

Summer 2026 - RAQA Graduate Program – April 15, 2026

ONLINE (ZOOM) COURSES

Note: Due to visa requirements, international students must attend courses on-campus. 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

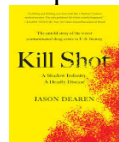
1.5 Credit Course

5000. Critical Analysis of Media Coverage of the Pharmaceutical Industry (990) crn: 14977

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

Faculty: K. Zimm

Required text:

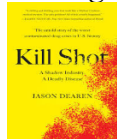


5000. Critical Analysis of Media Coverage of the Pharmaceutical Industry (3 credits, 991) crn: 14996

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

Faculty: K. Zimm

Required texts: 1. *Kill Shot: A Shadow Industry, a Deadly Disease*, by Jason Dearen.
2. *Drugs and the FDA: Safety, Efficacy, and the Public's Trust*, by Mikkael A. Sekeres.



5459. Drug Development (990) crn: 2539

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: May 18, June 1, 8, 15, 22, 29, July 6, 13, 20, 27, Aug 3, 10, 17.
Meets 12 times plus final exam. No class May 25. Make-ups, if needed, Aug 10 and 17.

Proctored exam: July 6 (Proctorio)

Faculty: J. Hayes

Not open to students who have completed RAQA 459.

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

Select one from below as approved by the instructor:

1. *Fair Doses: An Insider's Story of the Pandemic and the Global Fight for Vaccine Equity Hardcover* – October 28, 2025 by Seth Berkley (Author)

2. *Building Backwards to Biotech: The Power of Entrepreneurship to Drive Cutting-Edge Science to Market Paperback* – March 11, 2022, by Stephanie A. Wisner (Author)

3. *Genentech: The Beginnings of Biotech (Synthesis) Paperback* – April 8, 2013 by Sally Smith Hughes (Author)

Not open to students who have completed RAQA 459.

5472. Pharmaceutical Marketing (990) crn: 13919

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: May 18, June 1, 8, 15, 22, 29, July 6, 13, 20, 27, Aug 3, 10, 17.
Meets 12 times plus final exam. No class May 25. Make-ups, if needed, Aug 10 and 17.

Proctored exam: July 6 (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.

5476. Good Laboratory Practices (990) crn: 14983

This course uses Proctorio online proctoring.

7:00 pm - 10:00 pm Tuesdays: May 19, 26, June 2, 9, 16, 23, 30, July 7, 14, 21, 28, Aug 4.
Meets 12 times plus final exam. Make-ups, if needed, Aug 11 and 18.

Proctored exam: June 30 (Proctorio)

Faculty: E. Pittman

Text required: *Data Integrity, The Science, The Regulations, The Use*, ISBN-13: 2940184366869, Publisher: SQA, Available through Barnes and Noble

- FDA.COM for hardcopy or ecf.gov for electronic copy: 21 CFR 11, 58, 40 CFR 160, OECD (Suggest having a hard copy although not necessary)

Not open to students who have completed RAQA 486.

5477. Good Manufacturing Practices (990) crn: 4136

This course uses Zoom online proctoring.

6:00 pm - 9:30 pm Mondays: May 18, June 1, 8, 15, 22, 29, July 13, 20, 27, August 3, 10. Meets 10 times plus final exam. No class May 25 (Memorial Day) or July 6. Make-up, if needed, Aug 17. **Please note: The first class on May 18 will start at 7:00 pm ET.**

Proctored exam: Aug 10 (Zoom)

Faculty: M. Noonan

No required text.

Not open to students who have completed RAQA 487.

5478. High Purity Water Systems (990) crn: 12414

This course uses Proctorio online proctoring.

Prerequisite: college-level chemistry course.

6:00 pm - 9:00 pm Tuesdays: May 19, 26, June 2, 9, 16, 23, 30, July 7, 14, 21, 28, Aug 4, 11. Meets 12 times plus final exam. Make-ups, if needed, Aug 18 and 25.

Proctored exam: Aug 11 (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 open to students who have completed RAQA 488.

5495. IND/NDA Submissions (990) crn: 13915

This course uses Proctorio online proctoring.

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

6:00 pm - 9:00 pm Thursdays: May 21, 28, June 4, 11, 18, 25, July 9, 16, 23, 30, Aug 6, 13. Meets 12 times plus final exam. No class July 2. Make-ups, if needed, Aug 20 and 27.

Proctored exam: June 25 (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.

5497. Statistics for Clinical Trials (990) crn: 14985

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: May 19, 26, June 2, 9, 16, 23, 30, July 7, 14, 21, 28, Aug 4. Meets 12 times plus final exam. Make-ups, if needed, Aug 11 and 18.

Proctored exam: June 30 (Proctorio)

Faculty: K. Weiss

No text required.

Not open to students who have completed RAQA 497.

5501. Development of Sterile Products (990) crn: 14986

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 include their resume for written permission to register.

6:00 pm - 9:00 pm Thursdays: May 21, 28, June 4, 11, 18, 25, July 9, 16, 23, 30, Aug 6, 13, 20. Meets 12 times plus final exam. No class July 2. Make-up, if needed, Aug 27.

Proctored exam: Aug 20 (Proctorio)

Faculty: D. Casaburi

No required text.

