

Fall 2026 - RAQA Graduate Program – July 29, 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) 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

5000. FDA Inspection Readiness (990, 3 credits) crn: 58832

This course uses Proctorio online proctoring.

7:00 pm - 10:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8, 15.

Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 17 (Thursday).

Proctored exam: Dec 15 (Proctorio)

Faculty: E. Pittman

No required text.

WEEKEND COURSE

5459. Drug Development (990) crn: 60655

This course uses Proctorio online proctoring.

8:30 am - 2:00 pm Saturdays: Sept 12, 26, Oct 10, 24, Nov 7, 21, Dec 5. Meets 7 times plus final exam. Make-ups, if needed, Dec 12 or 19.

Proctored exam: Oct 24 (Proctorio)

Faculty: P. Smith

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.

5459. Drug Development (991) crn: 7407

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Thursdays: Sept 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 (Thanksgiving).

Make-up, if needed, Dec 17.

Proctored exam: Oct 29 (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.

5459. Drug Development (992) crn: 28608

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 28 (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.

5468. Validation of FUE (Facilities, Utilities and Equipment) (990) crn: 60656

This course uses Proctorio online proctoring.

Prerequisite: Good Manufacturing Practices (5477) or appropriate industry experience in GMPs.

7:00 pm - 10:00 pm Thursdays: Sept 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3, 10, 17. Meets 12 times plus final exam. No class Nov 26 (Thanksgiving).

Make-up, if needed, Dec 21 (Monday).

Proctored exam: Dec 17 (Proctorio)

Faculty: E. Muegge

No required text.

5473. Generic Drug Regulation (ANDAs) (990) crn: 60662

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459).

6:00 pm - 9:00 pm Mondays: **Sept 21**, 28, Oct 5, 12 (Columbus Day), 19, 26, Nov 2, 9, 16, 23, 30, Dec 7. Meets 12 times plus final exam. Make-up, if needed, Dec 14.

Proctored exam: Nov 2 (Proctorio)

Faculty: C. Ciliberto

No required text.

Not open to students who have taken RAQA 483.

5474. Process Validation (990) crn: 54364

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 Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 28 (Proctorio)

Faculty: K. Barnthouse

Required text: 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, Elsevier, 2016.

Not open to students who have taken RAQA 484.

5476. Good Laboratory Practices (990) crn: 58818

This course uses Proctorio online proctoring.

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

Proctored exam: Dec 16 (Proctorio)

Faculty: E. Pittman

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

- FDA.COM for hardcopy or ecfr.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 taken RAQA 486.

5477. Good Manufacturing Practices (990) crn: 9357

6:00 pm - 9:30 pm Thursdays: Sept 17, 24, Oct 1, 8, 15, 22, 29, Nov 12, 19, Dec 3, 10. Meets 10 times plus final exam. No class Nov 5 or Nov 26 (Thanksgiving). Make-up, if needed, Dec 17.

Proctored exam: Dec 10 (Zoom)

Faculty: M. Noonan

No required text.

Not open to students who have taken RAQA 487.

5477. Good Manufacturing Practices (991) crn: 34740

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: Sept 14, 21, 28, Oct 5, 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-up, if needed, Dec 14.

Proctored exam: Oct 26 (Proctorio)

Faculty: K. Zimm

No required text.

Not open to students who have taken RAQA 487.

5492. Production of Sterile Products (990) crn: 60672

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.

6:00 pm - 9:00 pm Mondays: Sept 14, 21, 28, Oct 5, 12 (Columbus Day), 19, 26, Nov 2, 9, 16, 30, Dec 7, 14. Meets 12 times plus final exam. No class Nov 23. Make-up, if needed, Dec 15 (Tuesday).

Proctored exam: Dec 14 (Proctorio)

Faculty: D. Casaburi

No required text.

Not open to students who have taken RAQA 492.

5494. Quality Audit (990) crn: 25897

This course uses Proctorio online proctoring.

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

7:00 pm - 10:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8, 15. Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 16 (Wednesday).

Proctored exams: Oct 27 and Dec 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 taken RAQA 494.

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

This course uses Proctorio online proctoring.

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

6:00 pm - 9:00 pm Thursdays: Sept 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 (Thanksgiving). Make-up, if needed, Dec 17.

