

Spring 2026 - RAQA Graduate Program – January 20, 2026

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.

Class times are scheduled in Eastern Time Zone

1.5 Credit Course

5000. FDA Inspection Readiness (990) (1.5 credits) crn: 57453 (ONLINE)

This course uses Proctorio online proctoring.

7:00 pm - 10:00 pm Tuesdays: Jan 27, Feb 3, 10, 17, 24, Mar 3, 10. Meets 6 times plus final exam. Make-ups, Mar 17 and 24.

Proctored exam: Mar 10 (Proctorio)

Faculty: E. Pittman

No required text.

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

This course uses Proctorio online proctoring.

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

Proctored exam: Mar 5 (Proctorio)

Faculty: D. Walsh

Required 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.

5473. Generic Drug Regulation (ANDAs) (990) crn: 57455 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459).

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

Proctored exam: Mar 5 (Proctorio)

Faculty: C. Ciliberto

No text required.

Not open to students who have completed RAQA 483.

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

This course uses Zoom online proctoring.

6:00 pm - 9:30 pm Mondays: Jan 26, Feb 2, 16 (Presidents' Day), 23, Mar 2, 9, 16, 23, Apr 6 (Passover), 13, 20. Meets 10 times plus final exam. No class Feb 9 and Mar 30. Make-up, if needed, Apr 27.

Proctored exam: Apr 20 (Zoom)

Faculty: M. Noonan

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 26, Feb 2, 9, 16 (Presidents' Day), 23, Mar 2, 9, 16, 23, 30, Apr 6 (Passover), 13, 20. Meets 12 times plus final exam. Make-up, if needed, Apr 27.

Proctored exam: Apr 20 (Proctorio)

Faculty: D. Casaburi

Required text: *Validation of Pharmaceutical Processes*, 3rd edition, ISBN: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 20, 27, Feb 3, 10, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 14 and 21.

Proctored exam: Mar 3 (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.

5494. Quality Audit (991) crn: 57425 (ONLINE)

This course uses Proctorio online proctoring.

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

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

Proctored Exam: Apr 16 (Proctorio)

Faculty: K. Huynh-Ba

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.

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 26, Feb 2, 9, 16 (Presidents' Day), 23, Mar 2, 9, 16, 23, 30, Apr 6 (Passover), 13. Meets 12 times plus final exam. Make-ups, if needed, Apr 20 and 27.

Proctored exam: Mar 2 (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.

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 Mondays: Jan 26, Feb 2, 9, 16 (Presidents' Day), 23, Mar 2, 9, 16, 23, 30, Apr 6 (Passover), 13. Meets 12 times plus final exam. Make-ups, Apr 20 and 27.

Proctored exam: Mar 9 (Proctorio)

Faculty: T. Genova

No required text.

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

This course uses Proctorio online proctoring.

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

Proctored Exam: Mar 5 (Proctorio)

Faculty: K. Weiss

No text required.

5514. Regulatory eSubmissions (990) crn: 42720 (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 Tuesdays: Jan 20, 27, Feb 3, 10, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 14 and 21.

Proctored exam: Mar 3 (Proctorio)

Faculty: R. Arbaugh

No required text.

5516. Cleaning Validation (990) crn: 57428 (ONLINE)

This course uses Proctorio online proctoring.

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

Proctored exam: Apr 15 (Proctorio)

Faculty: R. Forsyth

Recommended text: ISPE Cleaning Validation Guidance.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: Jan 26, Feb 2, 9, 16 (Presidents' Day), 23, Mar 2, 9, 16, 23, 30, Apr 6 (Passover), 13. Meets 12 times plus final exam. Make-ups, Apr 20 and 27.

Proctored exam: Mar 9 (Proctorio)

Faculty: J. Hayes

Required text: Students will be required to choose one of the following texts and write a book review:

1) *Rabid: A Cultural History of the World's Most Diabolical Virus*

B. Wasik and M. Murphy, ISBN-13: 978-0143123576

2) *Clinical Research the Best Career You Never Heard Of 10 Reasons to Get into the Research Industry NOW*, Alec Spinelli (ISBN-13: 979-8312292640)

3) *The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis* P. Offit (ISBN-13: 978-0300126051)

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

Proctored exam: Mar 4 (Proctorio)

Faculty: J. Scavone

No required text.

Not open to students who have completed RAQA 537.

5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 55465 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: Good Clinical Practices (5536) or appropriate experience in industry GCPs.

Please include resume with registration.

6:00 pm - 9:00 pm Mondays: Jan 26, Feb 2, 9, 23, Mar 2, 9, 16, 23, 30, Apr 6 (Passover), 13, 20, 27. Meets 12 times plus final exam. No class Feb 16. Make-up, if needed, May 4.

Proctored exam: Apr 27 (Proctorio)

Faculty: J. Little

Required text: *Pharmacovigilance: A Practical Approach*, Elsevier, 2025, ISBN: 0443118817, 9780443118814

5545. Post Approval Changes (PAC) (990) crn: 57443 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Jan 20, 27, Feb 3, 10, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 14 and 21.

