus final exam. Make-ups, if needed, Aug 13 and 20.

Proctored exam: June 25 (Proctorio)

Faculty: J. Hayes

Students will select one of the following and present a summary in class:

Making a Killing: The Deadly Implications of the Counterfeit Drug Trade, R. Bate. OR

China Rx: Exposing the Risks of America's Dependence on China for Medicine; Gibson; ISBN-10: 1633886417 OR

Protecting America's Health: FDA, Business, & One Hundred Years of Regulation; Hilts; ISBN-10: 0807855820.

5545. Post-Approval Changes (PAC) (990) crn: 14472 (ONLINE) Proctorio online proctoring

6:00 pm - 9:00 pm Mondays: May 19, June 2, 9, 16, 23, 30, July 7, 14, 21, 28, Aug 4, 11. Meets 12 times plus final exam. No class May 26 (Memorial Day). Make-ups, if needed, Aug 18 and 25.

Proctored exam: July 7 (Proctorio)

Faculty: K. Zimm

No required text.

5591. Global Regulatory Affairs (990) crn: 1733 (ONLINE) Proctorio online proctoring.

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

6:00 pm - 9:00 pm Thursdays: May 22, 29, June 5, 12, 19, 26, July 10, 17, 24, 31, Aug 7, 14. Meets 12 times plus final exam. No class July 3. Make-ups, if needed, Aug 21 and 28.

Proctored exam: June 26 (Proctorio)

Faculty: D. Larkins

No required text.

Not open to students who have completed RAQA 591.

5592. Food and Drug Law (990) crn: 1734 (ONLINE) Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: May 20, 27, June 3, 10, 17, 24, July 1, 8, 15, 22, 29, Aug 5. Meets 12 times plus final paper. Make-ups, if needed, Aug 12 and 19.

Proctored exam: July 15 (Proctorio)

Faculty: D. Cooke

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.

5596. Food Labeling and Regulatory Affairs (990) crn: 13921 (ONLINE) Proctorio online proctoring

6:00 pm - 9:30 pm Thursdays: May 22, 29, June 5, 12, 19, 26, July 10, 24, 31, Aug 7, 14. Meets 10 times plus final exam. No class July 3 and July 17. Make-ups, if needed, Aug 21 and 28.

Proctored exam: Aug 14 (Proctorio)

Faculty: M. Noonan

No required text.

5612. Bioethics for Pharmaceutical Professionals (990) crn: 14473 (ONLINE) Proctorio online proctoring

10:00 am - 1:30 pm Saturdays: May 17, 31, June 7, 14, 21, 28, July 12, 19, 26, Aug 2, 9. Meets 10 times plus final exam. No class May 24 and July 5. Make-ups, if needed, Aug 16 and 23.

Proctored exam: Aug 9 (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.

NEW COURSE!!

5650. Investigations in Industry (Internal, Quality, and Criminal) (990) crn: 13922 (ONLINE) Proctorio online proctoring

Prerequisite: Good Manufacturing Practices (5477) or industry GMP experience (send resume for approval).

6:00 pm - 9:00 pm Mondays: May 19, June 2, 9, 16, 23, 30, July 7, 14, 21, 28, Aug 4, 11. Meets 12 times plus final exam. No class May 26 (Memorial Day). Make-ups, if needed, Aug 18 and 25.

Proctored exam: July 14 (Proctorio)

Faculty: J. Banaszewski

Required text: *Handbook of Investigation and Effective CAPA Systems*, 3rd edition. Jose Rodriguez-Perez

AFTERNOON COURSE at Fort Washington – SOME CLASSES MEET ONLINE. Contact QARAREG@temple.edu if you wish to enroll but can't attend on-campus.

5650. Pharmaceutical Regulatory Leadership (101) crn: 13914

Suggested prerequisite: Drug Development (5459) OR Food and Drug Law (5592).

2:00 pm – 5:30 pm Wednesdays: May 21, 28, June 4, 11, 18, 25, July 2, 9, 16, 23. Meets 10 times plus final exam. Make-ups, if needed, July 30 and Aug 6.

In-class/online proctored exam: June 18

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.