Proctored exam: Oct 22 (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.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Thursdays: Sept 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 (Thanksgiving). Make-up, if needed, Dec 17.

Proctored exam: Oct 29 (Proctorio)

Faculty: M. Arentz

No required text.

Not open to students who have taken RAQA 496.

5498. Computerized System Validation (990) crn: 60657

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8, 15. Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 16 (Wednesday).

Proctored exams: Oct 27 and Dec 15 (Proctorio)

Faculty: M. Kellner

No text required.

Not open to students who have taken RAQA 498.

5501. Development of Sterile Products (990) crn: 60658

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: Sept 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3, 10, 17. Meets 12 times plus final exam. No class Nov 26 (Thanksgiving). Make-up, if needed, Dec 21 (Monday).

Proctored exam: Dec 17 (Proctorio)

Faculty: D. Casaburi

No required text.

Not open to students who have completed RAQA 501.

5514. Regulatory eSubmissions (990) crn: 58828

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: Sept 16, 23, 30, Oct 7, 14, 21, 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 28 (Proctorio)

Faculty: R. Arbaugh

No required text.

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

This course uses Proctorio online proctoring.

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

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 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: F. Diana

No required text.

5532. Global Labeling Regulation: Principles and Practices (990) crn: 60659

This course uses Proctorio online proctoring.

Suggested prerequisite: Drug Development (5459)

6:00 pm - 9:00 pm Mondays: (TENATIVE) Sept 14, 21, 28, Oct 5, 19, 26, Nov 2, 9, 16, 23, 30, Dec 7. Meets 12 times plus final exam. No class Oct 12 (Columbus Day). Make-up, if needed, Dec 14.

Proctored exam: TBD (Proctorio)

Faculty: V. Kozlovsky

5536. Good Clinical Practices (990) crn: 9358

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8. Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 15.

Proctored exam: Oct 27 (Proctorio)

Faculty: J. Scavone

No required text.

Not open to students who have taken RAQA 536.

5537 Clinical Trial Management (990) crn: 49401

This course uses Proctorio online proctoring.

Prerequisite: Good Clinical Practices (5536)

6:00 pm - 9:00 pm Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 28 (Proctorio)

Faculty: J. Scavone

No required text.

Not open to students who have completed RAQA 537.

5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 60660

This course uses Proctorio online proctoring.

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

7:00 pm - 10:00 pm Thursdays: Sept 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3, 10, 17. Meets 12 times plus final exam. No class Nov 26 (Thanksgiving).

Make-up, if needed, Dec 21 (Monday).

Proctored exam: Dec 17 (Proctorio)

Faculty: J. Robinson

No required text.

Not open to students who have taken RAQA 538.

5542. Pharmacopoeia Compliance: Understanding the Global Impact on RAQA (990) crn: 60661

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459)

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8, 15.

Meets 12 times plus final exam. No class Nov 24.

Make-up, if needed, Dec 16 (Wednesday).

Proctored exam: Dec 15 (Proctorio)

Faculty: J. Albanese

Click [here](#) to introductory video.

5545. Post Approval Changes (PAC) (990) crn: 60684 (Thursdays)

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Thursdays: Sept 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 (Thanksgiving). Make-up, if needed, Dec 17.

Proctored exam: Oct 29 (Proctorio)

Faculty: K. Zimm

No required text.

Not open to students who have taken RAQA 546.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 28, Nov 4, 11 (Veterans' Day), Dec 2, 9, 16. Meets 12 times plus final exam. No class Nov 18 and 25. Make-up, if needed, Dec 17 (Thursday).

Proctored exam: Oct 28 (Proctorio)

Faculty: D. Schoneker

No required text.

Not open to students who have taken RAQA 546.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Thursdays: Sept 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 (Thanksgiving). Make-up, if needed, Dec 17.

Proctored exam: Oct 22 (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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Mondays: Sept 14, 21, 28, Oct 5, 12 (Columbus Day), 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-up, if needed, Dec 14.

Proctored exam: Oct 26 (Proctorio)

Faculty: T. Genova
No required text.

