

**ADVANCED BIOTHERAPEUTICS:
MANUFACTURING AND REGULATORY AFFAIRS (ABMRA)
Spring 2025 Schedule**

Requirements for ABMRA MS from Temple U: 36 credits: 21 RAQA credits and 15 Jefferson credits.

Four Required RAQA Courses

- **Drug Development (RAQA 5459 OR P381) – Spring 2025**
- **Biologics/Biosimilars: A Regulatory Overview (5515) - Fall 2024**
- **Vaccines: Regulatory Affairs and Quality Assurance Issues (5572) – Spring 2025**
- **Global CMC Regulatory Compliance for Biopharmaceuticals & Biologics (5577) – Spring 2025**

Two Electives from:

- **Development of Sterile Products (5501) – Spring 2025**
- **Pharmaceutical Biotechnology (PS 8005) - Spring 2025**
- Statistical Quality Control (5451)
- Validation of FUE (5468)
- Biotechnology: Bioprocess Basics (5471)
- Process Validation (5474) – Fall 2024
- Advanced GMPs (5479)
- Production of Sterile Parenterals (5492) – Fall 2024
- **Sterilization Processes (5493) – Spring 2025**
- **Microbiological Concepts in Pharmaceutical Manufacturing (5512)- Spring 2025**
- **Regulatory eSubmissions (5514) – Spring 2025**
- Cleaning Validation (5516)
- Clinical Drug Safety & Pharmacovigilance (5538) OR Post Marketing Safety Surveillance (5571) (one or the other but not both)
- **Regulatory Intelligence (5544) – Spring 2025**
- **Pharmaceutical Quality Management Systems (5574) – Spring 2025**
- **Regulatory Sciences: Managing the Guidelines for Quality (5575) – Spring 2025**
- Process Analytical Technology (PAT) (5625)
- Statistical Design of Experiments (DOE)
- Process Monitoring (5629)

REQUIRED RAQA COURSES

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*, t. 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 15, 2022; K. 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.

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.

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>

RAQA ELECTIVE COURSES: in the ABMRA DEGREE PROGRAM

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.

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. 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.

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.

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 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) or Food and Drug Law (5592) or permission of the instructor.

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.

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.

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 March 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.