Proctored exam: Mar 3 (Proctorio)

Faculty: K. Zimm

No required text.

This course is also offered at Ambler, PA, Campus as a hybrid class. Please contact the RAQA office if you are interested in attending in-person.

Not open to students who have completed RAQA 545.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Jan 20, 27, Feb 3, 10, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7 (Passover), 14. Meets 12 plus final exam. Make-ups, if needed, Apr 21 and 28.

Proctored exams: Mar 3 and Apr 14 (Proctorio)

Faculty: K. Cassell

No required text.

Not open to students who have taken RAQA 570.

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

This course uses Proctorio online proctoring.

Prerequisites: Drug Development (5459)

6:00 pm - 9:30 pm Mondays: Jan 26, Feb 2, 9, 16 (Presidents' Day, recording), 23, Mar 2, 9, 23, 30, Apr 6 (Passover). Meets 10 times plus final exam. No class Mar 16. Make-ups, if needed, Apr 13 and 20.

Proctored exam: Mar 2 (Proctorio)

Faculty: M. Labruto

No required text.

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 20, 27, Feb 3, 10, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 14 and 21.

Proctored exam: Feb 24 (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.

7:00 pm - 10:00 pm Thursdays: Jan 22, 29, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 9, 16, 23. Meets 12 times plus final exam. No class Apr 2. Make-up, if needed, Apr 30.

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

Proctored Exam: Feb 26 (Proctorio)

Faculty: D. Larkins

No text required.

Not open to students who have completed RAQA 591.

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

This course uses Proctorio online proctoring.

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

5592. Food and Drug Law (991) crn: 25838 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Jan 20, 27, Feb 3, 10, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 14 and 21.

Proctored exam: Mar 3 (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 21, 28, Feb 11, 18, 25, Mar 4, 11, 18, 25, Apr 1 (Passover), 8, 15. Meets 12 times plus final exam. No class Feb 4. Make-ups, if needed, Apr 22 and 29.

Proctored exam: Mar 4 (Proctorio)

Faculty: D. Schoneker

No required text.

Not open to students who have completed RAQA 594.

5597. Food GMPs (990) crn: 51045 (ONLINE)

This course uses Zoom online proctoring.

6:00 pm - 9:30 pm Thursdays: Jan 22, 29, Feb 12, 19, 26, Mar 5, 12, 19, Apr 9, 16, 23. Meets 10 times plus final exam. No class Feb 5, Mar 26, and Apr 2 (Passover). Make-up, if needed, Apr 30.

Proctored Exam: Apr 23 (Zoom)

Faculty: M. Noonan

No required text.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Jan 20, 27, Feb 3, 10, 17, 24, Mar 3, 10, 17, 24, 31, Apr 7 (Passover), 14. Meets 12 plus final exam. Make-ups, if needed, Apr 21 and 28.

Proctored exam: Apr 14 (Proctorio)

Faculty: D. Cooke

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

Not open to students who have completed RAQA 611.

WEEKEND COURSE

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

This course uses Proctorio online proctoring.

10:00 am - 1:00 pm Saturdays: Jan 17, 24, 31, Feb 7, 14, 21, 28, Mar 7, 14, 21, 28, Apr 4 (Passover). Meets 12 times plus final exam. Make-ups, if needed, Apr 11 and 18.

Proctored exam: Feb 28 (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.

5650. Investigations in Industry (Internal, Quality, and Criminal) (990) crn: 45587 (ONLINE)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: 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 and 22.

Proctored exam: March 4 (Proctorio)

Faculty: J. Banaszewski

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

PHARMACEUTICAL SCIENCES COURSES - 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 Thursdays: Jan **29**, Feb 5, 12, 19, 26, Mar 5, 12, 19, 26, Apr 2 (Passover), 9, 16. Meets 12 times plus final exam. Make-ups, if needed, Apr 23 and 30.

Proctored Exam: Mar 12 (Proctorio)

Faculty: K. Zimm

No text required.

This course may not be offered again until Spring 2028.

8006. Physical Pharmacy (990) crn: 57444 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisites: Students are expected to have a strong science and math background and a previous course in physical chemistry. RAQA students must include resume with registration.

6:00 pm - 9:00 pm Mondays: Jan 26, Feb 2, 9, 16 (Presidents' Day), 23, Mar 2, 9, 16, 23, 30, Apr 6 (Passover), 13. Meets 12 times plus final exam. Make-ups, if needed, Apr 20 and 27.

Proctored exams: Mar 2 and Apr 13 (Proctorio)

Faculty: D. Lebo

Required text: *Martin's Physical Pharmaceutical Sciences*, J. Sinko, Lippincott Williams & Wilkins, 6th ed., (ISBN: 9780781850271).

Not open to students who have taken Pharmaceutics 485.

8007. Applied Biopharmaceutics (990) crn: 57445 (ONLINE)

This course uses Proctorio online proctoring.

Prerequisite: 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 written permission to register.

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

Proctored exam: Apr 15 (Proctorio)

Faculty: R. Fassih

No required text.

Not open to students who have completed Pharmaceutics 410.