5574. Pharmaceutical Quality Management Systems (990) crn: 46256

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459)

6:00 pm - 9:30 pm Mondays: Sept 14, 21, 28, Oct 5, 12 (Columbus Day), 19, 26, Nov 2, 16, 23.
Meets 10 times plus final exam. No class Nov 9. Make-ups, if needed, Nov 30 and Dec 7.

Proctored exam: Oct 19 (Proctorio)

Faculty: M. Labruto

No required text.

5577. Global CMCs - Biopharmaceuticals and Other Biologics (990) crn: 60663

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 21 (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>

5579. Regulatory and Legal Basis of Pharmacovigilance (990) crn: 60664

This course uses Proctorio online proctoring.

Suggested prerequisite: Post Marketing Safety Surveillance (5571) or Clinical Drug Safety and Pharmacovigilance (5538).

6:00 pm - 9:00 pm Wednesdays: **Sept 9**, 16, 23, 30, Oct 7, 14, 21, 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 exams: Oct 21 and Dec 9 (Proctorio)

Faculty: L. Thomas

Required texts: **1)** *Cobert's Manual of Drug Safety and Pharmacovigilance*, Third Edition

(2019); B. Cobert, W. Gregory, J. Thomas, ISBN-13: 978-981327884, AND **2)** *Mann's Pharmacovigilance*, edited by E. Andrews, and N. Moore, J. Wiley & Sons, Incorporated, 2014.

ProQuest Ebook Central, Free access via <https://ebookcentral.proquest.com/lib/templeunive-ebooks/detail.action?docID=1662669>. Or Temple Library:

<https://librarysearch.temple.edu/catalog/991036747819703811>

5591. Global Regulatory Affairs (990) crn: 23442

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 Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8. Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 15.

Proctored exam: Oct 20 (Proctorio)

Faculty: D. Larkins

No text required.

Not open to students who have completed RAQA 591.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 28 (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 taken RAQA 592.

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

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8. Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 15.

Proctored exam: Oct 27 (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 taken RAQA 592.

5595. Food Law (990) crn: 54379

6:00 pm - 9:30 pm Mondays: Sept 14, 28, Oct 5, 12 (Columbus Day), 19, 26, Nov 2, 16, 23, 30, Dec 7. Meets 10 times plus final exam. No class Sept 21 or Nov 9. Make-up, if needed, Dec 14.

Proctored exam: Dec 7 (Zoom)

Faculty: M. Noonan

No required text.

WEEKEND COURSE

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

This course uses Proctorio online proctoring.

10:00 am - 1:00 pm Saturdays: Sept 12, 19, 26, Oct 3, 10, 17, 24, 31, Nov 7, 14, 21, Dec 5. Meets 12 times plus final exam. No class Nov 28. Make-up, if needed, Dec 12.

Proctored exam: Oct 24 (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 taken RAQA 610.

5618. Clinical Data Management (990) crn: 60665

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459) or Good Clinical Practices (5536).

6:00 pm - 9:00 pm Mondays: Sept 14, 21, 28, Oct 5, 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-up, if needed, Dec 14.

Proctored exam: Oct 26 (Proctorio)

Faculty: J. Hayes

Required text: **1)** *Beyond Enrollment: Why Clinical Trials Struggle Long Before Enrollment Fails* by B. Pasek, ISBN-13 979-8196422744. **2)** *Practical Guide to Clinical Data Management* by S. Prokscha, ISBN-13 978-1032498232, 4th edition.

Not open to students who have taken RAQA 618.

5650. Investigations in Industry (Internal, Quality, and Criminal) (990) crn: 60666

This course uses Proctorio online proctoring.

6:30 pm - 9:30 pm Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 28 (Proctorio)

Faculty: J. Banaszewski

Required text: *Handbook of Investigation and Effective CAPA Systems*, 3rd edition. Jose Rodriquez-Perez (ISBN 978-1636940113 or ISBN 1636940110)

8002. Pharmaceutical Analysis (990) crn: 46377

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.

5:30 pm - 8:30 pm Mondays: Sept 14, 21, 28, Oct 5, 12, 19, 26, Nov 2, 9, 16, 23, 30, Dec 7. Meets 12 times plus final exam. Make-up, if needed, Dec 14.