Not open to students who have completed RAQA 501.

5505. Global Medical Device (990) crn: 14979

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Thursdays: May 21, 28, June 4, 11, 18, 25, July 9, 16, 23, 30, Aug 6, 13. Meets 12 times plus final exam. No class July 2. Make-ups, if needed, Aug 20 and 27.

Proctored exam: July 9 (Proctorio)

Faculty: M. Arentz

No required text.

5513. Active Pharmaceutical Ingredients (990) crn: 14981

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459)

6:00 pm - 9:00 pm Tuesdays: May 19, 26, June 2, 9, 16, 23, 30, July 7, 14, 21, 28, Aug 4. Meets 12 times plus final exam. Make-ups, if needed, Aug 11 and 18.

Proctored exam: June 30 (Proctorio)

Faculty: K. Zimm

No required text.

5514. Regulatory eSubmissions (990) crn: 13918

This course uses Proctorio online proctoring.

Strongly suggested prerequisite: Drug Development (5459) or IND/NDA Submissions (5495).

Include resume with registration.

6:00 pm - 9:00 pm Wednesdays: 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: July 8 (Proctorio)

Faculty: R. Arbaugh

No required text.

WEEKEND COURSE

5536. Good Clinical Practices (990) crn: 3423

This course uses Proctorio online proctoring.

10:00 am - 1:00 pm Saturdays: May 16, 30, June 6, 13, 20, 27, July 11, 18, 25, Aug 1, 8, 15.

Meets 12 times plus final exam. No class May 23 and July 4. Make-ups if needed, Aug 22 and 29.

Proctored exam: July 11 (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: 5872

This course uses Proctorio online proctoring.

Prerequisite: Good Clinical Practices (5536)

6:00 pm - 9:00 pm Wednesdays: 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: July 8 (Proctorio)

Faculty: J. Scavone

No required text.

Not open to students who have completed RAQA 537.

5543. Good Distribution Practices (GDPs) (990) crn: 14471

This course uses Proctorio online proctoring.

Prerequisite: Good Manufacturing Practices (5477)

6:00 pm - 9:00 pm Wednesdays: 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: July 8 (Proctorio)

Faculty: J. Hayes

Select one from below as approved by the instructor:

1. *Bottle of Lies: The Inside Story of the Generic Drug Boom Paperback* – June 23, 2020 by Katherine Eban (Author)

2. *Bitter Pills: The Global War on Counterfeit Drugs* 1st Edition by Muhammad H.Zaman (Author)

3. *China Rx: Exposing the Risks of America's Dependence on China for Medicine Paperback* – March 15, 2022 by Rosemary Gibson (Author), Janardan Prasad Singh (Author)

5572. Vaccines: RA and QA Issues (990) crn: 14984

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 Mondays: May 18, June 1, 8, 15, 22, 29, July 6, 13, 20, 27. Meets 10 times plus final exam. No class May 25. Make-ups, if needed, Aug 3 and 10.

Proctored exam: June 22 (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.

5576. Global CMC Issues and Regulatory Dossiers (990) crn: 14980

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: May 19, 26, June 2, 9, 16, 23, 30, July 7, 14, 21, 28, Aug 4. Meets 12 times plus final exam. Make-ups, if needed, Aug 11 and 18.

Proctored exam: June 30 (Proctorio)

Faculty: F. Diana

Not open to students who have completed RAQA 586.

5591. Global Regulatory Affairs (990) crn: 1733

This course uses Proctorio online proctoring.

Prerequisite: Food and Drug Law (5592) or Drug Development (5459), or permission of the instructor. Submit your resume with registration.

6:00 pm - 9:00 pm Thursdays: May 21, 28, June 4, 11, 18, 25, July 9, 16, 23, 30, Aug 6, 13. Meets 12 times plus final exam. No class July 2. Make-ups, if needed, Aug 20 and 27.

Proctored exam: June 25 (Proctorio)

Faculty: D. Larkins

No text required.

Not open to students who have completed RAQA 591.

5596. Food Labeling and Regulatory Affairs (990) crn: 13921

This course uses Zoom proctoring.

6:00 pm - 9:30 pm Thursdays: May 21, 28, June 4, 11, 18, 25, July 9, 23, 30, Aug 6, 13. Meets 10 times plus final exam. No class July 2 or July 16. Make-up, if needed, Aug 20.

Please note: The first class on May 21 will start at 7:00 pm ET.

Proctored exam: Aug 13 (Zoom)

Faculty: M. Noonan

No required text.

5615. Project Management for Pharmaceutical Professionals (990) crn: 14987

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 Wednesdays: 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 19 and 26.

Faculty: J. Sheldon

Proctored exam: June 24 (Proctorio)

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

PHARMACEUTICAL SCIENCES COURSES - Strong science background required.

8005. Pharmaceutical Biotechnology (990) crn: 14982

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: May 21, 28, June 4, 11, 18, 25, July 9, 16, 23, 30, Aug 6, 13, 20. Meets 12 times plus final exam. No class July 2. Make-up, if needed, Aug 27.

Proctored exams: June 18 and Aug 20 (Proctorio)

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 or ISBN 13: 9781420044379), 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.