Proctored exam: Dec 7 (Proctorio)

Faculty: M. Ilies, S. Mehrman, A. Fermier

Required text: TBD

Not open to students who have taken Pharmaceutics 411.

8005. Pharmaceutical Biotechnology (990) crn: 58834

This course uses Proctorio online proctoring.

Prerequisite: Strong science background required. This consists of general and organic chemistry, and also molecular biology or biochemistry courses.

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8, 15. Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 16 (Wednesday).

Proctored exams: Oct 20 and Dec 15 (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, 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.

PP 5001: Foundations of Health Outcomes and Real-World Evidence (3 credits)

Course Delivery: Fully online, asynchronous (Canvas), with optional synchronous office hours.

Planned assessments provided at class.

Faculty: U. Sambamoorthi

Course Description

This course introduces students to the foundations of health outcomes assessment and real-world evidence (RWE) and their application in contemporary healthcare decision-making. Students learn how outcomes data are generated, evaluated, compared, and applied across clinical, payer, and policy settings. Emphasis is placed on interpretation, critical evaluation, and communication of evidence rather than advanced statistical modeling. The course also introduces the role of artificial intelligence (AI) as a supportive tool for evidence synthesis, interpretation, and decision-making in health outcomes research.

PP 5002: Machine Learning Applications for Health Outcomes Decision-Making (3 credits)

Course Delivery: Fully online, asynchronous (Canvas), with optional synchronous office hours.

Planned assessments provided at class.

Faculty: U. Sambamoorthi

Course Description

This course introduces students to the applied use of machine learning (ML) and predictive analytics in health outcomes and real-world evidence contexts. The course emphasizes how ML methods are used to support risk prediction, patient stratification, utilization forecasting, and outcomes assessment, rather than focusing on software development or advanced coding. Students will learn how to interpret model outputs, evaluate performance, assess limitations and bias, and apply ML-informed insights to healthcare decision-making. Ethical considerations and responsible use of AI tools in health outcomes research are integrated throughout the course.

Global Clinical and Pharmacovigilance Regulations (GCPR)

WEEKEND COURSE

5459. Drug Development (990) crn: 60655

This course uses Proctorio online proctoring.

8:30 am - 2:00 pm Saturdays: Sept 12, 26, Oct 10, 24, Nov 7, 21, Dec 5. Meets 7 times plus final exam. Make-ups, if needed, Dec 12 or 19.

Proctored exam: Oct 24 (Proctorio)

Faculty: P. Smith

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.

5459. Drug Development (991) crn: 7407

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Thursdays: Sept 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 (Thanksgiving).

Make-up, if needed, Dec 17.

Proctored exam: Oct 29 (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.

5459. Drug Development (992) crn: 28608

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 28 (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.

5536. Good Clinical Practices (990) crn: 9358

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8. Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 15.

Proctored exam: Oct 27 (Proctorio)

Faculty: J. Scavone

No required text.

Not open to students who have taken RAQA 536.

5537 Clinical Trial Management (990) crn: 49401

This course uses Proctorio online proctoring.

Prerequisite: Good Clinical Practices (5536)

6:00 pm - 9:00 pm Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 28 (Proctorio)

Faculty: J. Scavone

No required text.

Not open to students who have completed RAQA 537.

5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 60660

This course uses Proctorio online proctoring.

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

7:00 pm - 10:00 pm (ET) Thursdays: Sept 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3, 10, 17. Meets 12 times plus final exam. No class Nov 26 (Thanksgiving).

Make-up, if needed, Dec 21 (Monday).

Proctored exam: Dec 17 (Proctorio)

Faculty: J. Robinson

No required text.

Not open to students who have taken RAQA 538.

5579. Regulatory and Legal Basis of Pharmacovigilance (990) crn: 60664

This course uses Proctorio online proctoring.

Suggested prerequisite: Post Marketing Safety Surveillance (5571) or Clinical Drug Safety and Pharmacovigilance (5538).

6:00 pm - 9:00 pm Wednesdays: **Sept 9**, 16, 23, 30, Oct 7, 14, 21, 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 exams: Oct 21 and Dec 9 (Proctorio)

Faculty: L. Thomas

Required texts: 1) *Cobert's Manual of Drug Safety and Pharmacovigilance*, Third Edition (2019); B. Cobert, W. Gregory, J. Thomas, ISBN-13: 978-981327884, AND 2) *Mann's Pharmacovigilance*, edited by E. Andrews, and N. Moore, J. Wiley & Sons, Incorporated, 2014.

ProQuest Ebook Central, Free access via <https://ebookcentral.proquest.com/lib/templeuniv-ebooks/detail.action?docID=1662669>. Or Temple Library:

<https://librarysearch.temple.edu/catalog/991036747819703811>

WEEKEND COURSE

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

This course uses Proctorio online proctoring.

10:00 am - 1:00 pm Saturdays: Sept 12, 19, 26, Oct 3, 10, 17, 24, 31, Nov 7, 14, 21, Dec 5. Meets 12 times plus final exam. No class Nov 28. Make-up, if needed, Dec 12.

Proctored exam: Oct 24 (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 taken RAQA 610.

5618. Clinical Data Management (990) crn: 60665

This course uses Proctorio online proctoring.

Prerequisite: Drug Development (5459) or Good Clinical Practices (5536).

6:00 pm - 9:00 pm Mondays: Sept 14, 21, 28, Oct 5, 12, 19, 26, Nov 2, 9, 16, 30, Dec 7. Meets 12 times plus final exam. No class Nov 23. Make-up, if needed, Dec 14.

Proctored exam: Oct 26 (Proctorio)

Faculty: J. Hayes

No required text.

Not open to students who have taken RAQA 618.

Pharmaceutical Regulatory Sciences (PRS)

5468. Validation of FUE (Facilities, Utilities and Equipment) (990) crn: 60656

This course uses Proctorio online proctoring.

Prerequisite: Good Manufacturing Practices (5477) or appropriate industry experience in GMPs.

7:00 pm - 10:00 pm Thursdays: Sept 17, 24, Oct 1, 8, 15, 22, 29, Nov 5, 12, 19, Dec 3, 10, 17.

Meets 12 times plus final exam. No class Nov 26 (Thanksgiving).

Make-up, if needed, Dec 21 (Monday).

Proctored exam: Dec 17 (Proctorio)

Faculty: E. Muegge

5474. Process Validation (990) crn: 54364

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 Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 28 (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 taken RAQA 484.

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

This course uses Proctorio online proctoring.

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

6:00 pm - 9:00 pm Thursdays: Sept 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 (Thanksgiving). Make-up, if needed, Dec 17.

Proctored exam: Oct 22 (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.

5498. Computerized System Validation (990) crn: 60657

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8. Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 15.

Proctored exam: Oct 27 and Dec 15 (Proctorio)

Faculty: M. Kellner

No required text.

Not open to students who have taken RAQA 498.

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

This course uses Proctorio online proctoring.

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

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 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: F. Diana

No required text.

5577. Global CMCs - Biopharmaceuticals and Other Biologics (990) crn: 60663

This course uses Proctorio online proctoring.

6:00 pm - 9:00 pm Wednesdays: Sept 16, 23, 30, Oct 7, 14, 21, 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 21 (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>

8002. Pharmaceutical Analysis (990) crn: 46377

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.

5:30 pm - 8:30 pm Mondays: Sept 14, 21, 28, Oct 5, 12, 19, 26, Nov 2, 9, 16, 23, 30, Dec 7. Meets 12 times plus final exam. Make-up, if needed, Dec 14.

Proctored exam: Dec 7 (Proctorio)

Faculty: M. Ilies, S. Mehrman, A. Fermier

Required text: TBD

Not open to students who have taken Pharmaceutics 411.

8005. Pharmaceutical Biotechnology (990) crn: 58834

This course uses Proctorio online proctoring.

Prerequisite: Strong science backgrounds required. This consists of general and organic chemistry, and also molecular biology or biochemistry courses.

6:00 pm - 9:00 pm Tuesdays: Sept 15, 22, 29, Oct 6, 13, 20, 27, Nov 3, 10, 17, Dec 1, 8, 15. Meets 12 times plus final exam. No class Nov 24. Make-up, if needed, Dec 16 (Wednesday).

Proctored exams: Oct 20 and Dec 15 (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, 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.